ACTEMRA SQ

MEDICATION(S)
ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, TYENNE 162 MG/0.9 ML SYRINGE, TYENNE AUTOINJECTOR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic or with a Targeted Synthetic DMARD. Crohn's Disease. Covid-19.

REQUIRED MEDICAL INFORMATION
See other criteria.

AGE RESTRICTION
See other criteria.

PRESCRIBER RESTRICTION
See other criteria.

COVERAGE DURATION
See other criteria.

OTHER CRITERIA
1.Giant Cell Arteritis (GCA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
i.The patient has tried one systemic corticosteroid (e.g., prednisone); AND
ii.The requested medication is prescribed by or in consultation with a rheumatologist.
B)Patient is Currently Receiving tocilizumab (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months (Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy). ; AND
ii.Patient meets at least ONE of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product)(Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.); OR
b)Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as decreased headache, scalp, or jaw pain; decreased fatigue, and/or improved vision.

2.Polyarticular Juvenile Idiopathic Arthritis (PJIA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i, ii, and iii):
i.The patient meets one of the following conditions (a, b, c, or d):

a)The patient has tried one other systemic therapy for this condition (e.g., methotrexate [MTX], sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug [NSAID]).
NOTE: A biologic also counts as a trial of one systemic therapy. A biosimilar of Actemra does not count.; OR
b)The patient will be starting on tocilizumab concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
c)The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
d)The patient has aggressive disease, as determined by the prescribing physician; AND
ii.The medication is prescribed by or in consultation with a rheumatologist.
iii.Patient meets ONE of the following conditions (a or b):
a) Patient has tried one adalimumab product; OR Note: A trial of Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria also counts.
b)According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

B)Patients Currently Receiving Tocilizumab (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product) Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b.Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

3.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial at least one biologic other than a tocilizumab product. A biosimilar of Actemra does not count. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD.; AND
ii.The requested medication is prescribed by or in consultation with a rheumatologist.
iii.Patient meets ONE of the following conditions (a or b):
a)Patient has tried one adalimumab product; OR
Note: A trial of Cimzia, Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria or subcutaneous also counts.
b) According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.
B)Patients Currently Receiving a Tocilizumab Product (SC or IV). Approve for 1 year if the patient meets BOTH of the following (i and ii)
i.Patient has been established on therapy for at least 6 months; AND

ii. Patient meets at least ONE of the following (a or b):
a)Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b)Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4.Systemic Juvenile Idiopathic Arthritis (SJIA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
i.The patient has tried one other systemic agent for this condition (e.g., a corticosteroid [oral, IV], a conventional synthetic disease-modifying antirheumatic drug [DMARD; e.g., methotrexate {MTX}, leflunomide, sulfasalazine], or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]), Kineret (anakinra SC injection), or Ilaris [canakinumab for SC injection]); AND
ii.The medication is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving a Tocilizumab Product (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) (Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.); OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.
5.Interstitial Lung Disease Associated with Systemic Sclerosis. Approve for 1 year if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve if the patient meets all of the following (i, ii, iii, iv, and v):
i.Patient is 18 years of age or older; AND
ii. Patient has elevated acute phase reactants defined as at least one of the following (a, b, or c):
a)C-reactive protein (CRP) 6 mg/mL or greater; OR
b)Erythrocyte sedimentation rate (ESR) 28 mm/h or greater; OR
c)Platelet count greater than or equal to 330 x 109/L; AND
iii.Forced vital capacity (FVC) is greater than 55 percent of the predicted value; AND
iv.Diagnosis is confirmed by high-resolution computed tomography; AND
v. Medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.
B)Patient is Currently Receiving a tocilizumab product (Subcutaneous or Intravenous). Approve if the patient meets all of the following (i, ii, and iii):
i.Patient is 18 years of age or older; AND
ii. Patient has experienced a beneficial response to therapy over the previous 1 year while receiving a tocilizumab product (Note: For a patient who has received less than 1 year of therapy, response to therapy is from baseline prior to initiating a tocilizumab product. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, improvement in 6-minute walk distance, and/or reduction in the number or severity of disease-related

exacerbations.); AND
iii.Medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.

Other Uses with Supportive Evidence

6.Polymyalgia Rheumatica (PMR). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
i.The patient has tried one systemic corticosteroid (e.g., prednisone); AND
ii.The requested medication is prescribed by or in consultation with a rheumatologist.
B)Patient is Currently Receiving a tocilizumab product (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product) (Note: Examples of objective measures are serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate], resolution of fever, and/or reduced dosage of corticosteroids.); OR
b)Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness; improved range of motion; and/or decreased fatigue.

CONTINUATION OF THERAPY:
2B, 3B – PJIA, RA – Patients Currently Receiving a tocilizumab product (SC or IV) and new to plan:
B)Approve for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a, b, c, d or e):
a.Patient has Polyarticular Juvenile Idiopathic Arthritis and has tried one adalimumab product (Note: A trial of Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria also counts.); OR
b.Patient has Rheumatoid Arthritis and has tried one adalimumab product (Note: A trial of Cimzia, Enbrel, and infliximab product (e.g., Remicade, biosimilars), or Simponi Aria or subcutaneous also counts.); OR
c.According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder. OR
d.According to the prescriber, the patient has been established on a tocilizumab intravenous product for at least 90 days; OR
e.Patient has been established on a tocilizumab subcutaneous product for at least 90 days and prescription claims history indicates at least a 90-day supply of a tocilizumab subcutaneous product was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving a tocilizumab subcutaneous product for at least 90 days AND the patient has been receiving a tocilizumab subcutaneous product via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to a tocilizumab subcutaneous product).

ADBRY

MEDICATION(S)
ADBRY, ADBRY AUTOINJECTOR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other Anti-Interleukin Monoclonal Antibodies (e.g. Dupixent)

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist, immunologist, or dermatologist

COVERAGE DURATION
Initial therapy: 4 months, Continuation: 1 year

OTHER CRITERIA
Atopic dermatitis:
Initial Therapy. Approve if the patient meets all of the following (A, B and C):
A.Patient has chronic atopic dermatitis; AND
B.Patient has atopic dermatitis involvement estimated to be 10 percent or more of the body surface area (BSA) according to the prescribing physician; AND
C.Patients meets all of the following (1, 2, and 3):
1.Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
2.This topical corticosteroid was applied daily for at least 28 consecutive days; AND
3.Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber.

Continuation Therapy. Approve if the patient meets the following criteria (A and B):
A.Patient has already received at least 4 months of therapy with Adbry; AND
Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.
B.Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Adbry therapy are marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other responses observed.

ADCIRCA/ALYQ/REVATIO/SILDENAFIL/TADALAFIL FOR PULMONARY ARTERIAL HYPERTENSION

MEDICATION(S)
ALYQ, SILDENAFIL 10 MG/12.5 ML VIAL, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Erectile dysfunction. Benign Prostatic hyperplasia.

REQUIRED MEDICAL INFORMATION
Member must have a diagnosis of Pulmonary Arterial Hypertension (PAH)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
N/A

ADEMPAS

MEDICATION(S)
ADEMPAS

COVERED USES
1. Treatment of adult with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class OR 2. Treatment of adult with pulmonary arterial hypertension (PAH), (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening.

EXCLUSION CRITERIA
Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterization

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH and CTEPH-must be prescribed by or in consultation with a cardiologist or a pulmonologist.

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.
CTEPH: Patient meets the following (a and b):
a.Patient has diagnosis of CTEPH that is inoperable or persistent or recurrent after surgical treatment (i.e., pulmonary endarterectomy)
b.CTEPH is symptomatic

ADRENACLICK/SYMJEPY

MEDICATION(S)
SYMJEPI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available. For authorization of Epinephrine Auto-Injector or Adrenaclick, the preferred product (Epi-Pen, Epi-Pen Jr, Epinephrine Auto-Injector) must be referenced in the following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

AFINITOR

MEDICATION(S)
EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Oncology indications will be reviewed by Evicore. Tuberous sclerosis complex-associated partial-onset seizures will be reviewed by Express Scripts - approved for pediatric and adult patients 2 years of age and older with tuberous sclerosis complex-associated partial-onset seizures.

AGENTS FOR GAUCHER DISEASE

MEDICATION(S)
CERDELGA, ELELYSO, MIGLUSTAT, VPRIV

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

COVERAGE DURATION
1 year

OTHER CRITERIA
Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation.

AGENTS FOR UREA CYCLE DISORDERS

MEDICATION(S)
RAVICTI, SODIUM PHENYLBUTYRATE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with more than one phenylbutyrate product

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION
1 year

OTHER CRITERIA
Urea cycle disorders – Initial: approve if genetic testing confirmed a mutation resulting in a urea cycle disorder.
Continuation: Approve if there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.

ALINIA

MEDICATION(S)
ALINIA 100 MG/5 ML SUSPENSION, NITAZOXANIDE 500 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The member must have one of the following diagnoses: diarrhea caused by Cryptosporidium parvum, diarrhea caused by Giardia lamblia, diarrhea caused by Giardia intestinalis and Entamoeba histolytica and/or E. Dispar OR diarrhea caused by Cryptosporidium parvum associated with HIV infection.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 days

OTHER CRITERIA
For the treatment of diarrhea caused by Cryptosporidium parvum (cryptosporidiosis):

Oral dosage (Suspension):

Adults and Adolescents: 500 mg PO every 12 hours with food for 3 days. Children 12 years and older: 500 mg PO every 12 hours with food for 3 days.

Children 4 to 11 years: 200 mg PO every 12 hours with food for 3 days. Children 1 to 3 years: 100 mg PO every 12 hours with food for 3 days.

Oral dosage (Tablets):

Adults and Adolescents: 500 mg PO every 12 hours with food for 3 days. Children 12 years and older: 500 mg PO every 12 hours with food for 3 days.

For the treatment of diarrhea caused by Giardia lamblia (giardiasis):

Oral dosage (Suspension):

Adults, Adolescents, and Children 12 years and older: 500 mg PO every 12 hours with food for 3 days.

Children 4 to 11 years: 200 mg PO every 12 hours with food for 3 days.

Children 1 to 3 years: 100 mg PO every 12 hours with food for 3 days.

Oral dosage (Tablets):

Adults, Adolescents, and Children 12 years and older: 500 mg PO every 12 hours with food for 3 days.

For the treatment of diarrhea caused by Giardia intestinalis† and Entamoeba histolytica† and/or E. dispar†:

Oral dosage (Tablets):

Adults and Adolescents: 500 mg PO twice daily for 3 days.

For the treatment of diarrhea caused by Cryptosporidium parvum associated with HIV infection.

Oral dosage (Suspension):

Adults and Adolescents: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 500 to 1000 mg PO twice daily for 14 days

Children 12 years and older: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 500 mg PO twice daily for up to 14 days

Children 4 to 11 years: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 200 mg PO twice daily for up to 14 days

Children 1 to 3 years: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 100 mg PO twice daily for up to 14 days

Oral dosage (Tablets):

Adults and Adolescents: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 500 to 1000 mg PO twice daily for 14 days

Children 12 years and older: In HIV-infected patients, clinical practice guidelines suggest that a regimen of 500 mg PO twice daily for up to 14 days.

AMBRISENTAN

MEDICATION(S)
AMBRISENTAN, LETAIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.

AMPYRA

MEDICATION(S)
DALFAMPRIDINE ER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The member has a diagnosis of Multiple Sclerosis, has sustained walking impairment AND the member is able to walk at least 25 feet with or without assistance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Neurologist.

COVERAGE DURATION
Initial: 1 months. Continuation: 3 years

OTHER CRITERIA
For continuation, authorization may be granted to members with multiple sclerosis for improvement in walking if the member has experienced an improvement in walking speed OR another objective measure of walking ability since starting Ampyra.

ANTICHOLINERGIC BETA AGONIST COMBO INHALERS

MEDICATION(S)
BEVESPI AEROSPHERE, DUAKLIR PRESSAIR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. For authorization of Bevespi Aerosphere and Duaklir Pressair, the preferred product (Stiolto Respimat and Anoro Ellipta) must be referenced in the following assessment:

Authorization requires that all the following criteria be met:

1. The requested drug is being prescribed for an FDA – approved indication, AND

2. The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3. One of the following:

a. The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b. The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c. The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d. The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

ANTICHOLINERGIC INHALERS-TUDORZA PRESSAIR

MEDICATION(S)
TUDORZA PRESSAIR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. For authorization of Tudorza Pressair, the preferred product (Incruse Ellipta and Spiriva) must be referenced in the following assessment:

Authorization requires that all the following criteria be met:

1. The requested drug is being prescribed for an FDA – approved indication, AND

2. The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc.), AND

3. One of the following: a. The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b. The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c. The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d. The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

ANTICOAGULANTS-PRADAXA/SAVAYSA/BEVYXXA

MEDICATION(S)
DABIGATRAN ETEXILATE, SAVAYSA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives

For authorization of dabigatran or Savaysa the preferred product (Eliquis AND Xarelto) must be referenced in the following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

ANTICONVULSANT THERAPY

MEDICATION(S)
APTIOM, BRIVIACT, FYCOMPA, MOTPOLY XR, SPRITAM, XCOPRI

COVERED USES
All FDA-approved indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Carbamazepine, divalproex sodium, gabapentin, lacosamide, lamotrigine, lamotrigine ODT, levetiracetam, oxcarbazepine, phenytoin, tiagabine, topiramate, valproic acid, and zonisamide are the preferred products. The drug must be prescribed within the manufacturer’s published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

ANTIMALARIAL AGENTS

MEDICATION(S)

ARAKODA, ATOVAQUONE-PROGUANIL HCL, CHLOROQUINE PH 250 MG TABLET, CHLOROQUINE PH 500 MG TABLET, COARTEM, KRINTAFEL, MEFLOQUINE HCL, PRIMAQUINE, PYRIMETHAMINE 25 MG TABLET

COVERED USES

N/A

EXCLUSION CRITERIA

The product is not being used for prophylaxis of malaria when traveling to endemic areas.

REQUIRED MEDICAL INFORMATION

Review for Renewal.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

N/A

OTHER CRITERIA

N/A

ANTISPASMODIC THERAPY

MEDICATION(S)
DARIFENACIN ER, GEMTESA, MYRBETRIQ, SOLIFENACIN SUCCINATE, TROSPIUM CHLORIDE ER

COVERED USES
All FDA-approved indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Oxybutynin (immediate release, extended release, and syrup), tolterodine, tolterodine ER, trospium immediate release and fesoterodine are the preferred products. The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

ARCALYST

MEDICATION(S)
ARCALYST

COVERED USES
Cryopyrin-Associated Periodic Syndrome, Deficiency of the Interleukin-1 Receptor Antagonist (DIRA), Pericarditis

EXCLUSION CRITERIA
1. Patients will be excluded from ArcalystTM therapy if there is evidence of any active or chronic infection (such as Hepatitis B, Hepatitis C, or tuberculosis), a strong history of neoplasm, or active systemic lupus erythematosus.
2. Concomitant use of other interleukin-1 antagonist or TNF agents.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
COVERAGE DURATION:
For CAPS (including FCAS and MWS): Initial: One Month. If positive response (confirm response based on current progress notes from the physician documenting disease stability and improvement), then Indefinite
For DIRA: Initial: 6 months, Continuation: 3 years
For Pericarditis: Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
1. Patient has a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including:
-Familial Cold Autoinflammatory Syndrome (FCAS) (classic signs and symptoms include recurrent, intermittent fever and rash that are often exacerbated by exposure to generalized cool ambient temperature [natural, artificial, or both]) -Muckle-Wells Syndrome (MWS) (classic signs and symptoms include fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature)
2. Age is: 12 or greater
3. Patient must be up to date and have received all recommended vaccines, or must receive all recommended vaccinations prior to initiation of therapy.
4. There is clinical documentation of significant functional impairment leading to limitations of activities of daily living (ADLs) (for example, limiting work, school, family or social activities; increased work absenteeism, prevented from participating in outdoor activities).

**It is also recommended that patients have been educated on strategies to adopt a compromised lifestyle with limitations on every day activities, including avoidance of triggers that cause flares, such as cooling temperatures, stress, and

exercise.

Deficiency of the Interleukin-1 Receptor Antagonist (DIRA);
1.Initial approval: Approve if the patient meets the following criteria:
a.Weighs at least 10 kg
b.Genetic test confirms a mutation in the IL1RN gene
c.Patient has demonstrated clinical benefit with anakinra subcutaneous infusion
d.The medication must be prescribed by, or in consultation with, a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders
e.Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy.
2.Continued approval: Approve if the patient has responded to therapy

Pericarditis
1.Initial approval: Approve if the patient meets the following criteria:
a.Age greater than or equal to 12 years of age
b.The medication must be prescribed by, or in consultation with, a rheumatologist or cardiologist
c.The patient has recurrent pericarditis
d.For the patient's current episode, the patient is receiving standard treatment or standard treatment is contraindicated
2.Continuation: Approve if the patient has had a clinical response to Arcalyst

ATYPICAL ANTIPSYCHOTICS

MEDICATION(S)
ABILIFY ASIMTUFII, ABILIFY MAINTENA, ARISTADA, ARISTADA INITIO, ASENAPINE MALEATE, CAPLYTA, FANAPT, INVEGA HAFYERA, INVEGA SUSTENNA, INVEGA TRINZA, LURASIDONE HCL, LYBALVI, PALIPERIDONE ER, PERSERIS, REXULTI 0.25 MG TABLET, REXULTI 0.5 MG TABLET, REXULTI 1 MG TABLET, REXULTI 2 MG TABLET, REXULTI 3 MG TABLET, REXULTI 4 MG TABLET, RISPERDAL CONSTA, RISPERIDONE ER, RYKINDO, SECUADO, UZEDY, VERSACLOZ, VRAYLAR, ZYPREXA RELPREVV

COVERED USES
All FDA-approved indications.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Aripiprazole, Clozapine, Clozapine ODT, fluphenazine, haloperidol, loxapine, olanzapine, perphenazine, pimozide, quetiapine, risperidone (tablet, ODT or solution), thioridazine, thiothixene, trifluoperazine, and ziprasidone are the preferred products. The drug must be prescribed within the manufacturer’s published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND two of the following: The member has demonstrated a failure of or intolerance to two preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to two preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to two preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

AUSTEDO

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR TITRATION KT(WK1-4)

COVERED USES
N/A

EXCLUSION CRITERIA
Impaired hepatic function, Concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and before starting Austedo), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting Austedo), Concomitant use of tetrabenazine, Current suicidality, Untreated or inadequately-treated depression, Non-Huntington's Disease related Chorea

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
1 year

OTHER CRITERIA
Austedo may be approved if the following criteria are met:

1. Patient has a diagnosis of chorea (involuntary movements) associated with Huntington's Disease and meets the following (a, b, and c and d):

a.Patient is 18 years of age or older
b.Diagnosis of Huntington's disease is confirmed by genetic testing
c.Prescribed by, or in consultation with, a neurologist
c.d.Patient has tried and failed or has intolerance to tetrabenazine

OR

2. Patient has a diagnosis of Tardive Dyskinesia and meets the following (a and b):

a.Patient is 18 years of age or older
b.Prescribed by, or in consultation with, a psychiatrist or neurologist

BASAL INSULIN

MEDICATION(S)
BASAGLAR KWIKPEN U-100, BASAGLAR TEMPO PEN U-100, INSULIN GLARGINE MAX SOLOSTAR, INSULIN GLARGINE SOLOSTAR U300, INSULIN GLARGINE-YFGN, LANTUS, LANTUS SOLOSTAR, REZVOGLAR KWIKPEN, TOUJEO MAX SOLOSTAR, TOUJEO SOLOSTAR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc.), AND

3.One of the following:

Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives

For authorization of insulin glargine, insulin glargine-YFGN, Semglee, Basaglar, Basaglar Tempo, Lantus, Rezvoglar or Toujeo the preferred product (Semglee-YFGN, Levemir, Tresiba) must be referenced in the following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

COVERED USES
Treatment of active systemic lupus erythematosus (SLE) and active lupus nephritis.

EXCLUSION CRITERIA
Concurrent Use with Other Biologics or Lupkynis

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, autoantibody status

AGE RESTRICTION
SC-18 years and older (initial). IV – 5 years and older SLE (initial), 18 years and older lupus nephritis (initial)

PRESCRIBER RESTRICTION
SLE-prescribed by, or in consultation with, a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus nephritis – nephrologist or rheumatologist (initial and continuation).

COVERAGE DURATION
SLE: 4 months initial, 3 years continuation. Lupus Nephritis – 6 months initial, 1 year continuation.

OTHER CRITERIA
Lupus Nephritis:
Initial: approve if the patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]).
Continuation: approve if the patient has responded to the requested medication.

SLE
Initial: The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician.
Continuation: Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND the patient has responded to Benlysta as determined by the prescriber.

BIMZELX

MEDICATION(S)
BIMZELX, BIMZELX AUTOINJECTOR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs), Treatment for Inflammatory bowel disease (Crohn's disease, ulcerative colitis)

REQUIRED MEDICAL INFORMATION
See Other Criteria

AGE RESTRICTION
See Other Criteria

PRESCRIBER RESTRICTION
See Other Criteria

COVERAGE DURATION
See Other Criteria

OTHER CRITERIA
1.Plaque Psoriasis (PP). Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
a.Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, iii and iv):
i.Patient is 18 years of age or older; AND
ii.Patient meets ONE of the following conditions (a or b):
a.Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
b.Patient has a contraindication to methotrexate, as determined by the prescriber; AND
iii.The medication is prescribed by or in consultation with a dermatologist; AND
iv.The patient has tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, and Tremfya [documentation required].
Note: A trial of multiple adalimumab products counts as ONE product.
b.Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following criteria (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Bimzelx) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by

psoriasis; AND
iii.Compared with baseline (prior to receiving Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

CONTINUATION OF THERAPY:
PP – Patients Currently Taking Bimzelx and new to plan.
A)Approve for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a or b):
a.Patient has Tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, or Tremfya [documentation required].; OR
Note: A trial of multiple adalimumab products counts as ONE product.
b.Patient has been established on Bimzelx for at least 90 days days and prescription claims history indicates at least a 90-day supply of Bimzelx was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Bimzelx for at least 90 days AND the patient has been receiving Bimzelx via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Bimzelx).

BOSENTAN

MEDICATION(S)
BOSENTAN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.
CTEPH: Patient meets the following (1 and 2):
1.Patient has diagnosis of CTEPH that is inoperable or persistent/recurrent after surgical treatment (i.e., pulmonary endarterectomy)
2.CTEPH is symptomatic

BYETTA/BYDUREON

MEDICATION(S)
BYDUREON BCISE, BYETTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives

For authorization of Byetta or Bydureon the preferred product (Trulicity, Victoza, Ozempic, Rybelsus) must be referenced in

the following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

BYLVAY

MEDICATION(S)
BYLVAY

COVERED USES
Treatment of pruritis in patients 3 months of age or older with progressive familial intrahepatic cholestasis (PFIC). Treatment of cholestatic pruritis in patients 12 months of age and older with Alagille Syndrome (ALGS).]

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
PFIC: 3 months and older (initial therapy) ALGS: 12 months and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in progressive familial intrahepatic cholestasis for PFIC or Alagille syndrome for ALGS (initial and continuation)

COVERAGE DURATION
Initial-6 months, continuation-1 year

OTHER CRITERIA
Progressive Familial Intrahepatic Cholestasis, Initial therapy-approve if the patient meets the following (i, ii, iii, and iv):
i.Patient has moderate-to-severe pruritus, according to prescriber AND
ii.Diagnosis of progressive familial intrahepatic cholestasis type 1 or type 2 was confirmed by genetic testing AND
iii.Patient does not have any of the following (a, b, or c):
a)Cirrhosis OR
b)Portal hypertension OR
c)History of a hepatic decompensation event AND
Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.
iv.Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

Progressive Familial Intrahepatic Cholestasis, continuation-approve if the patient has had a response to therapy and does not have any of the following (a, b, or c):
a)Cirrhosis OR
b)Portal hypertension OR
c)History of a hepatic decompensation event
Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.

Alagille Syndrome, Initial therapy, approve if the patient meets the following:
i.Patient has moderate-to-severe pruritis, according to the prescriber; AND
ii.Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation; AND
iii.Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory; AND
iv.Patient has tried at least two systemic medications for Alagille syndrome, unless contraindicated (examples include cholestyramine, naltrexone, rifampicin, sertraline, ursodiol); AND
v.Patient does NOT have any of the following (a, b or c):
a)Cirrhosis
b)Portal hypertension
c)History of a hepatic decompensation event
Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.

Alagille Syndrome, Continuation Therapy, approve if the patient has had a response to therapy and does not have any of the following (a, b, or c):
a)Cirrhosis OR
b)Portal hypertension OR
c)History of a hepatic decompensation event
Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.

CAMZYOS

MEDICATION(S)
CAMZYOS

COVERED USES
N/A

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by a cardiologist

COVERAGE DURATION
Initial: 8 months. Continuation: 1 year

OTHER CRITERIA
For Obstructive Hypertrophic Cardiomyopathy: 1.Initial Therapy. Approve if the patient meets ALL of the following criteria (a, b, c and d):
a. Patient meets both of the following (i and ii): i. Patient has at least one symptom associated with obstructive hypertrophic cardiomyopathy (examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise) AND ii.Patient has NYHA Class II or III symptoms of heart failure (Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest) b.Patient with left ventricular hypertrophy meets one of the following (i or ii): i. Patient has maximal left ventricular wall thickness greater than or equal to 15 mm, OR ii. Patient has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm c. Patient has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]) d. Patient has LVEF greater than or equal to 55 percent 2. Patient is Currently Receiving Camzyos. Approve if the patient meets ALL of the following criteria: a. Patient has been established on therapy for at least 8 months b. Patient meets both of the following (a and b): i. Currently or prior to starting therapy, patient has or has experienced at least one symptom associated with obstructive hypertrophic cardiomyopathy (examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise) AND ii. Currently or prior to starting therapy, patient is in or was in NYHA Class II or III heart failure (Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest) c. Patient has a current LVEF greater than or equal to 50 percent d. Patient meets at least one of the following (a or b): i. Patient experienced a beneficial clinical response when assessed by at least one objective measure (Note: Examples include improved peak oxygen consumption/mixed

venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index) AND ii. Patient experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy (Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores)

CARGLUMIC ACID

MEDICATION(S)
CARGLUMIC ACID

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic testing

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases

COVERAGE DURATION
NAGS – pt meets criteria no genetic test – 3 mo. Pt has genetic test – 12 months. All other: 7 days

OTHER CRITERIA
NAGS deficiency with hyperammonemia: Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency.

PA or MMA with hyperammonemia, acute treatment: Approve if the patient’s plasma ammonia level is greater than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.

CAYSTON

MEDICATION(S)
CAYSTON

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cystic fibrosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Member has Pseudomonas aeruginosa colonization in the lungs and has recurrence despite prior use of tobramycin inhalation solution or tobramycin resistance.

CGRP INHIBITORS

MEDICATION(S)
AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY SYRINGE, EMGALITY PEN, EMGALITY SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

REQUIRED MEDICAL INFORMATION
Diagnosis of migraine headaches. Previous therapies tried.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Chronic or episodic migraine: Initial coverage: 3 months, Continuation of coverage: 12 months. Episodic cluster (Emgality): 6 months.

OTHER CRITERIA
For migraine headache initiation of therapy:

Adequate trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil.

AND

The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND associated symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia and phonophobia). For episodic cluster headache: approve if the patient has between one headache every other day and eight headaches per day.

For continuation of therapy: Prescriber confirms that the member had a reduction in migraine days per month from baseline after a 3-month trial.

CHENODAL

MEDICATION(S)
CHENODAL

COVERED USES
N/A

EXCLUSION CRITERIA
Patient with calcified (radiopaque) stones

REQUIRED MEDICAL INFORMATION
Patient has diagnosis of radiolucent gallstones in well-opacifying gallbladder as visualized by oral cholecystography.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial and continuation: 1 year

OTHER CRITERIA
For initial therapy, patient must meet both of the following (1 and 2):
1.Patient has tried and failed or has a contraindication or intolerance to ursodiol.
2.Patient is not a candidate for cholecystectomy

For continuation of therapy: Provider confirms patient’s condition requires continued treatment as demonstrated by oral cholecystograms or ultrasonograms.

CHOLBAM

MEDICATION(S)
CHOLBAM

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with Chenodal

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed FAB-MS or genetic testing, LFTs

AGE RESTRICTION
Initial: 3 months, Continuation: 1 year

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a hepatologist, metabolic specialist, or GI.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
Bile acid synthesis disorders due to single enzyme defects:
1.Initial: Diagnosis is based on abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis
2.Continuation: Patient has responded to initial Cholbam treatment with an improvement in LFTs and does not have complete biliary obstruction
Bile acid synthesis disorders due to peroxisomal disorders (PD), including Zellweger Spectrum disorders
1.Initial: Diagnosis of PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g. rickets).
2.Continuation: Patient has responded to initial therapy based on improvement of liver function (e.g. AST or ALT) AND does not have complete biliary obstruction.

CIALIS/TADALAFIL FOR BPH

MEDICATION(S)
TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Erectile Dysfunction. Concomitant use of nitrates. Use in patients who have had a total prostatectomy.

REQUIRED MEDICAL INFORMATION
The member must have a diagnosis of benign prostatic hyperplasia. The dose is 2.5mg or 5mg once daily (10mg and 20mg strengths not covered)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial duration 3 months. If BPH symptoms improve (AUA-SI score decrease), approve for 1 year.

OTHER CRITERIA
The daily dose is prescribed as 2.5 mg or 5 mg once daily. The member must have symptoms of at least moderate severity that are bothersome, as defined by the American Urological Association Symptom Index (AUA-SI) greater than or equal to 8. Must have tried and failed or be intolerant of or contraindicated to two other drugs, one each from any two of the following different therapeutic classes: Alpha-1 adrenergic blockers (terazosin, doxazosin, tamsulosin, alfuzosin, silodosin) tried for a minimum of one month at the maximum tolerated dose, 5-alpha reductase inhibitors (finasteride, dutasteride) tried for a minimum of four months at the maximum tolerated dose, combination alpha-1 adrenergic blocker/5-alpha reductase inhibitors (dutasteride/tamsulosin) tried for a minimum of four months at the maximum tolerated dose.

CIBINQO

MEDICATION(S)
CIBINQO

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD). Concurrent use with an anti-interleukin monoclonal antibody. Concurrent use with other Janus Kinase inhibitors. Concurrent use with Xolair. Concurrent use with other Potent immunosuppressants (e.g. azathioprine, cyclosporine). COVID-19.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
Initial - 3 months. Continuation - 1 year.

OTHER CRITERIA
Atopic dermatitis: Approve for the duration noted if the patient meets one of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
i.Patient is 12 years of age or older AND
ii.Patient meets one of the following (a or b):
a)Patient has had a 3-month trial of at least ONE traditional systemic therapy OR
b)Patient has tried at least ONE traditional systemic therapy but was unable to tolerate a 3-month trial AND
Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to “step back” and try a traditional systemic agent for atopic dermatitis.
iii.The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
B)Patient is Currently Receiving Cibinqo. Approve for 1 year if the patient meets the following (i, ii, and iii):
i.Patient has already received at least 90 days of therapy with Cibinqo AND
Note: A patient who has received less than 90 days of therapy or who is restarting therapy with Cibinqo should be considered under Initial Therapy.
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND
iii.Compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such

as decreased itching.

CIMZIA

MEDICATION(S)
CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Ankylosing Spondylitis (AS). Approve Cimzia for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if Cimzia is prescribed by or in consultation with a rheumatologist AND the patient has tried TWO of the following: Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product.
B)Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (a and b):
a.Has been established on therapy for at least 6 months; AND
b.Patient meets at least one of the following (i or ii):
i. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) (Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
ii.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2.Crohn’s Disease in an Adult. Approve Cimzia for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii and iv):
i.The patient is 18 years of age or older; AND

ii.The patient meets one of the following conditions (a b, c or d):
a)The patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
b)The patient has tried one other conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate [MTX]). Note: A previous trial of a biologic other than the requested drug also counts as a trial of one other agent for Crohn's disease. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.; OR
c)Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
d)Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
iii.Cimzia is prescribed by or in consultation with a gastroenterologist.
iv.The patient has tried one adalimumab product.
B)Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (a and b):
a.Patient has been established on therapy for at least 6 months; AND
b.Patient meets at least one of the following (i or ii):
i. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug (Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.)
ii.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

3.Non-Radiographic Axial Spondyloarthritis (nr-axSpA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.The patient has objective signs of inflammation, defined as at least one of the following (a or b):
a)C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
b)Sacroiliitis reported on magnetic resonance imaging (MRI); AND
ii.Cimzia is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug (Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g. CRP, ESR).
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

4.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, iii, and iv):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine,

acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count.. These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the
prescribing physician; AND
iii.Cimzia is prescribed by or in consultation with a dermatologist.
iv.The patient has tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, and Tremfya [documentation required]. Note: a trial of multiple adalimumab products count as ONE product.
B)Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on the requested drug for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

5.Psoriatic Arthritis (PsA). Approve Cimzia for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if Cimzia is prescribed by or in consultation with a rheumatologist or a dermatologist AND the patient has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi SC, Stelara SC, Taltz, Tremfya, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products count as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.
B)Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (a and b):
a.Patient has been established on the requested drug for at least 6 months; AND
b.Patient meets at least one of the following (i or ii);
i.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) (Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).)
ii.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

6.Rheumatoid Arthritis (RA). Approve Cimzia for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii and iii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine). NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic other than the requested drug. A biosimilar of the requested drug does not count. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD; AND

ii.Cimzia is prescribed by or in consultation with a rheumatologist.
iii.The patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products count as ONE product.
B)Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (a and b);
a.Patient has been established on the requested drug for at least 6 months; AND
b.Patient meets at least one of the following (i or ii);
i.Patient experienced a beneficial clinical response when assessed by at least one objective measure (Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).)
ii.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

7.Spondyloarthritis (SpA), Other Subtypes (e.g., undifferentiated arthritis, reactive arthritis [Reiter's disease]) [NOTE: For ankylosing spondylitis, psoriatic arthritis, or non-radiographic axial spondyloarthritis, refer to the respective criteria under FDA-approved indications]. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, and iii):
i.The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
ii.The patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate [MTX], leflunomide, sulfasalazine]; AND
iii.The medication is prescribed by or in consultation with a rheumatologist.

B)Patients Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a and b);
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

CONTINUATION OF THERAPY
1B, 2B, 4B, 5B, 6B- Patients Currently Taking Cimzia and new to plan.
A)Approve Cimzia for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a, b, c, d, e, or f)

a)The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the

prescriber has verified that the patient has been receiving Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR

b)The patient has RA and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product; OR

c)The patient has AS and has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR [documentation required]; Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product; OR

d)The patient has PsA and has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi SC, Stelara SC, Taltz, Tremfya, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.; OR

e)The patient has plaque psoriasis and has tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, and Tremfya [documentation required]. Note: A trial of multiple adalimumab products counts as ONE product.; OR

f)The patient has CD and has tried one adalimumab product.

CONTINUOUS GLUCOSE MONITOR-MEDICAL NECESSITY

MEDICATION(S)
EVERSENSE SENSOR-HOLDER, EVERSENSE SMART TRANSMITTER, GUARDIAN 4 GLUCOSE SENSOR, GUARDIAN 4 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN RT CHARGER, GUARDIAN TEST PLUG

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Prior authorization is required for prescription drug coverage of non-preferred Continuous Glucose Monitor (CGM) and associated supplies (Guardian, Enlite, Real-Time, Minimed, Eversense)

The requested non-preferred Continuous Glucose Monitor (CGM) will be covered with prior authorization when the following criteria is met: Due to a valid medical reason, the patient is unable to use the preferred products (i.e., Dexcom products, Freestyle Libre). Documentation must be submitted.

COPAXONE

MEDICATION(S)
COPAXONE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The member has a diagnosis of a relapsing form of multiple sclerosis.

Previous therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
For Copaxone (brand name) coverage, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to the preferred product, glatiramer (generic), for the given diagnosis, (B) The member has a documented contraindication to the glatiramer (generic), (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic), OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic) for the requested indication. If the member was previously started on brand name Copaxone for a covered use, they are not required to try the generic glatiramer.

CORTICOSTEROID INHALERS

MEDICATION(S)
ALVESCO, PULMICORT FLEXHALER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc.), AND

3.One of the following:
Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives
For authorization of Pulmicort or Alvesco, the preferred product (Arnuity, Asmanex, QVar) must be referenced in the following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse

reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

COSENTYX

MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX SENSOREADY (2 PENS), COSENTYX SENSOREADY PEN, COSENTYX SYRINGE, COSENTYX UNOREADY PEN

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs). Crohn's Disease. Rheumatoid Arthritis. Uveitis.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Ankylosing Spondylitis (AS). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following (i and ii):
i. Patient has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of Cimzia, an infliximab Product (e.g. Remicade, biosimilars), or Simponi Aria or subcutaneous also counts [documentation required].
ii. Cosentyx is prescribed by or in consultation with a rheumatologist.
B)Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b.Compared with baseline (prior to initiating Cosentyx subcutaneous or intravenous), patient experienced an improvement

in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
i. Patient is 6 years of age or older; AND
ii. Patient meets ONE of the following conditions (a or b):
a.Patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than Cosentyx. A biosimilar of Cosentyx does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR
b.Patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii. Cosentyx is prescribed by or in consultation with a dermatologist.
iv. Patient has tried TWO of Enbrel, an adalimumab product, Sotyktu, Skyrizi subcutaneous, Tremfya, Stelara subcutaneous, Taltz, and Otezla [documentation required]. Note: A trial of multiple adalimumab products counts as one product.
B)Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cosentyx subcutaneous) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to initiating Cosentyx), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, and iii):
i.Patients meets one of the following (a or b)
a.Patient is 18 years of age or older: Patient has tried TWO of Enbrel, an adalimumab product, Skyrizi subcutaneous, Tremfya, Stelara subcutaneous, Taltz, Rinvoq/Rinvoq LQ, Xeljanz/XR, and Otezla [documentation required]. Note: A trial of Cimzia, an infliximab product (e.g. Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi [documentation required]. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product a trial of either or both Xeljanz products (Rinvoq and Rinvoq LQ) collectively counts as one product.; OR
b.Patient is less than 18 years of age and has tried one of Enbrel, Rinvoq/Rinvoq LQ or Stelara SC [documentation required].
ii.Cosentyx is prescribed by or in consultation with a rheumatologist or a dermatologist; AND
iii.Patient is 2 years of age or older
B)Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on Cosentyx subcutaneous or intravenous for at least 6 months; AND
ii. Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous or intravenous). Note: Examples of standardized measures of disease activity include

Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Cosentyx), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4.Non-radiographic axial spondyloarthritis. Approve for the duration noted if the patient meets ONE of the following:
A)Initial therapy. Approve for 6 months if the patient meets ALL of the following (i, ii and iii):
i. Patient has tried TWO of Cimzia, Taltz, and Rinvoq [documentation required].
Note: A trial of an Enbrel, an adalimumab product, an infliximab Product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required]. A trial of multiple adalimumab products counts as ONE product.
ii. Prescribed by or in consultation with a rheumatologist
iii. Patient has objective signs of inflammation, defined as C-reactive protein elevated beyond upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging.
B)Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on Cosentyx subcutaneous or intravenous for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous or intravenous). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Cosentyx, patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

5.Enthesitis-Related Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets both of the following (i and ii):
i.Patients is 4 years of age or older; AND
ii.The medication is prescribed by or in consultation with a rheumatologist.
B)Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on Cosentyx subcutaneous for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous). Note: Examples of objective measures include the Juvenile Arthritis Disease Activity Score (JADAS); Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b.Compared with baseline (prior to initiating Cosentyx subcutaneous), patient experienced an improvement in at least one

symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.
6.Hidradenitis Suppurativa. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
i.Patient is 18 years of age or older; AND
ii.Patient has tried at least one other therapy. Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.; AND
iii.The medication is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous). Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.; AND
iii.Compared with baseline (prior to initiating Cosentyx subcutaneous), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.

CONTINUATION OF THERAPY:
1B, 2B, 3B, 4B – AS, nr-axSpA, PP, PsA– Patients Currently Taking Cosentyx and new to plan.
A)Approve for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a, b, c, d, e, or f):
a)Patient has AS and has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, Xeljanx/XR. [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required].
b)Patient has nr-axSpA and has tried TWO of Cimzia, Taltz, and Rinvoq [documentation required]. Note: A trial of an Enbrel, an adalimumab product, an infliximab Product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required]. A trial of multiple adalimumab products counts as ONE product.
c)Patient has PP and has tried TWO of Enbrel, an adalimumab product, Skyrizi subcutaneous, Sotyktu, Tremfya, Stelara subcutaneous, Taltz, and Otezla [documentation required]. A trial of multiple adalimumab products counts as ONE product.
d)Patient is 18 years of age or older with PsA and has tried TWO of Enbrel, an adalimumab product, Skyrizi subcutaneous, Tremfya, Stelara subcutaneous, Taltz, Rinvoq/Rinvoq LQ, Xeljanz/XR, and Otezla [documentation required]. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts [documentation required]. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq or Rinvoq LQ) collectively counts as ONE product.; OR
e)Patient is less than 18 years of age with PsA and has tried ONE of Enbrel, Rinvoq/Rinvoq LQ or Stelara SC [documentation required]. Note: A trial of another TNFi counts towards a trial of Enbrel [documentation required]. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.; OR
f)According to the prescriber, the patient with AS, nr-axSpA, or PsA has been established on Cosentyx intravenous for at least 90 days; OR
g)Patient has been established on Cosentyx for at least 90 days and prescription claims history indicates at least a 90-day supply of Cosentyx was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required]. Note: In cases when 130 days of

the patient’s prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Cosentyx for at least 90 days AND the patient has been receiving Cosentyx via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cosentyx).

CRINONE, ENDOMETRIN, PROGESTERONE INJECTION

MEDICATION(S)
CRINONE, ENDOMETRIN, PROGESTERONE 500 MG/10 ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
Infertility unless the patient's certificate of coverage includes infertility treatment and benefits.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year. Review for renewal.

OTHER CRITERIA
Patients Certificate of Coverage includes infertility treatment and benefits OR the patient has a diagnosis of secondary amenorrhea and has tried and failed oral progestin therapy.

DAYBUE

MEDICATION(S)
DAYBUE

COVERED USES
Treatment of Rett syndrome

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, MECP2 gene mutation

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Rett Syndrome – approve if patient meets A and B: A)Patient has a pathogenic mutation in the MECP2 gene AND B)Patient has classical/typical Rett syndrome, according to the Rett Syndrome Diagnostic Criteria

DEFERASIROX

MEDICATION(S)
DEFERASIROX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, ferritin levels

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION
1 year

OTHER CRITERIA
1.For Chronic iron overload due to blood transfusions: Ferritin level consistently greater than 1000 mcg/L
2.For chronic overload in non-transfusion dependent thalassemia syndromes (member meets both a and b):
a.Patient has liver iron concentration levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of deferasirox
b.Patient has serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment

DEFERIPRONE

MEDICATION(S)
DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY)

COVERED USES
N/A

EXCLUSION CRITERIA
Transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

REQUIRED MEDICAL INFORMATION
Diagnosis, ANC

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Member meets all of the following (1, 2 and 3):
1.Diagnosis of transfusional iron overload due to one of the following (a, b or c):
a.Thalassemia syndromes
b.Sickle cell disease
c.Transfusional-dependent anemia
2.Absolute neutrophil count (ANC) is greater than 1.5 x 10^9/L
3.Has tried and failed, has intolerance or contraindication to one chelation therapy (e.g. generic deferasirox)

DICHLORPHENAMIDE

MEDICATION(S)
DICHLORPHENAMIDE, KEVEYIS

COVERED USES
Treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior medication trials, potassium levels

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 2 months, Continuation: 3 years

OTHER CRITERIA
Hypokalemic periodic paralysis (HypoPP) and related variants – initial therapy: Members must meet all of the following (1, 2, 3, and 4):
1.HypoPP has been confirmed by one of the following (a, b or c):
a.Serum potassium concentration of less than 3.5 mEq/L during a paralytic attack OR
b.Family history of the condition OR
c.Genetically confirmed skeletal muscle calcium or sodium channel mutation
2.Member had improvements in paralysis attack symptoms with potassium intake
3.Member has tried and failed oral acetazolamide therapy
4.The prescribing physician has excluded other reasons for acquired hypokalemia (e.g. renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse)
Hyperkalemia periodic paralysis (HyperPP) and related variants – initial therapy: Members must meet all of the following (1, 2, and 3):
1.HyperPP has been confirmed by one of the following (a, b, c or d)
a.An increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack OR
b.Serum potassium concentration during a paralytic attack greater than 5.0 mEq/L OR
c.A family history of the condition OR
d.Genetically confirmed skeletal muscle sodium channel mutation
2.Prescribing physician has excluded other reasons for acquired hyperkalemia (e.g. drug abuse, renal and adrenal dysfunction)

3.Member has tried and failed oral acetazolamide therapy

HypoPP, HyperPP and related variants – continuation of therapy: Patient has responded to dichlorphenamide (e.g. decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.

DIFICID

MEDICATION(S)
DIFICID

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis is Clostridiodes difficile (C. difficile)-associated diarrhea

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Ten days.

OTHER CRITERIA
Must first try and fail or have recurrence of disease after two courses vancomycin in the past 90 days. If members are allergic to vancomycin, Dificid will be approved. If members are continuing therapy started during a hospitalization, Dificid will be approved.

If criteria satisfied, approve for 20 tablets.

DOPTELET

MEDICATION(S)
DOPTELET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of thrombocytopenia. Platelet count.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Thrombocytopenia with chronic liver disease-7 days. Chronic Immune Thrombocytopenia initial-3 months, continuation-3 years.

OTHER CRITERIA
A.Treatment of thrombocytopenia in patients with CLD who are scheduled to undergo a procedure: Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Doptelet therapy.

B.Chronic ITP
a.Initial: Approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding AND has tried one other therapy or the patient has undergone splenectomy
b.Continuation: Approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.

DOXEPIN TOPICAL

MEDICATION(S)
DOXEPIN 5% CREAM, PRUDOXIN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

OTHER CRITERIA
The patient had an inadequate response, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).

DPP-4 INHIBITORS

MEDICATION(S)
ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLIT 12.5-30 MG, ALOGLIPTIN-PIOGLIT 25-15 MG TB, ALOGLIPTIN-PIOGLIT 25-30 MG TB, ALOGLIPTIN-PIOGLIT 25-45 MG TB, SAXAGLIPTIN HCL, SAXAGLIPTIN-METFORMIN ER, SITAGLIPTIN, SITAGLIPTIN-METFORMIN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Prior authorization is required for prescription drug coverage of non-preferred dipeptidyl peptidase-4 (DPP-4) inhibitors, including alogliptin, alogliptin-pioglitazone, saxagliptin, saxagliptin-metformin ER and sitagliptin.

Preferred products include: Glyxambi, Janumet, Januvia, Jentadueto, Tradjenta

Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer’s published dosing guidelines or the dose falls within dosing

guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

a.The member has demonstrated a failure of or intolerance to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the listed formulary alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the listed formulary agents used for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

DROXIDOPA

MEDICATION(S)
DROXIDOPA

COVERED USES
Neurogenic orthostatic hypotension

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medication history, Reauth: positive clinical response to therapy

AGE RESTRICTION
18 years and older.

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or neurologist

COVERAGE DURATION
Initial: 2 months, Continuation: 1 year

OTHER CRITERIA
Neurogenic orthostatic hypotension (nOH) – initial - approve if the patient meets ALL of the following criteria:
a.Patient has been diagnosed with symptomatic nOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy AND
b.Patient has tried and failed, has contraindication or intolerance to midodrine and fludrocortisone acetate

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML SYRINGE

COVERED USES
Atopic Dermatitis, moderate to severe or Asthma (moderate to severe), eosinophilic phenotype or oral corticosteroid-dependent, add-on maintenance treatment for patients inadequately controlled chronic rhinosinusitis with nasal polyposis, Eosinophilic esophagitis, prurigo nodularis.

EXCLUSION CRITERIA
Concurrent use of Dupixent with another Monoclonal Antibody Therapy (i.e. Adbry, Cinqair, Fasenra, Nucala, Tezspire, or Xolair). Concurrent use of Dupixent with Janus Kinase Inhibitors (JAKis) [oral or topical].

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
See other criteria.

PRESCRIBER RESTRICTION
See other criteria.

COVERAGE DURATION
See other criteria.

OTHER CRITERIA
1Asthma.
Approve for the duration noted if the patient meets one of the following conditions (A or B):
A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, and v):
i. Patient is 6 years of age or older; AND
ii. Patient meets ONE of the following criteria (a or b):
a) Patient has a blood eosinophil level 150 cells per microliter or greater within the previous 6 weeks or within 6 weeks prior to treatment with Dupixent or another monoclonal antibody therapy that may lower blood eosinophil levels; OR
Note: Examples of monoclonal antibody therapies that may lower blood eosinophil levels include Dupixent, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
b) Patient has oral (systemic) corticosteroid-dependent asthma according to the prescriber (e.g., the patient has received 5 mg or greater oral prednisone or equivalent per day for 6 months or more); AND
iii. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
a) An inhaled corticosteroid; AND
b) At least one additional asthma controller or asthma maintenance medication; AND
Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta2-agonists,

inhaled long-acting muscarinic antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Fasenra, Nucala, Tezspire, and Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfil the requirement for both criteria an and b.

iv. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):

Note: "Baseline" is defined as prior to receiving Dupixent or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Dupixent, Cinqair, Fasenra, Nucala, Tezspire, and Xolair.

a) Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR

b) Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR

c) Patient has a forced expiratory volume in 1 second (FEV1) < 80% predicted; OR

d) Patient has an FEV1/forced vital capacity (FVC) < 0.80; OR

e) Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND

v. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):

i. Patient has already received at least 6 months of therapy with Dupixent; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 1A (Asthma, Initial Therapy).

ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND

iii. Patient has responded to therapy as determined by the prescriber.

Note: Examples of a response to Dupixent therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department visits, or urgent care visits due to asthma; decreased requirement for oral corticosteroid therapy.

1Atopic Dermatitis.

Approve for the duration noted if the patient meets one of the following conditions (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets the following criteria (i, ii, iii, and iv):

i. Patient is 6 months of age or older; AND

ii. Patient has atopic dermatitis involvement estimated to be 10% of the body surface area or greater according to the prescriber; AND

iii. Patient meets ALL of the following criteria (a, b, and c):

(1) Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND

(2) This topical corticosteroid was applied daily for at least 28 consecutive days; AND

(3) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND

iv. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i and ii):

i. Patient has already received at least 4 months of therapy with Dupixent; AND

Note: A patient who has received < 4 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 2A (Atopic Dermatitis, Initial Therapy).

ii. Patient has responded to therapy as determined by the prescriber.

Note: Examples of a response to Dupixent therapy are marked improvements in erythema, induration/papulation/edema,

excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other responses observed.

1Eosinophilic Esophagitis

. Approve for the duration noted if the patient meets one of the following conditions (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, vi and vii):

i. Patient is 1 years of age or older; AND

ii. Patient weighs 15 kg or greater; AND

iii. Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating intraepithelial eosinophils or greater per high-power field; AND

iv. Patient does not have a secondary cause of eosinophilic esophagitis; AND

Note: Examples of secondary causes of eosinophilic esophagitis are hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, and food allergy.

v. Patient has received at least 8 weeks of therapy with a proton pump inhibitor; AND

vi. Patient meets ONE of the following (a or b):

a) Patient has tried dietary modifications to treat/manage eosinophilic esophagitis; OR

b) The provider has determined that the patient is not an appropriate candidate for dietary modifications; AND

Note: Examples of dietary modifications to treat eosinophilic esophagitis include an elemental diet or an elimination diet.

vii. The medication is prescribed by or in consultation with an allergist or gastroenterologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i and ii):

i. Patient has already received at least 6 months of therapy with Dupixent; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 3A (Eosinophilic Esophagitis, Initial Therapy).

ii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):

a) Reduced intraepithelial eosinophil count; OR

b) Decreased dysphagia/pain upon swallowing; OR

c) Reduced frequency/severity of food impaction.

1Chronic Rhinosinusitits with Nasal Polyps.

Approve for the duration noted if the patient meets one of the following conditions (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, and vi):

i. Patient is 18 years of age or older; AND

ii. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND

iii. Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; AND

iv. Patient meets BOTH of the following (a and b):

a) Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; AND

b) Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent; AND

v. Patient meets ONE of the following (a, b, or c):

a) Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR

b) Patient has a contraindication to systemic corticosteroid therapy; OR

c) Patient has had prior surgery for nasal polyps; AND

vi. The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose,

and throat [ENT] physician specialist).

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):

i. Patient has already received at least 6 months of therapy with Dupixent; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 3A (Nasal Polyps, Initial Therapy).

ii. Patient continues to receive therapy with an intranasal corticosteroid; AND

iii. Patient has responded to therapy as determined by the prescriber.

Note: Examples of a response to Dupixent therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell.

1Prurigo Nodularis.

Approve for the duration noted if the patient meets one of the following conditions (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, and vi):

i. Patient is 18 years of age or older; AND

ii. Patient has 20 identifiable nodular lesions or greater in total on both arms, and/or both legs, and/or trunk; AND

iii. Patient has experienced pruritus for 6 weeks or greater; AND

iv. Patient meets ONE of the following (a or b):

a) Patient's prurigo nodularis is NOT medication-induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease; OR

b) The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed, according to the prescriber; AND

v. Patient meets ALL of the following criteria (a, b, and c):

a) Patient has tried at least one high- or super-high-potency prescription topical corticosteroid; AND

b) This topical corticosteroid was applied daily for at least 14 consecutive days; AND

c) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND

vi. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i and ii):

i. Patient has already received at least 6 months of therapy with Dupixent; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 5A (Prurigo Nodularis, Initial Therapy).

ii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):

a) Reduced nodular lesion count; OR

b) Decreased pruritus; OR

c) Reduced nodular lesion size.

EGRIFTA

MEDICATION(S)
EGRIFTA SV

COVERED USES
N/A

EXCLUSION CRITERIA
Use in the management of abdominal obesity in patients without HIV infection.

Use in the management of HIV-related cachexia, weight loss, or fat distribution other than lipodystrophy.

REQUIRED MEDICAL INFORMATION
Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.

AGE RESTRICTION
Adults, 18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
N/A

EMPAVELI

MEDICATION(S)
EMPAVELI

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with Soliris or Ultomiris.

REQUIRED MEDICAL INFORMATION
Treatment of paroxysmal nocturnal hemoglobinuria (PNH), in adults.

AGE RESTRICTION
PNH – 18 years and older (initial therapy and continuation)

PRESCRIBER RESTRICTION
PNH – prescribed by or in consultation with a hematologist (initial therapy and continuation)

COVERAGE DURATION
PNH – initial 4 months, continuation 1 year

OTHER CRITERIA
Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages AND for a patient transitioning to Empaveli from Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion), the prescriber attests that these medications will be discontinued within 4 weeks after starting Empaveli. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis)

ENBREL

MEDICATION(S)
ENBREL 25 MG/0.5 ML SYRINGE, ENBREL 25 MG/0.5 ML VIAL, ENBREL 50 MG/ML SYRINGE, ENBREL MINI, ENBREL SURECLICK

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with biologic therapy or targeted synthetic DMARD. Crohn's Disease, Inflammatory Myopathies (Polymyosistis, Dermatomyositis, Inclusion Body Myositis), Hidradenitis Suppurativa, Polymyalgia Rheumatica (PMR), Sarcoidosis, Large Vessel Vasculitis (e.g., Giant Cell Arteritis, Takayasu's Arteritis), Wegener's Granulomatosis

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria for indication specific prescriber restrictions.

COVERAGE DURATION
See other criteria for approval duration

OTHER CRITERIA
Rheumatoid Arthritis

1.Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i and ii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD; AND
ii.The etanercept product is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Etanercept Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity

Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

2.Ankylosing Spondylitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Etanercept Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

3.Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis {JRA}] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis.] Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i and ii):
i.The patient meets one of the following conditions (a, b, c, or d):
a)The patient has tried one other systemic therapy for this condition (e.g., methotrexate [MTX], sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug [NSAID] { e.g., ibuprofen, naproxen}).
NOTE: A previous trial of a biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count; OR
b)The patient will be starting on an etanercept product concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
c)The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
d)The patient has aggressive disease, as determined by the prescribing physician; AND
ii.The etanercept product is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Etanercept Product. Approve for 1 year if the patient meets BOTH of the following (i and ii);
i. Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

4.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
i.The patient is greater than or equal to 4 years of age; AND
ii.The patient meets one of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.; OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.The etanercept product is prescribed by or in consultation with a dermatologist.

B)Patients Currently Receiving an Etanercept Product.
i.Approve for 1 year if the patient meets ALL of the following (a, b and c):
a.Patient has been established on therapy for at least 3 months; AND
b.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an etanercept product) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
c.Compared with baseline (prior to receiving an etanercept product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

5.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the etanercept product is prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patients Currently Receiving an Etanercept Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate)
b.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths).

Other Uses with Supportive Evidence

6.Behcet's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy: Approve for 3 months if the patient meets BOTH of the following (i and ii):
i.The patient has tried at least one conventional therapy (e.g., systemic corticosteroids {methylprednisolone}, immunosuppressants [azathioprine, methotrexate {MTX}, mycophenolate mofetil, tacrolimus, Leukeran® {chlorambucil}, cyclophosphamide, or cyclosporine], interferon alfa). A patient who has already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count; AND
ii.The etanercept product is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.
B)Patient is Currently Receiving an Etanercept Product: Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); ulcer depth, number, and/or lesion size.
iii.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as decreased pain, or improved visual acuity (if ophthalmic manifestations).

7.Graft-Versus-Host Disease (GVHD). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)For initial therapy, approve one month if the patient meets BOTH of the following (i and ii):
i.Patient has tried at least one conventional systemic treatment for graft-versus-host disease (Examples of conventional systemic treatments include systemic corticosteroids [e.g. methylprednisolone], antithymocyte globulin, cyclosporine, tacrolimus, and mycophenolate mofetil); AND
ii.The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.
B)For patients currently receiving an Etanercept Product, approve for 3 months if the patient meets BOTH of the following (i and ii):
i.Patient has been established on an etanercept product for at least 1 month; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product. Note: An example of objective measures is normalization of liver function tests, red blood cell count, or platelet count, or resolution of fever or rash.
b.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).

8.Pyoderma Gangrenosum. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)For initial therapy, approve for 4 months if the patient meets BOTH of the following criteria (i and ii):
i.The patient meets ONE of the following (a or b):
a)The patient has tried one systemic corticosteroid (e.g. prednisone); OR
b)The patient has tried one other immunosuppressant (e.g., mycophenolate mofetil, cyclosporine) for at least 2 months or was intolerant to one of these agents; AND
ii.The etanercept product is prescribed by or in consultation with a dermatologist.

B)For patients currently receiving an Etanercept Product, approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 4 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an etanercept product) in at least one of the following: size, depth, and/or number of lesions; AND
iii.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesion(s).

9.Spondyloarthritis (SpA), Other Subtypes (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter's disease]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications]. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.The patient meets ONE of the following conditions (a or b):
a)The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate {MTX}, leflunomide, sulfasalazine] has been tried; OR
b)The patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following [(1) or (2)]:
(1)C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
(2)Sacroiliitis reported on magnetic resonance imaging (MRI); AND
ii.The etanercept product is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Etanercept Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); OR
b)Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

10.Still's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)For initial therapy, approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
i.Patient has tried one corticosteroid; AND
ii.Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) such as methotrexate (MTX) given for at least 2 months or was intolerant to a conventional synthetic DMARD. Note: A previous trial of one biologic other than the requested drug (e.g. Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection], Arcalyst [rilonacept subcutaneous injection], Ilaris [canakinumab subcutaneous injection]) also counts towards a trial of one other systemic agent for Still's disease. A biosimilar of the requested biologic does not count); AND
iii.The etanercept product is prescribed by or in consultation with a rheumatologist.
B)For patients currently receiving an Etanercept Product, approve 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on this medication for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):

a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an etanercept product). Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b.Compared with baseline (prior to initiating an etanercept product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

ENDARI

MEDICATION(S)
L-GLUTAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Endari will be used to reduce the acute complications of sickle cell disease.

AGE RESTRICTION
The patient is greater than or equal to 5 years of age.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
The patient is currently taking Hydroxyurea or has an intolerance or contraindication to Hydroxyurea therapy.

ENSPRYNG

MEDICATION(S)
ENSPRYNG

COVERED USES
Member has diagnosis of neuromyelitis optica spectrum disorder

EXCLUSION CRITERIA
Concomitant use with Soliris (eculizumab), rituximab or Uplizna (inebilizumab-cdon)

REQUIRED MEDICAL INFORMATION
Diagnosis, Previous therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or ophthalmologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
For initial therapy, patient must meet following criteria (i, ii, AND iii):

i.Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-aquaporin-4 antibody AND

ii.Patient is currently receiving or has previously tried two of the following systemic therapies used in the maintenance setting (a, b, c, or d):

a.Azathioprine OR

b.Corticosteroid OR

c.Mycophenolate mofetil OR

d.Rituximab AND

(Note: An exception to the requirement for a trial of a systemic therapy can be made if the patient has already tried Soliris (eculizumab injection) or Uplizna (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent.

iii.Patient has a history of at least one relapse (acute attack from neuromyelitis spectrum disorder) in the last 12 months.

If patient is currently receiving Enspryng, approve if the patient meets the following (i AND ii):

i.Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-aquaporin-4 antibody

ii.According to the prescriber, patient has had clinical benefit from the use of Enspryng

Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.

ENTOCORT EC/BUDESONIDE EC

MEDICATION(S)
BUDESONIDE DR, BUDESONIDE EC

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
The medication must be ordered by a gastroenterologist.

COVERAGE DURATION
Indefinite

OTHER CRITERIA
N/A

ENTYVIO SC

MEDICATION(S)
ENTYVIO PEN

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
a.Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv and v):
i.Patient is 18 years of age or older; AND
ii.According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous; AND
iii.Patient meets ONE of the following (a or b):
a.Patient has had a trial of ONE systemic therapy; OR
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of a biologic also counts as a trial of one systemic agent for ulcerative colitis.
b.Patient meets BOTH of the following [(1) and (2)]:
(1)Patient has pouchitis; AND
(2)Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema
iv.Patient meets ONE of the following (a or b):
a.Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Zymfentra, Omvoh subcutaneous, Rinvoq, Simponi subcutaneous, Xeljanz/XR [documentation required]; OR
Note: A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and

Xeljanz XR) collectively counts as ONE product. A trial of an infliximab product (e.g., Remicade, biosimilar), Omvoh intravenous, Skyrizi subcutaneous or Stelara intravenous also counts [documentation required].
b.According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Entvyio IV.
v.The medication is prescribed by or in consultation with a gastroenterologist.
b.Patient is Currently Receiving Entyvio (Subcutaneous or Intravenous). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on Entyvio subcutaneous or intravenous for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy with Entyvio subcutaneous or intravenous is reviewed under criterion A (Initial Therapy).
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

2.Crohn's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):
a)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv and v):
i.Patient is 18 years of age or older; AND
ii.According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous; AND
iii.Patient meets ONE of the following (a, b, c, or d):
a.Patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated in this patient; OR
b.Patient has tried one conventional systemic therapy for Crohn's disease. Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already received a biologic are not required to "step back" and try another agent. A trial of mesalamine does not count as a systemic therapy for Crohn's disease.; OR
c.Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
d.Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
iv.The medication is prescribed by or in consultation with a gastroenterologist.
v.Patient meets ONE of the following (a or b):
a.Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Zymfentra, Cimzia, Rinvoq [documentation required]. Note: a trial of multiple adalimumab products counts as ONE product. A trial of an infliximab intravenous product (e.g., Remicade, biosimilars), Skyrizi intravenous, or Stelara intravenous also counts [documentation required].; OR
b.According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Entvyio IV.
b)Patient is Currently Receiving Entyvio Intravenous or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months. Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior

to initiating the requested drug). Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool

CONTINUATION OF THERAPY:
UC – Patients Currently Taking Entyvio and new to plan.
A)Approve for 1 year if the patient meets ONE of the following conditions (a, b, or c)
a)Patient has Ulcerative Colitis and has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Zymfentra, Omvoh subcutaneous, Rinvoq, Simponi subcutaneous, Xeljanz/XR [documentation required]; OR
Note: A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of an infliximab product (e.g., Remicade, biosimilars), Omvoh intravenous, Skyrizi subcutaneous or Stelara intravenous also counts [documentation required].
b)Patient has Crohn's disease and has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Zymfentra, Cimzia, Rinvoq [documentation required]; OR
Note: A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of an infliximab intravenous product (e.g., Remicade, biosimilars), Skyrizi subcutaneous, or Stelara intravenous also counts [documentation required].
c)According to the prescriber, the patient has been established on Entyvio intravenous for at least 90 days; OR
d)Patient has been established on Entyvio subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Entyvio subcutaneous was dispensed within the past 130 days [verification in prescription claims history required], or if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Entyvio subcutaneous for at least 90 days AND the patient has been receiving Entyvio subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Entyvio subcutaneous).

EPCLUSA

MEDICATION(S)
EPCLUSA 150-37.5 MG PELLET PKT, EPCLUSA 200 MG-50 MG TABLET, EPCLUSA 200-50 MG PELLET PACK, SOFOSBUVIR-VELPATASVIR

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding ribavirin

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
3 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION
Criteria will be applied consistent with current AASLD/IDSA guidance

OTHER CRITERIA
Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. Preferred medications are: Mavyret and Harvoni.

One of the following a, b, c, or d: a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR d. The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Lennox-Gastaut Syndrome (LGS) OR Severe Myoclonic Epilepsy in Infancy (SMEI), also known as Dravet Syndrome OR tuberous sclerosis complex.

AGE RESTRICTION
The member is 1 year of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For seizures associated with Lennox-Gastaut Syndrome, the patient must have a previous trial of ONE of the following: lamotrigine, topiramate, rufinamide, clobazam, valproate, felbamate or clonazepam. For seizures associated with Dravet Syndrome, the patient must have a previous trial of ONE of the following: valproate, clobazam, topiramate, Diacomit or Fintepla. For tuberous sclerosis complex – approve if the patient has tried at least one other antiepileptic drug.

EVEKEO

MEDICATION(S)
AMPHETAMINE SULFATE

COVERED USES
N/A

EXCLUSION CRITERIA
Weight loss.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
The drug must be used for a medically accepted indication not otherwise excluded from the Commercial Certificate of Coverage.

EVRYSDI

MEDICATION(S)
EVRYSDI

COVERED USES
N/A

EXCLUSION CRITERIA
Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)

COVERAGE DURATION
4 months

OTHER CRITERIA
A.Spinal Muscular Atrophy, Initial Treatment - Approve if the patient meets all of the following (a, b and c):
a.Patient has baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams: (i, ii, iii, iv, v, vi, or vii)
i.Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22],
ii.Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
iii.Hammersmith Functional Motor Scale Expanded (HFMSE)
iv.Hammersmith Infant Neurological Exam Part 2 (HINE-2)
v.Motor Function Measure-32 Items (MFM-32)
vi.Revised Upper Limb Module (RULM) test
vii.World Health Organization motor milestone scale
b.Has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required]
c.The patient meets all of the following criteria (i, ii and iii):
i.has two to four survival motor neuron 2 (SMN2) gene copies [documentation required]
ii.The patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required]
iii.For patients who have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued

B.Patients currently receiving Evrysdi – approve if the patient meets all of the following (a, b and c):
a.Patient meets all of the requirements for initial therapy
b.Patient has responded to Evrysdi
c.Patient continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) physician monitoring/assessment tool OR patient must have had a positive clinical response from pretreatment baseline (i.e., within the past 4 months) from one of the following exams: (i, ii, iii, iv, v, vi or vii):
i.Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22],
ii.Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
iii.Hammersmith Functional Motor Scale Expanded (HFMSE)
iv.Hammersmith Infant Neurological Exam Part 2 (HINE-2)
v.Motor Function Measure-32 Items (MFM-32)
vi.Revised Upper Limb Module (RULM) test
vii.World Health Organization motor milestone scale.

FASENRA

MEDICATION(S)
FASENRA, FASENRA PEN

COVERED USES
N/A

EXCLUSION CRITERIA
Member will not be using in combination with Xolair or another anti-interleukin monoclonal antibody

REQUIRED MEDICAL INFORMATION
Diagnosis of severe asthma, with an eosinophilic phenotype. Previous therapy. Peripheral blood eosinophil count.

AGE RESTRICTION
6 years or older

PRESCRIBER RESTRICTION
The drug is being prescribed by or in consultation with an allergist, immunologist or pulmonologist.

COVERAGE DURATION
Initial 6 months. Continuation, indefinitely.

OTHER CRITERIA
Pharmacy Benefit Criteria Only: Additional medical drug benefit criteria may be required if the patient is receiving the medication at the hospital or clinic.

The patient has a diagnosis of severe asthma, with an eosinophilic phenotype. The member must have peripheral blood eosinophil count greater than or equal to 150 cells per microliter, within the previous 6 weeks (prior to treatment of with any anti-interleukin [IL-5] therapy). The member must have received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled long acting beta agonist, inhaled long acting muscarinic antagonist, leukotriene receptor antagonist, theophylline. The patient's asthma continues to be uncontrolled as defined by one of the following: Experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, Experienced one or more asthma exacerbations requiring hospitalization or treatment in an emergency department in the previous year, Patient has a FEV1 less than 80 percent predicted, Patient has FEV1/FVC less than 0.80, Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 consecutive months. For continuation of therapy, if the member meets the following criteria, then therapy will be continued indefinitely: The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy), AND The patient continues to receive therapy with an inhaled corticosteroid.

FILSPARI

MEDICATION(S)
FILSPARI

COVERED USES
Reducing proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression

EXCLUSION CRITERIA
Concurrent use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin receptor blockers [ARBs]), endothelin receptor antagonists, or aliskiren

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values (proteinuria and/or urine protein-to-creatinine ratio, eGFR)

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist

COVERAGE DURATION
Initial – 9 months. Continuation – 1 year.

OTHER CRITERIA
Primary Immunoglobulin A Nephropathy:
1.Initial Criteria – approve if patient meets all the following criteria:
i.Diagnosis has been confirmed by biopsy
ii.Patient is at high risk of disease progression, defined by meeting the following criteria (a and b):
a)Patient meets ONE of the following [(1) or (2)]:
(1)Proteinuria greater or equal to 1.0 g/day; OR
(2)Urine protein-to-creatinine ratio greater or equal to 1.5 g/g; AND
b)Patient has received the maximum or maximally tolerated dose of ONE of the following for at least 30 days prior to starting Filspari [(1) or (2)]:
(1)Angiotensin converting enzyme inhibitor (e.g. lisinopril, enalapril); OR
(2)Angiotensin receptor blocker (e.g. losartan, valsartan); AND
iii.Patient has an estimated glomerular filtration rate greater or equal to 30 mL/min/1.73 m2
2.Continuation Criteria – approve if patient meets all the following criteria:
i.Diagnosis has been confirmed by biopsy
ii.Patient has had a response to Filspari according to the prescriber (Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline)
iii.Patient has an estimated glomerular filtration rate greater or equal to 30 mL/min/1.73 m2

FILSUVEZ

MEDICATION(S)
FILSUVEZ

COVERED USES
Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa [EB]

EXCLUSION CRITERIA
Combination with Vyjuvek.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
6 months of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist or wound care specialist

COVERAGE DURATION
3 months

OTHER CRITERIA
Dystrophic epidermolysis bullosa (DEB)/Junctional epidermolysis bullosa (EB): 1.Initial therapy: Patient meets ALL of the following (a, b and c): a.Patient has at least one clinical feature of epidermolysis bullosa b.Patient has one or more open wound(s) that will be treated (i.e., target wound[s]) c.Target wound(s) meet the following, according to the prescriber (i, ii, iii and iv): i.Target wound(s) is clean in appearance and does not appear to be infected ii.Target wound(s) is 10 cm2 to 50 cm2 iii.Target wound(s) is greater than or equal to 21 days and less than 9 months old iv.Squamous cell and/or basal cell carcinoma has been ruled out for the target wound(s)
2.Continuation of therapy: Patient meets ALL of the following (a, b and c): a.The target wound(s) remains open b.The target wound(s) has decreased in size from baseline c.For patients new to the plan, they will also need to have met initial criteria at time of treatment with the requested medication

FINTEPLA

MEDICATION(S)
FINTEPLA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
2 years and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist (initial therapy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome-continuation-approve if the patient is responding to therapy.

FIRAZYR

MEDICATION(S)
ICATIBANT, SAJAZIR

COVERED USES
N/A

EXCLUSION CRITERIA
Icatibant will not be used in combination with other approved treatments for acute hereditary angioedema (HAE) attacks.

REQUIRED MEDICAL INFORMATION
Diagnosis of HAE and icatibant is being used for the treatment of acute HAE attacks.

AGE RESTRICTION
18 years or older

PRESCRIBER RESTRICTION
Prescribed by an immunologist, allergist, otolaryngologist or rheumatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Hereditary Angioedema due to C1 Inhibitor (C1-INH) deficiency (Type I or Type II):
a.Treatment of acute attacks – initial therapy: The patient has HAE type I or II as confirmed by the following diagnostic criteria (i and ii):
i.The patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND
ii.The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values.

b. Continuation of therapy: Patients who have treated previous acute HAE attacks with icatibant – the patient has had a favorable clinical response (e.g. decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.

FIRDAPSE

MEDICATION(S)
FIRDAPSE

COVERED USES
N/A

EXCLUSION CRITERIA
History of seizures (initial therapy).

REQUIRED MEDICAL INFORMATION
Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). Seizure history, lab and test results.

AGE RESTRICTION
6 years and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a neuromuscular specialist.

COVERAGE DURATION
For initiation of therapy: 3 months

For continuation of therapy: 1 year

OTHER CRITERIA
Initial therapy: Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician.

Continuation therapy: Patient continues to derive benefit (e.g., improved muscle strength, improvement in mobility) from Firdapse, according to the prescribing physician.

GALAFOLD

MEDICATION(S)
GALAFOLD

COVERED USES
The medication is being used for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

EXCLUSION CRITERIA
Concomitant use of enzyme replacement therapy (ERT) is excluded. Severe renal impairment (eGFR less than 30 ml/min/1.73m2) or ESRD requiring dialysis.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
16 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease.

COVERAGE DURATION
3 years

OTHER CRITERIA
Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

GATTEX

MEDICATION(S)
GATTEX

COVERED USES
N/A

EXCLUSION CRITERIA
Members with biliary and/or pancreatic disease.

Members with active gastrointestinal malignancy.

REQUIRED MEDICAL INFORMATION
Diagnosis of short bowel syndrome, dependent on parenteral support. Parenteral nutrition (PN) and/or intravenous (IV) fluid dependency.

AGE RESTRICTION
Member is 1 year of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
6 months initial, 12 months continuation.

OTHER CRITERIA
For initial authorization, chart notes supporting the use of parenteral nutrition/IV fluids for 12 months and current volume of parenteral support in liters per week. For continuation, the provider must provide medical records documenting tolerance and effectiveness of therapy. Effectiveness of therapy is defined as a decrease in parenteral nutrition/IV volume from baseline weekly requirement at start of Gattex treatment.

GIP/GLP-1 AGONIST

MEDICATION(S)
MOUNJARO

COVERED USES
Type 2 diabetes mellitus

EXCLUSION CRITERIA
Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza)

REQUIRED MEDICAL INFORMATION
Diagnosis, previous medication tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime

OTHER CRITERIA
For Type 2 diabetes mellitus (T2DM), member must meet all of the following: 1.Member has documented diagnosis of T2DM 2. Member has tried or has contraindication to metformin.

GLEEVEC

MEDICATION(S)
IMATINIB MESYLATE

COVERED USES
Graft Versus Host Disease (GVHD)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For chronic graft versus host disease – approve if the patient has tried at least one conventional systemic treatment (for example, corticosteroids, Imbruvica).

For oncology indications, reach out to eviCore to complete the authorization.

GLP-1 AGONIST

MEDICATION(S)

LIRAGLUTIDE, OZEMPIC 0.25-0.5 MG/DOSE PEN, OZEMPIC 1 MG/DOSE (4 MG/3 ML), OZEMPIC 2 MG/DOSE (8 MG/3 ML), RYBELSUS, TRULICITY, VICTOZA 2-PAK, VICTOZA 3-PAK

COVERED USES

Treatment of type 2 diabetes mellitus.

EXCLUSION CRITERIA

Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza, Mounjaro)

REQUIRED MEDICAL INFORMATION

Diagnosis, previous medications tried

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Lifetime

OTHER CRITERIA

For Type 2 diabetes mellitus (T2DM), member must meet all of the following:

1.Member has documented diagnosis of T2DM

2.Member has tried or has contraindication to metformin

GROWTH HORMONE

MEDICATION(S)

GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN-SAIZENPREP, SEROSTIM, ZOMACTON

COVERED USES

N/A

EXCLUSION CRITERIA

1.Constitutional delay of growth and puberty.
2.Down's syndrome
3.Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions such as asthma, juvenile rheumatoid arthritis, after renal/heart/liver/or bone marrow transplantation
4.Kidney transplant patients (children) with a functional renal allograft.
5.Liver transplantation.
6.Cardiac transplantation.
7.Bone marrow transplantation without total body irradiation (cranial radiation)
8.Congenital adrenal hyperplasia.
9.Bony dysplasias (achondroplasia, hypochondroplasia).
10.Osteogenesis imperfecta.
11.X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets).
12.Myelomeningocele.
13.Dilated cardiomyopathy and heart failure.
14.Athletic ability (enhancement).
15. Aging (i.e., antiaging); to improve functional status in elderly patients; and somatopause.
16. Infertility.
17.Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure.
18.Osteoporosis, postmenopausal women or idiopathic in men, or glucocorticoid-induced.
19.Adults with end-stage renal disease undergoing hemodialysis.
20.HIV-infected patients with alterations in body fat distribution
21.Crohn’s disease.
22.Chronic fatigue syndrome.
23.Fibromyalgia.
24.Cystic fibrosis.
25.Familial dysautonomia
26.Burn injury
27.Central precocious puberty
28.Multiple system atrophy (MSA)
29.Thalassemia
30.Obesity

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
Authorization requires that the following criteria be met.

A.Growth Hormone Deficiency: For coverage of formulary Genotropin; Humatrope; Norditropin Flexpro; Nutropin AQ; Saizen; Omnitrope; Zomacton (all listed products except Serostim) requires patients to meet one of the following criteria:

A1.Children or adolescents diagnosed with acquired growth hormone deficiency for INITIAL TREATMENT must meet the following criteria (a through d).

a.The patient must be evaluated by an endocrinologist.

b.Provocative growth hormone testing: The patient must have a documented growth hormone deficiency as defined by a diminished serum growth hormone response to stimulation testing of < 10 ng/mL. The results of one of the following stimulation tests support the diagnosis of growth hormone deficiency: levodopa, insulin-induced hypoglycemia, arginine, clonidine, and glucagon. One stimulation test is required to exclude normal children. Children severely affected by growth hormone deficiency fail growth hormone stimulation tests. Some children will achieve stimulated growth hormone concentrations above 10 ng/mL and should be reviewed for authorization with criteria A.2. below.

c.Height: The patient's baseline height must be < the tenth percentile for gender and age

d.Growth velocity: Children aged < 3 years must have a pretreatment growth rate of < 7 cm per year, and children aged 3 years and older must have a growth rate < 4 cm per year OR for a child/adolescent less than 18 years of age the growth velocity is <10th percentile for age and gender based on at least 6 months of growth data.

Initial Coverage Duration: 12 Months

Authorizations can be given for the following conditions where children are growth hormone deficient:

Children who have undergone brain radiation. Somatropin is recommended for patients who have undergone brain radiation if they meet the criteria for children A.1.a., A.1.b and A.1.d (Do not have to meet baseline height criteria as defined in A.1.c.). Children who have undergone brain radiation and have demonstrated growth hormone deficiency often begin treatment with somatropin when the rate of growth slows significantly.

Congenital hypopituitarism. Somatropin is recommended for infants or children with congenital hypopituitarism. Patients must be evaluated by an endocrinologist (criteria A.1.a above) and meet the criteria for children per A.1.b above. (Do not have to meet height or growth rate criteria as defined in A.1.c. and A.1.d. above).

Panhypopituitarism. Patient haspituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary “bright spot” on magnetic resonance image or computed tomography must be evaluated by an endocrinologist. Growth hormone stimulation testing is not required. These patients either have severe isolated growth hormone deficiency or multiple pituitary hormone deficiencies.

Children who have had a hypophysectomy (surgical removal of pituitary gland). Approve.

Children/Adolescents with growth hormone deficiency for CONTINUED TREATMENT with somatropin therapy.

In patients less than 12 years who have been receiving somatropin for at least 12 months, the growth rate must have increased significantly in the most recent year. In children or adolescents who respond to growth hormone the growth rate increases by 4cm/year or more in most recent year. Further authorization is not recommended when the height velocity is < 4 cm/year in the most recent year. Review patient’s growth rate annually.
These criteria do not apply to adolescents with documented hypopituitarism.

In adolescents aged older than or equal to 12 years and less than or equal to 18 years with prior therapy with somatropin for growth hormone deficiency, the growth rate must have increased significantly in the most recent AND the epiphyses must be open. In children or adolescents who respond to growth hormone the growth rate increases by 4cm/year in most recent year AND epiphyses are open. Further authorization is not recommended when the growth rate is < 4 cm/year and/or if the epiphyses are closed. Review patient’s growth rate and x-ray evidence of epiphyses annually.
These criteria do not apply to adolescents with documented hypopituitarism.

Adolescents/young adults who have previously responded to somatropin with increases in height velocity and who have completed linear growth (defined as growth rate less than 4cm/year) may continue receiving somatropin therapy as a transition adolescent or adult with growth hormone deficiency. See criteria A3.

Adolescents or young adults greater than 18 years of age, the growth rate must have increased by 4cm/year or more in most recent year AND epiphyses must remain open. Somatropin should not be authorized when the mid-parental height is attained. Mid-parental height is the father’s height plus the mother’s height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female. Review annually.

Ongoing Coverage Duration: 12 months

A2.Non-growth hormone deficient short stature (idiopathic short stature) for INITIAL TREATMENT in children or adolescents whose epiphyses remain open. For coverage of somatropin on a 6-month trial basis, patients must meet ALL of the following criteria (a through e).

a.Height: The patient’s baseline height must be < the fifth percentile for gender and age.

b.Growth velocity (pretreatment growth rate):
•Children aged less than 3 years must have a pretreatment growth rate of < 7 cm per year;
•Children aged 3 years and older must have a growth rate < 4 cm per year; OR
•For a child of any age the growth velocity is <10th percentile for age and gender based on at least 6 months of growth

data.

c.The child has a condition for which growth hormone is effective (or will possibly be effective during the initial trial of therapy).

d.An endocrinologist must certify treatment based on bone-age x-ray

e. The child does not have constitutional delay of growth and puberty

[Children or adolescents with dysmorphic phenotypes such as skeletal dysplasias or Turner syndrome, those born SGA, and those with clearly identified causes of short stature (e.g., celiac disease, inflammatory bowel disease, juvenile chronic arthritis, growth hormone deficiency or growth hormone resistance, hypothyroidism, Cushing's syndrome) should be excluded from review for idiopathic short stature.]

Initial Coverage Duration: 6 months

Children/Adolescents with non-growth hormone deficient sort stature for CONTINUED TREATMENT with somatropin therapy after initial trial. After the 6-month trial, approve for an additional 12-months if:
•The annualized growth rate doubles in comparison to the previous year (e.g., if the growth velocity was 3 cm/year for the year prior to treatment, then after 6 months of growth hormone therapy, the growth velocity must be at least 3 cm in 6 months [1.5 cm/6 months baseline]); or if the growth velocity was 2 cm/year for the year prior to treatment, then after 6 months of growth hormone therapy, the growth velocity must be at least 2 cm in 6 months [1 cm/6 months baseline] OR
•Patients 7 years or greater and less than 12 years: approve if height has increased by 4cm/year or more in the most recent year
•Patients 12 years or greater and 18 years or less, approve f the height has increased by 4cm/yr in the most recent year AND the epiphyses are open
•Adolescents and young adults greater than 18 years of age, approve if the height has increased by 4cm/hear or more in the most recent year, AND the epiphyses are open, AND the mid-parental height is not yet attained. Mid-parental height is the father's height plus the mother's height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female.

Continued Coverage Duration: 12 months

A3.Adults or transition adolescents diagnosed with growth hormone deficiency for INITIAL TREATMENT must meet the following criteria (a, b, c and d):

a.The patient must be evaluated by or in consultation with an endocrinologist.

b. The endocrinologist must certify that somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability or for body building.

c.The patient must have a documented diagnosis of somatotropin (growth hormone) deficiency syndrome that is one of the following:

Adult onset. Growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or

subarachnoid hemorrhage; OR

Childhood onset. Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. Note: Somatropin is not recommended in adults who had growth hormone treatment of conditions as children or adolescents that were not due to growth hormone deficiency such as Turner syndrome, idiopathic short stature, or SGA. Retesting these patients when final height is attained is not indicated.

d.Note: d is either i, ii or iii.
i. The patient must have a negative response to one standard growth hormone stimulation test as follows:

Adults: The insulin tolerance test or the glucagon stimulation test must be used. The peak growth hormone response for the insulin tolerance test must be 5.0 mcg/L or less or for the glucagon test must be 3.0 mcg/L or less. If the GHRH plus arginine test is available, it can be used. [The insulin tolerance test is the gold-standard test for diagnosis of growth hormone deficiency. There is no information of the effects of increased BMI or central adiposity on the insulin tolerance test. There are no normative data by BMI for the glucagon or arginine tests. The insulin tolerance test is contraindicated in patients with ischemic heart disease or seizure disorders or in the elderly. Clonidine and levodopa are not useful tests in adults.]

OR

Transition Adolescents: (adolescents with childhood onset growth hormone deficiency who are transitioning from childhood to adulthood): The patient must be off somatropin for at least one month before retesting. The insulin tolerance test or the glucagon stimulation test must be used. The peak growth hormone response for the insulin tolerance test must be 5.0 mcg/L or less or for the glucagon test must be 3.0 mcg/L or less. If the GHRH plus arginine test is available, it can be used. See note below. The transition period is when statural growth is completed, usually before age 20 years (arbitrary age range 15 to 25 years).

Note: rarely, the arginine alone test may be used in adults or transition adolescents if both the insulin tolerance and the glucagon stimulation tests are contraindicated and glucagon is not available. With the arginine test, the peak growth hormone response must be less than or equal to 0.4 mcg/L.

Note: Growth hormone releasing hormone (GHRH, sermorelin, Geref) is no longer available in the U.S. When GHRH was available, GHRH plus arginine was considered the best alternative to the insulin tolerance test in adults. For adults or transition adolescents who have had a GHRH plus arginine test, the peak growth hormone response should be as follows.
less than or equal to 11.0 mcg/L in patients with a BMI less than 25 kg/m2;
less than or equal to 8.0 mcg/L with BMI greater than or equal to 25 and less than 30 kg/m2; and
less than or equal to 4.0 mcg/L with BMI greater than or equal to 30 kg/m2.

Note: According to the American Association of Clinical Endocrinologists (AACE) medical guidelines patients with childhood growth hormone deficiency previously treated with somatropin replacement in childhood should be re-tested after final height is achieved and somatropin therapy discontinued for at least one month.

OR both of the following:

ii. The patient (adult onset or transition adolescent) has 3 or more of the following pituitary hormone deficiencies: thyroid stimulating hormone (TSH) deficiency, adrenocorticotropin hormone (ACTH) deficiency, gonadotropin deficiency (leutinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and arginine vasopressin (AVP) deficiency (central diabetes insipidus).

AND

Serum IGF-I less than 84 micrograms/liter (11 nmol/liter) or less using the Esoterix Endocrinology competitive binding RIA OR if another assay is used, the age and gender adjusted serum IFG-I SDS is below the lower limits of the normal reference range for the reporting laboratory. If other assays are used, the serum IFG-I level reference range should be provided by the laboratory and show an abnormally low IFG-I based on age and gender. In transition adolescents, the IFG-I is determined when the patient has been off somatropin therapy for at least one month. Other causes of low serum IGF-I must be excluded (e.g., malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy) before using IGF-I as a maker of growth hormone deficiency. Serum IGF-I alone is not specific enough for diagnosis.

iii.: Adults with childhood onset growth hormone deficiency including those with known mutations; embryonic/congenital defects, irreversible hypothalamic-pituitary structural lesions and those with evidence of panhypopituitarism (3 or more pituitary hormone deficiencies) and serum IGF-I levels below the age- and sex- appropriate reference range off growth hormone therapy. These patients do not have to meet any of the criteria of d.i. or d.ii. A growth hormone stimulation test is not required in these patient exceptions.

Coverage Duration: 12 Months

Patients (adults and transition adolescents) with growth hormone deficiency who are CONTINUING TREATMENT with somatropin therapy.
Adults or transition adolescents with prior therapy with somatropin for growth hormone deficiency should be reviewed annually. The patient must be evaluated by an endocrinologist or in consultation with an endocrinologist and this physician must certify that somatropin is not being used for anti-aging therapy or to enhance athletic performance/body building.

Coverage Duration: 12 Months

[Adult growth hormone deficiency can be predicted with greater than 90% accuracy by the presence of 3 or 4 pituitary hormone deficiencies in addition to serum IGF-1 concentration that is less than 2.5 percentile or less than -2 SDS. This is in the absence of conditions that lower IGF-I. Patients with 3 or more pituitary hormone deficiencies and an IGF-1 level below the reference range do not need a growth hormone stimulation test. Because of the nature of the cause of growth hormone deficiency in children with structural lesions with multiple hormone deficiencies and those with proven genetic causes, a low IGF-1 at least one month off somatropin therapy is sufficient documentation of persistent growth hormone deficiency without additional provocative testing in these adults with childhood-onset growth hormone deficiency.]

A4.Turner’s syndrome. Somatropin is approvable for patients with short stature associated with Turner’s syndrome, demonstrated by chromosome analysis. Evaluation of growth hormone secretion is not necessary because these children do not have abnormal growth hormone secretion.

Patients with Turner syndrome who are continuing somatropin therapy.

After the first year of therapy with somatropin the growth rate must have increased significantly in the most recent year according to the prescribing physician and the epiphyses must be open. These patients should be reviewed annually for this growth rate and x-ray evidence that the epiphyses are not closed. In children or adolescents who respond to growth hormone the height velocity at least doubles by the end of the first year. Patients should be reviewed annually for growth rate and further authorization is not recommended when the growth rate is less than 2.5 cm/year in the most recent year and/or the epiphyses are closed.

Coverage Duration: 12 months

A5.Children with SHOX (short stature homeobox-containing gene) deficiency. Somatropin is approvable in children with SHOX deficiency, demonstrated by chromosome analysis, and whose epiphyses are not closed. The patient must be evaluated by an endocrinologist. Baseline height must be less than the third percentile for gender/age. Evaluation of growth hormone secretion is not necessary because these children do not have abnormal growth hormone secretion.

Children or adolescents with SHOX deficiency who are continuing somatropin therapy.
After the first year of therapy with somatropin the growth rate must have increased significantly in the most recent year according to the prescribing physician and the epiphyses must be open. These patients should be reviewed annually for this growth rate and x-ray evidence that the epiphyses are not closed. In children or adolescents who respond to growth hormone the height velocity at least doubles by the end of the first year. Patients should be reviewed annually for growth rate and further authorization is not recommended when the growth rate is less than 2.5 cm/year in the most recent year and/or the epiphyses are closed.

Coverage Duration: 12 months

A6.Children or adolescents with chronic renal insufficiency (chronic kidney disease). Somatropin is approvable for growth failure in children with chronic renal insufficiency as defined by an abnormal creatinine clearance. Patients must be evaluated by an endocrinologist or a nephrologist. Evaluation of growth hormone secretion is not necessary. Somatropin is also approvable in children who develop chronic renal insufficiency after a kidney transplant.

Children or adolescents with chronic renal insufficiency who are continuing somatropin therapy.
After the first year of therapy with somatropin the growth rate must have increased significantly in the most recent year according to the prescribing physician and the epiphyses must be open. These patients should be reviewed annually for this growth rate and x-ray evidence that the epiphyses are not closed. In children or adolescents who respond to growth hormone the height velocity at least doubles by the end of the first year. Patients should be reviewed annually for growth rate and further authorization is not recommended when the growth rate is less than 2.5 cm/year in the most recent year and/or the epiphyses are closed.

Coverage Duration: 12 months

A7.Prader-Willi syndrome. Children must have growth failure due to Prader-Willi syndrome, and all Prader-Willi patients (children and adults) must be evaluated by or in consultation with an endocrinologist

Patients with Prader-Willi syndrome who are continuing somatropin therapy.
In children or adolescents, after the first year of therapy with somatropin, the growth rate must have increased significantly in the most recent year according to the prescribing physician and the epiphyses must be open. These patients should be

reviewed annually for this growth rate and x-ray evidence that the epiphyses are not closed. In children or adolescents who respond to growth hormone the height velocity at least doubles by the end of the first year. Children or adolescents should be reviewed annually for growth rate and further authorization is not recommended when the height velocity is less than 2.5 cm/year in the most recent year and/or the epiphyses are closed. Adolescents should be reviewed annually for growth rate and further authorization is not recommended when the height velocity is less than 2.5 cm/year in the most recent year. When the epiphyses are closed and the height velocity is less than 2.5cmyear, the patient can be reviewed for continuation of therapy as an adult with Prader-Willi Syndrome.

Adults with Prader-Willi syndrome who are on somatropin should be reviewed annually. The patient must be evaluated by an endocrinologist or in consultation with an endocrinologist and this physician must certify that somatropin is not being used for anti-aging therapy or to enhance athletic performance/body building.

Coverage Duration: 12 months

A8.Short children born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Patients must meet the following criteria, a, b, c and d. (Evaluation of growth hormone secretion and bone age is not necessary, although some patients may have a diminished serum growth hormone response to stimulation testing and meet the criteria for children described in A.1 [a through c] above.)
a.Patient must be evaluated by an endocrinologist.
b.Patient must have been born SGA, which is defined as birth weight and/or birth length that is greater than 2 SD below the mean for gestational age and gender, and did not have sufficient catch-up growth before age 2 to 4. Most children born SGA will show catch-up growth by age 2.
c.Age.
•Patient is greater than or equal to 2 years of age and less than or equal to 8 years.
d.Height: The patient's baseline height must be < fifth percentile.

Children born SGA or with IUGR including Silver-Russell syndrome who are continuing somatropin therapy.
In children less than 12 years of age, approve if the growth rate has increased significantly, by greater than or equal to 4cm/year in the most recent year. These children should be reviewed annually for this growth rate.
In children aged greater than or equal to 12 years and less than or equal to 18 approve if the growth rate has increased by greater than or equal to 4 cm/year in the most recent year AND if the epiphyses remain open.
In adolescents and young adults 18 years or older, approve if the growth rate has increased by greater than or equal to 4 cm/year in the most recent year AND if the epiphyses remain open AND if the mid-parental height has not been attained. (mid-parental height is the father's height plus the mother's height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female.)
These patients should be reviewed annually for this growth rate.

Somatropin is FDA approved for treatment of growth failure in children born SGA who fail to manifest catch-up growth by age 2 to 4 years. In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.

A9. Children or adolescents with Noonan Syndrome. Children with growth failure due to Noonan Syndrome must be evaluated by an endocrinologist and the patient's baseline height must be less than fifth percentile using a growth chart for children with Noonan Syndrome.

Children or adolescents with Noonan syndrome who are continuing somatropin therapy.

After the first year of therapy with somatropin the growth rate must have increased significantly in the most recent year according to the prescribing physician and the epiphyses must be open. These patients should be reviewed annually for this growth rate and x-ray evidence that the epiphyses are not closed. In children or adolescents who respond to growth hormone the height velocity at least doubles by the end of the first year. Patients should be reviewed annually for growth rate and further authorization is not recommended when the growth rate is less than 2.5 cm/year in the most recent year and/or the epiphyses are closed.

Coverage Duration: 12 months

B.For coverage of formulary Genotropin; Humatrope; Norditropin Flexpro; Nutropin AQ; Saizen; Omnitrope; Zomacton (all listed products except Serostim) requires patients to meet the following criteria:

1.Short bowel syndrome. Somatropin is approvable for 4 weeks for adults with short bowel syndrome who are receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet that is adjusted for individual patient requirements and preferences). A second 4-week course of therapy may be approved if the adult responded to somatropin therapy with a decrease in requirement for specialized nutritional support, according to the prescribing physician. Patient must be aged 18 years or older and therapy is limited to 8-weeks of treatment (2 x 4-week courses) per year.

C.For coverage of formulary somatropin (Serostim) patients must meet the following criteria:

C1.Adults with HIV infection with wasting or cachexia must meet ALL of the following criteria (a through e).

a.The patient must be HIV-positive adult (aged 18 years or older) and have wasting or cachexia.

b.The patient must have one of the following: documented unintentional weight loss of greater than or equal to 10% from baseline; OR weight less than 90 percent of the lower limit of ideal body weight; OR body mass index (BMI) less than or equal to 20 kg/m2. The following formula can be used to calculate BMI: BMI equals body weight in kilograms divided by height meters squared (m2), ie, BMI = kg/m2. Clinical trials that established safety and efficacy included patients meeting this criterion.

c.The patient must have wasting or cachexia that is due to malabsoprtion, poor diet, opportunistic infection, or depression, and other causes have been addressed prior to starting somatropin.

d.The patient must have been on antiretroviral therapy for 30 days or greater prior to beginning somatropin therapy and will continue antiretroviral therapy throughout the course of somatropin treatment; and

e. Confirmation that Serostim is not being used for treatment of alterations in body fat distribution such as increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump.

Coverage Duration: Initial authorization 12 or 24 weeks. Repeat 12 or 24-week courses of somatropin may be authorized in patients who have received an initial 12 or 24-week course of somatropin for HIV infection with wasting or cachexia provided that they have been off somatropin for at least 1 month and meet previous criteria C.1.a, b, c, d and e.

C2.HIV-associated failure to thrive (wasting/cachexia). Children aged less than or equal to 17 years with HIV- associated failure to thrive

COVERAGE DURATION: Review for Renewal

HAEGARDA

MEDICATION(S)
HAEGARDA

COVERED USES
Prophylaxis for hereditary angioedema.

EXCLUSION CRITERIA
Concomitant Use with Other HAE Prophylactic Therapies (e.g., Orladeyo, Takhzyro).

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results (C1-INH protein, C4 levels), reauth: number and severity of HAE attacks

AGE RESTRICTION
6 years or older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis
Initial Therapy: Approve if the patient meets all of the below:
1.The patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b):
a.The patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values [documentation required] AND
b.The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].

Continuation of therapy: Patient meets both of the following (1 and 2):
1.Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months
2.Patient has experienced a reduction in the number of HAE attacks from baseline

HARVONI

MEDICATION(S)
HARVONI 33.75-150 MG PELLET PK, HARVONI 45-200 MG PELLET PACKT, HARVONI 45-200 MG TABLET, LEDIPASVIR-SOFOSBUVIR

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding ribavirin.

REQUIRED MEDICAL INFORMATION
The drug is being used for the treatment of chronic hepatitis C (CHC) (genotypes and indications as referenced under Coverage Durations), where chronic is defined as disease lasting for at least 6 months. For treatment naïve members without cirrhosis, pre-treatment HCV RNA is required to determine coverage duration approved.

AGE RESTRICTION
3 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with GI, hepatologist, ID, or liver transplant MD.

COVERAGE DURATION
12 weeks or 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA
For Ledipasvir-Sofosbuvir 90-400 mg, criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. Preferred medications are: Mavyret and Harvoni (NOTE: Mavyret AND Harvoni must be attempted prior to alternative product).

One of the following:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred

formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

Criteria will be applied consistent with current AASLD/IDSA guidance.

HETLIOZ

MEDICATION(S)
HETLIOZ LQ, TASIMELTEON

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Non-24 hour sleep-wake disorder-Patient is totally blind with no perception of light. Diagnosis of non-24 hour sleep-wake cycle disorder. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

AGE RESTRICTION
For Non-24 hour sleep-wake disorder: 18 years or older. For SMS-3 years and older.

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders

COVERAGE DURATION
6 months initial, 12 months cont.

OTHER CRITERIA
Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month. Cont - Approve if pt has received at least 6 months of therapy (i.e., 6 months of treatment) with tasimelteon under the guidance of a physician who specializes in the treatment of sleep disorders AND has achieved adequate results with tasimelteon therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep).

For SMS-approve

HUMIRA

MEDICATION(S)
ADALIMUMAB-ADAZ(CF), ADALIMUMAB-ADAZ(CF) PEN, ADALIMUMAB-ADBM(CF), ADALIMUMAB-ADBM(CF) PEN, ADALIMUMAB-ADBM(CF) PEN CROHNS, ADALIMUMAB-ADBM(CF) PEN PS-UV, ADALIMUMAB-ADBM(CF)PEN, ADALIMUMAB-RYVK(CF), ADALIMUMAB-RYVK(CF) AUTOINJECT, CYLTEZO(CF), CYLTEZO(CF) PEN, CYLTEZO(CF) PEN CROHN'S-UC-HS, CYLTEZO(CF) PEN PSORIASIS-UV, HUMIRA 40 MG/0.8 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA PEN 40 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA PEN CROHN-UC-HS 40 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 10 MG/0.1 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 20 MG/0.2 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 40 MG/0.4 ML SYR (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEDI CROHN 80 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEDI CROHN 80-40 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 40 MG/0.4 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 80 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN CRHN-UC-HS 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PEDI UC 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PS-UV-AHS 80-40 (ONLY NDCS STARTING WITH 00074), HYRIMOZ(CF), HYRIMOZ(CF) PEDIATRIC CROHN'S, HYRIMOZ(CF) PEN, HYRIMOZ(CF) PEN CROHN-UC START, HYRIMOZ(CF) PEN PSORIASIS, SIMLANDI(CF) AUTOINJECTOR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD. Polymyalgia Rheumatica (PMR)

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
Preferred adalimumab products: Cyltezo/adalimumab-adbm, Humira (NDCs starting with 00074), Hyrimoz (NDCs starting with 61314)/adalimumab-adaz, Simlandi/adalimumab-ryvk.

FDA-Approved Indications

1.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i and ii):

i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for RA is not required to "step back" and try a conventional synthetic DMARD); AND
ii.The adalimumab product is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii. Patient meets at least one of the following (a or b):
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure (Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; AND
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

2.Ankylosing Spondylitis (AS). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

3.Crohn's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i.The patient is 6 years of age or older; AND
ii.The patient meets ONE of the following conditions (a, b, c, or d):
a)Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient (Note: Examples of corticosteroids are prednisone, methylprednisolone); OR
b)Patient has tried one other conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate [MTX]. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.

OR
c)The patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
d)The patient has had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
iii.The adalimumab product is prescribed by or in consultation with a gastroenterologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
ii. Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product) Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

4.Juvenile Idiopathic Arthritis (JIA) [or juvenile rheumatoid arthritis {JRA}] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
i.The patient meets ONE of the following conditions (a, b, c, or d):
a)The patient has tried one other systemic therapy for this condition (e.g., methotrexate [MTX], sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug [NSAID] {e.g., ibuprofen, naproxen}). A previous trial of one biologic other than the requested drug also counts as a trial of one systemic therapy for JIA. A biosimilar of the requested biologic does not count.; OR
b)The patient will be starting on an adalimumab product concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
c)The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
d)The patient has aggressive disease, as determined by the prescribing physician; AND
ii.The adalimumab product is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has established on therapy for at least 6 months; AND
ii. Patient meets at least one of the following (a or b);
a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.

5.Hidradenitis Suppurativa. Approve for the duration noted if the patient meets ONE of the following (A or B):

A)Initial Therapy. Approve for 3 months if the patients meets BOTH of the following (i and ii):
i.The patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids [such as triamcinolone, prednisone], systemic antibiotics [for example, clindamycin, dicloxacillin, erythromycin], isotretinoin); AND
ii.The adalimumab product is prescribed by or in consultation with a dermatologist
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.
iii.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.
6.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.The adalimumab product is prescribed by or in consultation with a dermatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient Meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an adalimumab product) in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

7.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortuium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR

b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

8.Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii and iii):
i.The patient is 5 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has had a trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.
OR
b)Patient meets BOTH of the following [1 and 2]:
1.Patient has pouchitis; AND
2.Patient has tried an antibiotic (e.g. metronidazole and ciprofloxacin), probiotic, corticosteroid enema (e.g. hydrocortisone enema), or mesalamine enema; AND
iii.The adalimumab product is prescribed by or in consultation with a gastroenterologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product) Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

9.Uveitis (including other posterior uveitides and panuveitis syndromes). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
i.The patient has tried ONE of the following therapies: periocular, intraocular, or systemic corticosteroids [for example, triamcinolone, betamethasone, methylprednisolone, prednisone] or immunosuppressives (e.g., methotrexate [MTX], mycophenolate mofetil, cyclosporine and azathioprine) for this condition.
NOTE: A trial of one biologic other than the requested drug also counts. A biosimilar of the requested biologic does not count.; AND
ii.The adalimumab product is prescribed by or in consultation with an ophthalmologist.
B)Patients Currently Receiving an adalimumab product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii. Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures include best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, or anterior chamber cell grade or vitreous haze

grade.
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, and/or blurred vision, or improvement in visual acuity.

Other Uses with Supportive Evidence

10.Behcet's Disease. Approve for duration noted if the patient meets ONE of the following criteria (A or B):
A)The patient meets BOTH of the following (i and ii):
i.Initial therapy. Approve for 3 months if the patient meets ONE of the following conditions (a or b):
a)The patient has tried at least ONE conventional therapy (e.g., systemic corticosteroids [for example, methylprednisolone], immunosuppressants [for example, azathioprine, methotrexate {MTX}, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran® [chlorambucil], cyclophosphamide, interferon alfa). A trial of one biologic other than the requested drug also counts. A patient who has already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count.; OR
b)The patient has ophthalmic manifestations of Behcet's disease; AND
ii.The adalimumab product is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.
B)Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); or ulcer depth, number, and/or lesion size.; AND
iii.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations).

11.Pyoderma Gangrenosum. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 4 months if the patient meets BOTH of the following (i and ii):
i.The patient meets ONE of the following conditions (a or b):
a)The patient has tried one systemic corticosteroid (e.g., prednisone); OR
b)The patient has tried one other immunosuppressant (e.g., mycophenolate mofetil, cyclosporine) for at least 2 months or was intolerant to one of these agents; AND
ii.The agent is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 4 months;
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an adalimumab product) in at least one of the following: size, depth, and/or number of lesions; AND
iii.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesions.

12.Sarcoidosis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):

i.Patient has tried at least ONE corticosteroid for this condition (e.g., prednisone); AND
ii.Patient has tried at least one immunosuppressive agent (e.g., methotrexate [MTX], azathioprine, cyclosporine, Leukeran, leflunomide, cyclophosphamide, mycophenolate mofetil), an infliximab product, chloroquine, or Thalomid® (thalidomide capsules); AND
iii.The agent is prescribed by or in consultation with a pulmonologist, ophthalmologist, or dermatologist.
B)Patient is Currently Receiving and Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i. Patient has been established on therapy for at least 3 months; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures are dependent upon organ involvement but may include lung function (e.g., predicted forced vital capacity and/or 6-minute walk distance); serum markers (e.g., C-reactive protein, liver enzymes, N-terminal pro-brain natriuretic peptide [NT-proBNP]); improvement in rash or skin manifestations, neurologic symptoms, or rhythm control; or imaging (e.g., if indicated, chest radiograph, magnetic resonance imaging [MRI], or echocardiography).; AND
iii.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath.

13.Scleritis or Sterile Corneal Ulceration. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.The patient has tried ONE other therapy for this condition (e.g., oral non-steroidal anti-inflammatory drugs [NSAIDs] such as indomethacin, naproxen, or ibuprofen; oral, topical [ophthalmic] or IV corticosteroids [such as prednisone, prednisolone, methylprednisolone]; methotrexate [MTX]; cyclosporine; or other immunosuppressants); AND
ii.The agent is prescribed by or in consultation with an ophthalmologist.
B)Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product). Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); AND
b.Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity.

14.Spondyloarthritis (SpA), Other Subtypes (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter's disease], arthritis associated with inflammatory bowel disease [IBD]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications]. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.The patient meets one of the following conditions (a or b):
a)The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate {MTX}, leflunomide, sulfasalazine] has been tried; OR
b)The patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following

[(1) or (2)]:
(1)C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
(2)Sacroiliitis reported on magnetic resonance imaging (MRI); AND
ii.The agent is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product) Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

HYFTOR

MEDICATION(S)
HYFTOR

COVERED USES
Treatment of facial angiofibroma associated with tuberous sclerosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
6 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex

COVERAGE DURATION
Initial-3 months. Continuation-1 year

OTHER CRITERIA
Facial angiofibroma associated with tuberous sclerosis, initial- approve if the patient meets the following criteria (i. and ii.): i.Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a)There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b)According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii.Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each. Continuation-approve if the patient meets the following criteria (i. and ii.): i.Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a)There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b)According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell

astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii.Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas

IDIOPATHIC PULMONARY FIBROSIS (OFEV AND ESBRIET)

MEDICATION(S)
OFEV, PIRFENIDONE

COVERED USES
Idiopathic pulmonary fibrosis. For Ofev only – also approved for interstitial lung disease associated with systemic sclerosis and chronic fibrosing interstitial lung disease.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Interstitial pulmonary fibrosis (IPF)/Chronic fibrosing interstitial lung disease (ILD) – Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis – prescribed by or in consultation with a pulmonologist or rheumatologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
For Ofev and pirfenidone: IPF – must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.

For Ofev only: Interstitial lung disease associated with systemic sclerosis – approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography.

For Ofev only: Chronic fibrosing interstitial lung disease – approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.

IMBRUVICA

MEDICATION(S)
IMBRUVICA 140 MG CAPSULE, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION

COVERED USES
Graft Versus Host Disease (GVHD)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For Graft versus host disease (GVHD) – approve if the patient has tried one conventional systemic treatment for GVHD (e.g. corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib). For oncology indications, reach out to eviCore to complete the authorization.

IMPAVIDO

MEDICATION(S)
IMPAVIDO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of visceral leishmaniasis caused by Leishmania donovani, cutaneous leishmaniasis caused by Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis, and mucosal leishmaniasis caused by Leishmania braziliensis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION
1 month

OTHER CRITERIA
N/A

INGREZZA

MEDICATION(S)
INGREZZA, INGREZZA INITIATION PK(TARDIV), INGREZZA SPRINKLE

COVERED USES
N/A

EXCLUSION CRITERIA
Non-Huntington's related chorea

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
18 years and older.

PRESCRIBER RESTRICTION
TD - Prescribed by, or in consultation with, a neurologist or psychiatrist. Chorea HD – prescribed by or in consultation with a neurologist.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
Moderate to Severe Tardive dyskinesia:
Initial use: TD diagnosis has been confirmed by all of the following (1, 2 and 3):
1.Patient has had a stable drug and dose medication exposure of one of the following (a, b or c):
a.Typical or first generation antipsychotic agents (e.g. chlorpromazine, haloperidol, fluphenazine)
b.Atypical or second-generation antipsychotic agents (e.g. clozapine, risperidone, olanzapine)
c.Dopamine receptor-blocker used in treatment of nausea and gastroparesis (e.g. prochlorperazine, promethazine, metoclopramide)
2.Symptoms persist despite one of the following (a or b):
a.Discontinuation or reduction in dose of offending agent(s)
b.Discontinuation or reduction in dose of offending agent(s) is not possible
3.Patient has presence of involuntary athetoid or choreiform movements
Continued use: Patient has experienced an improvement or maintenance of symptoms while on Ingrezza based on reduction in abnormal involuntary movement scale (AIMS) or Dyskinesia Identification System: Condensed User Scale (DISCUS) from baseline.

Chorea associated with Huntington's disease – approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).

INSULIN

MEDICATION(S)
ADMELOG, ADMELOG SOLOSTAR, AFREZZA, APIDRA, APIDRA SOLOSTAR, FIASP, FIASP FLEXTOUCH, FIASP PENFILL, FIASP PUMPCART, INSULIN ASPART, INSULIN ASPART FLEXPEN, INSULIN ASPART PENFILL, INSULIN ASPART PROT MIX 70-30, LYUMJEV, LYUMJEV KWIKPEN U-100, LYUMJEV KWIKPEN U-200, LYUMJEV TEMPO PEN U-100, NOVOLIN 70-30, NOVOLIN 70-30 FLEXPEN, NOVOLIN N, NOVOLIN N FLEXPEN, NOVOLIN R, NOVOLIN R FLEXPEN, NOVOLOG, NOVOLOG FLEXPEN, NOVOLOG MIX 70-30, NOVOLOG MIX 70-30 FLEXPEN, NOVOLOG PENFILL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The patient assurance program (PAP) is in place for our commercial line of business, allowing members access to low-cost medications on our preferred insulin products. Prior authorization is required for prescription drug coverage of any non-preferred insulin. Products affected include: Admelog, Afrezza, Apidra, Fiasp, insulin aspart, insulin aspart mix 70-30, Lyumjev, Novolin 70-30, Novolin N, Novolin R, Novolog Mix 70-30

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer’s published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc.), AND

3.One of the following:

a.The member has demonstrated a failure of or intolerance to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the preferred formulary/preferred drug list alternatives for the given diagnosis.

Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the listed formulary alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the listed formulary agents used for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

INTERMEZZO

MEDICATION(S)
ZOLPIDEM TART 1.75 MG TAB SL, ZOLPIDEM TART 3.5 MG TABLET SL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis is for as needed use for the treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep (the insomnia must be characterized by difficulty returning to sleep after middle of the night awakening).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
One year.

OTHER CRITERIA
N/A

INTRAROSA/OSPHENA

MEDICATION(S)
INTRAROSA, OSPHENA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Osphena and Intrarosa: Diagnosis of dyspareunia (moderate to severe), due to vulvar and vaginal atrophy associated with menopause. For Osphena only: moderate to severe vaginal dryness to vulvar and vaginal atrophy associated with menopause.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year.

OTHER CRITERIA
N/A

ISTURISA

MEDICATION(S)
ISTURISA 1 MG TABLET, ISTURISA 5 MG TABLET

COVERED USES
Treatment of adult patients with Cushing's disease

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior treatments, Reauth: clinical response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Cushing's disease – Initial – patient is not able to undergo pituitary surgery or surgery has not been curative for condition AND patient has trialed/failed, has intolerance or contraindication to both ketoconazole and cabergoline. Continuation: Meets initial criteria and has documentation of positive clinical response to therapy (e.g. clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of disease).

ITRACONAZOLE

MEDICATION(S)
ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, ITRACONAZOLE 100 MG/10 ML CUP

COVERED USES
N/A

EXCLUSION CRITERIA
Vaginal candidiasis hypersensitivity syndrome.

REQUIRED MEDICAL INFORMATION
Approved Diagnoses include (Note: additional requirements indicated in 'Other Criteria' section):

Onychomycosis-must be medically significant (i.e., causing impaired mobility, discomfort, or in the presence of diabetes)

Tinea or Pityriasis Versicolor

Tinea Capitis and Barbae

Tinea Cruris, Faciei, Manuum, Imbricata, and Pedis (Nonmoccasin or Chronic type)

Tinea Corporis

Plantar-type or Moccasin-type dry chronic Tinea Pedis

Vaginal Candidiasis

Other superficial and Systemic Mycosis

Blastomycosis, pulmonary and extrapulmonary

Histoplasmosis, chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis

Aspergillosis, pulmonary and extrapulmonary

Recurrent vulvovaginal or vaginal candidiasis (prevention)

Patient has been started and stabilized on IV intraconazole therapy or oral intraconazole for a systemic infection and it is being used as continuation therapy

Oral and esophageal candidiasis

Febrile neutropenia

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Twelve weeks. Review for renewal.

OTHER CRITERIA
Tinea or Pityrisis Versicolor requires one trial and failure of ketoconazole or a topical antifungal agent first. Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole first. Tinea Cruris, Faciei, Manuum, Imbricata and Pedis (non moccasin or chronic type) require failure of one topical antifungal agent. Tinea Corporis requires failure of one topical antifungal agent first, except when condition is considered extensive. Vaginal Candidiases requires failure of both one topical antifungal regimen and one trial of oral fluconazole (patients of age less than 16 years are excluded from a trial of a topical vaginal antifungal preparation). For oral and esophageal candidiasis, must try and fail ketoconazole or fluconazole first. Itraconazole may be covered for other systemic infection if used for continuation of itraconazole therapy that has already been started and stabilized. Itraconazole may be used first line when the prescriber is a Pulmonologist or an Infectious Disease physician.

IVERMECTIN

MEDICATION(S)
IVERMECTIN 3 MG TABLET

COVERED USES
Strongyloidiasis, Onchocerciasis, Pediculosis, Scabies, Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Trichuriasis, and Wucheria bancrofti infections.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 days

OTHER CRITERIA
N/A

JAKAFI

MEDICATION(S)
JAKAFI

COVERED USES
Graft Versus Host Disease (GVHD)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For oncology indications, reach out to eviCore to complete the authorization.

JOENJA

MEDICATION(S)
JOENJA

COVERED USES
Treatment of Activated phosphoinositide 3-kinase delta syndrome

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an immunologist, pulmonologist, gastroenterologist, hematologist, geneticist or an infectious diseases physician who treats patients with primary immune deficiencies

COVERAGE DURATION
Initial – 6 months, Continuation – 1 year

OTHER CRITERIA
Activated phosphoinositide 3-kinase delta syndrome (APDS), initial therapy – approve if the patient meets all of the following criteria (i, ii, and iii): i.Patient weighs greater than or equal to 45 kg ii.Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iii.Patient has at least one clinical finding or manifestations consistent with APDS (Note: examples of clinical findings or manifestations of APDS include recurrent sinopulmonary infections, recurrent herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, and organ dysfunction).
APDS, continuation – approve if the patient meets all of the following criteria (i, ii, iii, and iv): i.Patient has been established on therapy for at least 6 months (a patient who has received less than 6 months of therapy or who is restarting therapy should be considered under initial therapy) ii.Patient weighs greater than or equal to 45 kg, AND iii.Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iv.Patient has had a positive clinical response in the signs and manifestations of APDS. (Note: Examples of positive clinical response in the signs and manifestations of APDS include reduction of: lymph node size, spleen size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.)

JYNARQUE

MEDICATION(S)
JYNARQUE

COVERED USES
N/A

EXCLUSION CRITERIA
Patient is currently receiving Samsca (tolvaptan tablets). Patients with Stage 5 CKD

REQUIRED MEDICAL INFORMATION
Diagnosis, renal function

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist

COVERAGE DURATION
1 year (initial and continuation)

OTHER CRITERIA
Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]), according to the prescriber.

KALBITOR

MEDICATION(S)
KALBITOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist/immunologist or a physician in the treatment of hereditary angioedema (HAE) or related disorders (initial and continuation)

COVERAGE DURATION
1 year

OTHER CRITERIA
HAE due to C1 inhibitor (C1-INH) Deficiency (Type I or Type II), Treatment of Acute Attacks, initial therapy – approve if patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b):
a) Patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values [documentation required] AND
b) Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].

Patients who have treated previous acute HAE attacks with Kalbitor – approve if the patient has a diagnosis of HAE type I or II [documentation required] as described with above diagnostic criteria AND according to the prescriber, the patient has had a favorable clinical response with Kalbitor treatment.

KALYDECO

MEDICATION(S)
KALYDECO

COVERED USES
N/A

EXCLUSION CRITERIA
Patients who are homozygous for the F508del mutation. Combination use with Orkambi, Trikafta or Symdeko.

REQUIRED MEDICAL INFORMATION
For patients new to therapy, CFTR gene mutation status required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CFTR gene mutation cnfrmed,lifetime. If cont use from prior to joining plan and mutation unknwn, 3mo

OTHER CRITERIA
Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

KERENDIA

MEDICATION(S)
KERENDIA

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with spironolactone or eplerenone

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values (eGFR, UACR, potassium), medication trials

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Diabetic kidney disease, approve if the patient meets the following criteria (i, ii, iii, and iv):
i.Patient has a diagnosis of type 2 diabetes AND
ii.Patient meets one of the following (a or b):
a.Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR
b.According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND
iii.Patient has tried/failed, has a contraindication or intolerance to one sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g. Jardiance, Farxiga)
iv.Patient meets all of the following (a, b, and c) despite use (if not intolerant or contraindicated) of ACEI/ARB and SGLT2:
a.Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND
b.Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND
c.Serum potassium level less than or equal to 5.0 mEq/L.

KEVZARA

MEDICATION(S)
KEVZARA

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic or with a Targeted Synthetic DMARD. Ankylosing Spondylitis (AS). COVID-19 (Coronavirus Disease 2019)

REQUIRED MEDICAL INFORMATION
See other criteria below

AGE RESTRICTION
See other criteria below

PRESCRIBER RESTRICTION
See other criteria below

COVERAGE DURATION
See other criteria below

OTHER CRITERIA
1.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD); AND
ii.Kevzara is prescribed by or in consultation with a rheumatologist.
iii.The patient meets ONE of the following conditions (a or b):
a.) The patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of multiple tocilizumab products counts as ONE product. A trial of tocilizumab intravenous, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]; OR
b.)According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder.

B)Patients Currently Receiving Kevzara. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND

ii.Patient meets at least one of the following (a or b):
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.
2.Polymyalgia Rheumatica. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.Patient has tried one systemic corticosteroid; AND
Note: An example of a systemic corticosteroid is prednisone.
ii.The medication is prescribed by or in consultation with a rheumatologist.
B)Patient is Currently Receiving Kevzara. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii. Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Kevzara); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentationrate), resolution of fever, and/or reduced dosage of corticosteroids
b.Compared with baseline (prior to initiating Kevzara), patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness; improved range of motion; and/or decreased fatigue.

3.Polyarticular Juvenile Idiopathic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
i.Patient weighs 63 kg or greater; AND
ii.Patient meets one of the following (a, b, c or d):
a.Patient has tried one other systemic therapy for this condition; OR
Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of one biologic other than the requested drug also counts as a trial of one systemic therapy for Juvenile Idiopathic Arthritis. A biosimilar of the requested drug does not count.
b.Patient will be starting on Kevzara concurrently with methotrexate, sulfasalazine, or leflunomide; OR
c.Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
Note: Examples of absolute contraindications to methotrexate include pregnancy, breastfeeding, alcoholic liver disease, immunodeficiency syndrome, and blood dyscrasias; OR
d.Patient has aggressive disease, as determined by the prescriber; AND
iii.The medication is prescribed by or in consultation with a rheumatologist
iv.Patient meets ONE of the following conditions (a or b):
a.Patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq/Rinvoq LQ, or Xeljanz [documentation required]; OR
Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A

trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of a tocilizumab intravenous product (Actemra intravenous, biosimilar), Orencia intravenous or subcutaneous, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria also counts [documentation required].
b.According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.
B)Patient is Currently Receiving Kevzara. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.Patient meets at least ONE of the following (1 or 2):
1.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested medication); OR
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
2.Compared with baseline (prior to initiating the requested medication), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

CONTINUATION OF THERAPY – RA, PJIA in patients new to the plan:
Approve Kevzara for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (i, ii, or iii):
i.The patient meets ONE of the following conditions (a, b, or c):
a)The patient has been established on Kevzara for at least 90 days and prescription claims history indicates at least a 90-day supply of Kevzara was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kevzara for at least 90 days AND the patient has been receiving Kevzara via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kevzara); OR
b)Patient has Rheumatoid Arthritis and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of multiple tocilizumab products counts as one product. A trial of tocilizumab intravenous (Actemra intravenous, biosimilar), Cimzia, an infliximab product (e.g., Remicade, biosimilars), Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]; OR
c)Patient has Juvenile Idiopathic Arthritis and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, Rinvoq LQ, or Xeljanz [documentation required]; OR
Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of a tocilizumab intravenous product (Actemra intravenous, biosimilar), Orencia intravenous or subcutaneous, an infliximab product (e.g.,

Remicade, biosimilars), or Simponi Aria also counts [documentation required]
d)According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder.

KINERET

MEDICATION(S)
KINERET

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD. COVID-19. Akylosing Spondylitis (AS). Lupus Arthritis. Osteoarthritis (OA).

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i.The patient has had a 3-month trial of a biologic OR targeted synthetic DMARD for this condition, unless intolerant; AND
NOTE: This is a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. [NOTE: Conventional synthetic DMARDs such as methotrexate [MTX], leflunomide, hydroxychloroquine, and sulfasalazine do not count.]
ii.Kineret is prescribed by or in consultation with a rheumatologist.
iii.The patient has tried TWO of tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of tocilizumab IV (Actemra IV, biosimilar), Cimzia, Orencia IV or SC, an infliximab product (e.g., Remicade, biosimilars), Kevzara, and Simponi Aria or SC also counts [documentation required].
B)Patients Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a. Patient experienced beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II,

Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.
2.Cryopyrin-Associated Periodic Syndromes (CAPS). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i and ii):
i.Kineret is being used for treatment of Neonatal Onset Multisystem Inflammatory Disease (NOMID), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and/or chronic infantile neurological cutaneous and articular (CINCA) syndrome; AND
ii.Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.
B)Patients Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has established on this medication for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as fewer cold-induced attacks; less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.
3.Deficiency of Interleukin-1 Receptor Antagonist. Approve for the duration noted if the patient meets one of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.Genetic testing has confirmed a mutation in the IL1RN gene; AND
ii.The medication is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.
B)Patient is Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on this medication for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), reduction in proteinuria, and/or stabilization of serum creatinine.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as improvement of skin or bone symptoms; less joint pain/tenderness, stiffness, or swelling.

Other Uses with Supportive Evidence

4.Systemic Juvenile Idiopathic Arthritis (SJIA). Approve for the duration noted if the patient meets ONE of the following (A or B):
i.Initial Therapy. Approve for 6 months if the medication is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on this medication for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior

to initiating the requested drug). Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

5.Still's Disease, Adult Onset. Approve for duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i and ii):
i.Patient meets ONE of the following conditions (a, b or c):
a.Patient meets ALL of the following criteria (1 and 2):
1.The patient has tried one corticosteroid; AND
2.The patient has had an inadequate response to one conventional synthetic disease-modifying antirheumatic drug (DMARD) such as methotrexate (MTX) given for at least 2 months or was intolerant to a conventional synthetic DMARD. Note: A previous trial of a biologic other than the requested drug (e.g. Actemra IV or SQ, Arcalyst, Ilaris) also counts towards a trial of one other systemic agent for Still's disease. A biosimilar of the requested biologic does not count.; OR
b.Patient has at least moderate to severe active systemic features of this condition, according to the prescriber. Note: Examples of moderate to severe active systemic features include fever, rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis; OR
c.Patient has active systemic features with concerns of progression to macrophage activation syndrome, as determined by the prescriber; AND
ii.Kineret is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on this medication for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.); or
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.
6.COVID-19 (Coronavirus Disease 2019). Forward all requests to the Medical Director. Note: This includes requests. For cytokine release syndrome associated with COVID-19.
Kineret has been granted Emergency Use Authorization (EUA) for treatment of Coronavirus disease 2019 (COVID-19) in hospitalized adults with positive viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). The recommended dose under the EUA is 100 mg daily by subcutaneous injection for 10 days.

Additionally, guidelines from ACR recommend consideration of Kineret (greater than 4 mg/kg/day) for children with COVID-19 and hyperinflammation refractory to intravenous immunoglobulin and glucocorticoids, or in patients with contraindications to long-term use of glucocorticoids. Initiation of Kineret prior to invasive mechanical ventilation may be beneficial. Kineret is also recommended in a similar population of children with multisystem inflammatory syndrome and features of macrophage activation syndrome associated with COVID-19. Per these guidelines, a prolonged course of immunomodulatory treatment extending for 2 or 3 weeks or longer may be necessary to avoid rebound inflammation.

CONTINUATION OF THERAPY:

1B – RA – Patients Currently Taking Kineret – patients new to plan.

A)Approve Kineret for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a or b):

a)Patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]; OR

Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of tocilizumab intravenous (Actemra IV, biosimilar), Cimzia, Orencia subcutaneous or intravenous, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi Aria or subcutaneous also counts [documentation required].

b)Patient has been established on Kineret at least 90 days and prescription claims history indicate at least a 90-day supply of Kineret was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required].

Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kineret for at least 90 days AND the patient has been receiving Kineret via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kineret).

KORLYM

MEDICATION(S)
KORLYM, MIFEPRISTONE 300 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The member must have a confirmed diagnosis of endogenous Cushings syndrome, requiring control of hyperglycemia secondary to hypercortisolism, with Type 2 Diabetes Mellitus or glucose intolerance. Members must not be pregnant, as evidenced by a documented negative pregnancy test prior to the initiation of treatment. For continuation of therapy, the member must achieve 25% or greater improvement in glucose tolerance, as measured by a standard two-hour glucose tolerance test after 12 weeks of treatment, OR must achieve improved glycemic control as evidenced by the member's HbA1C value.

AGE RESTRICTION
Aged 18 years or older.

PRESCRIBER RESTRICTION
Endocrinologist or specialist in treating Cushing's syndrome.

COVERAGE DURATION
Initial authorization 3 months. If improvement met, then lifetime.

OTHER CRITERIA
The member must have failed surgery, or is not a candidate for surgery. Members must utilize adequate measures such as non-hormonal contraceptive methods to prevent pregnancy.

KOSELUGO

MEDICATION(S)
KOSELUGO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Koselugo will be used for the treatment of pediatric patients with neurofibromatosis type 1 (NF1).

AGE RESTRICTION
2 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, oncologist, or a medical geneticist.

COVERAGE DURATION
3 years

OTHER CRITERIA
For neurofibromatosis type 1, must have symptomatic, inoperable plexiform neurofibromas (PN).

LITFULO

MEDICATION(S)
LITFULO

COVERED USES
Treatment of severe alopecia areata

EXCLUSION CRITERIA
Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate)

REQUIRED MEDICAL INFORMATION
Diagnosis of severe alopecia areata

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Alopecia areata, initial therapy: approve if the patient: 1.Has a current episode of alopecia areata lasting for greater than or equal to 6 months without spontaneous re-growth 2.Has greater than or equal to 50 percent scalp hair loss 3.Does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss or other causes of hair loss other than alopecia areata

Alopecia areata, continuation of therapy: approve if the patient meets the following: 1.Has been established on Litfulo for at least 6 months (less than 6 months or a restart, review under initial therapy) 2.Experienced a beneficial clinical response defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss 3.The prescriber states the patient continues to require systemic therapy for treatment of alopecia areata.

LIVMARLI

MEDICATION(S)
LIVMARLI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of cholestatic pruritis in patients 1 year of age or older with Alagille syndrome. Treatment of patients 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in Alagille syndrome or PFIC (initial and continuation)

COVERAGE DURATION
Initial-6 months, continuation-1 year

OTHER CRITERIA
Alagille Syndrome, initial-approve if the patient meets (i, ii and iii):

i.Patient has moderate-to-severe pruritus, according to prescriber AND

ii.Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND

iii.Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

PFIC Initial: Approve if patient meets all of the following (i, ii and iii):
i.Patient has moderate-to-severe pruritis, according to prescriber AND
ii.Diagnosis of PFIC was confirmed by genetic testing demonstrating a gene mutation affiliated with PFIC (including ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND
iii.Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

Alagille Syndrome or PFIC, continuation-approve if the patient has had a response to therapy.

LIVTENCITY

MEDICATION(S)
LIVTENCITY

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with ganciclovir or valganciclovir

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist, or a physician affiliated with a transplant center.

COVERAGE DURATION
2 months

OTHER CRITERIA
Cytomegalovirus Infection, Treatment-approve if the patient meets the following criteria (A, B, and C):

A)Patient weighs greater than or equal to 35 kg, AND

B)Patient is post-transplant, AND

Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant.

C)Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir

LUCEMYRA

MEDICATION(S)
LUCEMYRA

COVERED USES
Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month

OTHER CRITERIA
The prescriber indicates that there was a documented trial and failure with clonidine (oral or topical patch) prior to Lucemyra approval.

LUPKYNIS

MEDICATION(S)
LUPKYNIS

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with biologics or with cyclophosphamide

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist or rheumatologist (initial therapy and continuation)

COVERAGE DURATION
Initial-6 months, Continuation-1 year

OTHER CRITERIA
Lupus Nephritis, Initial therapy- Approve if the patient meets all of the following criteria (A, B, and C): A) Patient has autoantibody-positive systemic lupus erythematosus (SLE), defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody, B) Patient meets ONE of the following (a or b) a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant intolerance with these medications, C) Patient has an estimated glomerular filtration rate (eGFR) greater than 45 mL/min/m2. Lupus Nephritis, Continuation therapy- Approve if the patient meets all of the following criteria (A and B):

A) Patient meets ONE of the following (a or b): a) Medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid OR b) Patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy OR significant intolerance with these medications, B) Patient has responded to therapy with the requested medication.

LUPRON

MEDICATION(S)
LEUPROLIDE 2WK 14 MG/2.8 ML KT

COVERED USES
N/A

EXCLUSION CRITERIA
The diagnosis must not be for infertility unless the patient has an infertility rider.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

MAVYRET

MEDICATION(S)
MAVYRET

COVERED USES
Chronic hepatitis C virus (Genotypes 1-6) without cirrhosis, Chronic hepatitis C virus (Genotypes 1-6) with compensated cirrhosis (Child Pugh A), Chronic hepatitis C genotype 1 who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4a protease inhibitor, but not both.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Member is 3 years of age or older.

PRESCRIBER RESTRICTION
The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION
Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA
Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with Mavyret.

Criteria will be applied consistent with current AASLD/IDSA guidance.

METHAMPHETAMINE/DESOXYN

MEDICATION(S)
METHAMPHETAMINE HCL

COVERED USES
N/A

EXCLUSION CRITERIA
Use in patients for weight loss.

REQUIRED MEDICAL INFORMATION
Diagnosis of attention-deficit hyperactivity disorder or narcolepsy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

MODAFINIL/ARMODAFINIL

MEDICATION(S)
ARMODAFINIL, MODAFINIL 100 MG TABLET, MODAFINIL 200 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis for a covered use. For Sleep Work Shift Disorder, other sleep disorders or contributing factors to sleep disorder have been ruled out, such as sleep apnea, restless leg syndrome/periodic limb movements, insomnia, or other causes for circadian rhythm misalignment (depression, gastrointestinal problems).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For narcolepsy, the prescriber is a neurologist or sleep specialist

COVERAGE DURATION
For sleep work disorder, 12 months. Other indications, Lifetime.

OTHER CRITERIA
For narcolepsy, therapy will be allowed if one of the following is met: The member tried and failed or has a contraindication to TWO first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dextroamphetamine, Methamphetamine, Methylphenidate (or their branded products: Adderall, Adderall XR, Dexedrine Spansules, Procentra, Zenzedi, Desoxyn, Methylin, Concerta, Daytrana, Metadate CD, Metadate ER, Quillivant, Ritalin, Ritalin LA, Ritalin SR), OR the member has a history of substance abuse.

For Sleep Work Shift Disorder, the member must have a documented shift work schedule (night shifts, rotating shifts) AND Other sleep disorders or contributing factors to sleep disorder have been ruled out, such as sleep apnea, restless leg syndrome/periodic limb movements, insomnia, or other causes for circadian rhythm misalignment (depression, gastrointestinal problems).

For Obstructive Sleep Apnea (a, b, and c):

a.The member has documented obstructive sleep apnea

b.The member must have made a maximal effort and failed treatment with CPAP for an adequate period of time

c.Modafinil or armodafinil must be used in conjunction with CPAP, or the patient must be unable to tolerate CPAP.

Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue.

Excessive daytime sleepiness (EDS) associated with myotonic dystrophy (approve for modafinil only)

Adjunctive/augmentation for treatment of depression in adults (approve for modafinil only) - Approve if the patient is concurrently receiving other medication therapy for depression.

MULPLETA

MEDICATION(S)
MULPLETA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of thrombocytopenia. Platelet count, date of procedure.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 days

OTHER CRITERIA
Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.

MULTAQ

MEDICATION(S)
MULTAQ

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
The medication must be ordered by a cardiologist.

COVERAGE DURATION
Indefinite

OTHER CRITERIA
N/A

MULTIPLE SCLEROSIS AGENTS-EXTAVIA/PLEGRIDY

MEDICATION(S)
EXTAVIA, PLEGRIDY, PLEGRIDY PEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

a.The member has demonstrated a failure of or intolerance to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the preferred formulary/preferred drug list alternatives for the given diagnosis. NOTE: preferred formulary alternatives include: Rebif/Rebif Rebidose and Betaseron. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the listed formulary alternatives. Documentation including the

medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to a majority (2 or more in a class with at least 2 alternatives, or 1 in a class with only 1 alternative) of the listed formulary agents used for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

MYALEPT

MEDICATION(S)
MYALEPT

COVERED USES
N/A

EXCLUSION CRITERIA
Partial lipodystrophy, HIV-related lipodystrophy, Liver disease (including nonalcoholic steatohepatitis), metabolic disease (without concurrent evidence of generalized lipodystrophy)

REQUIRED MEDICAL INFORMATION
Diagnosis is complication of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
N/A

MYCAPSSA

MEDICATION(S)
MYCAPSSA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
1 Year

OTHER CRITERIA
Acromegaly: Approve if the patient meets the following criteria (A and B):

A.Patient has (or had) a pre-treatment (baseline) insulin-like growth factor 1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory, AND

Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of a somatostatin analog (e.g., Mycapssa® [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen™, Sandostatin® {generics}, Sandostatin® LAR Depot], Signifor® LAR [pasireotide injection], Somatuline® Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert® [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories.

B.According to the prescriber, patient has responded to one octreotide acetate injection product or Somatuline® Depot (lanreotide injection)

NASAL CORTICOSTEROIDS

MEDICATION(S)
AZELASTINE-FLUTICASONE, OMNARIS, QNASL, QNASL CHILDREN, RYALTRIS, ZETONNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Brand nasal corticosteroids may be approved if all of the following criteria is met:

1. the member must try and fail two other products, AND

2. the prerequesite drugs must be either (a. or b): a. Over the counter nasal corticosteroids (e.g. Flonase OTC, Nasacort OTC, Rhinocort AQ) OR b. Generic legend products (e.g. flunisolide, momentasone), AND

3. the two prerequisite drugs must be different chemical entities.

NGENLA

MEDICATION(S)
NGENLA

COVERED USES
Treatment of pediatric patients with growth failure due to inadequate endogenous growth hormone secretion

EXCLUSION CRITERIA
Use for athletic enhancement, anti-aging purposes or idiopathic short stature (ISS)

REQUIRED MEDICAL INFORMATION
Diagnosis, test results (e.g., growth hormone stim test results, growth rates, pituitary hormone levels, MRI/CT results)

AGE RESTRICTION
Greater than or equal to 3 years of age and less than 18 years old

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Growth Hormone Deficiency in a pediatric patients, initial-Approve if the patient meets the following:
A)Patient meets one of the following (i, ii, iii, iv, or v):
i.Patient meets one of the following (1 or 2):
(1)Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR
(2)Patient meets BOTH of the following criteria (a and b):
(i)Patient has had at least one growth hormone stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory AND
(ii)Patient has at least one risk factor for growth hormone deficiency (for example, the height for age curve has deviated downward across two major height percentiles [e.g., from above the 25th percentile to below the 10th percentile], the child's growth rate is less than the expected normal growth rate based on age and gender, low insulin-like growth factor (IGF)-1 and/or IGFBP-3 levels, the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician, the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile], the patient is status post craniopharyngioma resection, the patient has optic nerve hypoplasia, the patient has a growth hormone gene deletion)

ii.Patient has undergone brain radiation or tumor resection AND patient meets at least one of the following (1 or 2):
(1)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced

hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR
(2)Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin)

iii.Patient has congenital hypopituitarism AND meets one of the following (1, 2 or 3):
(1)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR
(2)Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin) OR
(3)Patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk

iv.Patient has multiple pituitary hormone deficiencies and meets one of the following (1 or 2):
(1)Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin, OR
(2)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory

v.Patient has had a hypophysectomy (surgical removal of pituitary gland)-approve.

Growth Hormone Deficiency in a pediatric patients, continuation of Ngenla or switching to Ngenla from another growth hormone agent (after being established on either therapy for at least 10 months): Approve if the patient meets one of the following:
A.Patient is <12 years of age and height has increased by 2 cm/year or more in the most recent year OR
B.Patient is greater than or equal to 12 and <18 years of age and meets both of the following:
a.Patient’s height has increased by 2 cm/year or more in the most recent year AND
b.Patient’s epiphyses are open

NITISINONE

MEDICATION(S)
NITISINONE, ORFADIN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION
1 year

OTHER CRITERIA
Hereditary Tyrosinemia, Type 1 – approve if diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone.

NUCALA

MEDICATION(S)
NUCALA

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another anti-interleukin (IL) monoclonal antibody.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria below.

PRESCRIBER RESTRICTION
See other criteria below.

COVERAGE DURATION
Asthma/EGPA/polyps: Initial 6 months. HES: Initial, 8 months. Continuation asthma/EGPA/HES/polyps: If criteria met for continuation, then therapy will be approved lifetime.

OTHER CRITERIA
For asthma, all of the following conditions must be met (A, B, C, D, E, F, and G):
A.The patient has a diagnosis of severe asthma, with an eosinophilic phenotype.

B.Patient is 6 years or older.

C.The drug is being prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist.

D.The drug will NOT be used in combination with Xolair or another anti-interleukin [IL] monoclonal antibody.

E.The member must have peripheral blood eosinophil count greater than or equal to 150 cells per microliter, within the previous 6 weeks (prior to treatment with any IL-5 therapy).

F.The member must have received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following:
•inhaled long acting beta agonist
•inhaled long acting muscarinic antagonist
•leukotriene receptor antagonist
•theophylline
•(Note: an exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made

if the patient has already received anti-IL-5 therapy [e.g Cinqair, Fasenra])

G.The patient's asthma continues to be uncontrolled as defined by one of the following:
•Experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year
•Experienced one or more asthma exacerbations requiring hospitalization or treatment in an emergency department in the previous year
•Patient has a FEV1 less than 80 percent predicted
•Patient has FEV1/FVC less than 0.80
•Patient's asthma worsens upon tapering of oral corticosteroid therapy
For initial therapy for eosinophilic granulomatosis with polyangiitis (EGPA), all the following conditions must be met (A, B, C, D and E):
A.The patient has a history or the presence of an eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL)-5 therapy (e.g., Nucala, Cinquair, Fasenra).
B.The drug is being prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist.
C.The member is 18 years of age or older
D.The drug will NOT be used in combination with Xolair or another anti-interleukin [IL] monoclonal antibody.
E.The patient has active, non-severe disease

For initial therapy for Hypereosinophilic Syndrome (HES), all the following conditions must be met:
A.Prescribed by or in consultation with an allergist, immunologist, pulmonologist, hematologist or rheumatologist.
B.Patient is 12 years of age or older.
C.The drug will not be used in combination with Xolair or another anti-interleukin (IL) monoclonal antibody.
D.Patient has had HES for greater than or equal to 6 months
E.Patient has FIP1L1-PDGFR alpha-negative disease
F.Patient does not have an identifiable non-hematologic secondary cause of HES
G.Prior to initiating therapy with any anti-interleukin-5 therapy, the patient has/had a blood eosinophil level of greater than or equal to 1000 cells/microliter.

For initial therapy for Chronic rhinosinusitis with nasal polyposis, all of the following conditions must be met:
A.Patient is 18 years of age or older.
B.Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.
C.The drug will not be used in combination with Xolair or another anti-interleukin (IL) monoclonal antibody.
D.Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan
E.Patient has experienced 2 or more of the following symptoms for at least 6 months: nasal congestion/obstruction/discharge and/or reduction/loss of smell
F.Patient meets BOTH of the following (a and b):
a.Patient has received at least 3 months of therapy with intranasal corticosteroid AND
b.Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala
G.Patient meets 1 of the following (a, b or c):
a.Patient has received at least 1 course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years OR
b.Patient has a contraindication to systemic corticosteroid therapy OR
c.Patient has had prior surgery for nasal polyps

Asthma:
For continuation of therapy, if the member meets the following criteria, then therapy will be continued indefinitely:
1. The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy), AND

2. The patient continues to receive therapy with an inhaled corticosteroid

EGPA:
1.For continuation of therapy for EGPA - The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels).

HES:
1.For continuation of therapy for HES – The patient has received at least 8 months of therapy with Nucala (patients who have received less than 8 months of therapy or who are restarting therapy should be reviewed under initial therapy) and patient has responded to Nucala therapy.

Chronic rhinosinusitis with nasal polyposis
1.For continuation of therapy – approve if the patient has received at least 6 months of therapy, continues to receive treatment with an intranasal corticosteroid and has responded to treatment.

NUEDEXTA

MEDICATION(S)
NUEDEXTA

COVERED USES
Pseudobulbar affect

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, Reauth: documented improvement with medication (e.g. reduction in episodes of inappropriate laughing or crying)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a neurologist or a psychiatrist.

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year.

OTHER CRITERIA
Pseudobulbar Affect - Diagnosis is confirmed by one of the following:
a.Physician attestation that the patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying consistent with PBA at baseline
b.Patient has a brain injury or neurologic disease from one of the following: amyotrophic lateral sclerosis, multiple sclerosis, Parkinson’s disease, stroke or traumatic brain injury.

NUPLAZID

MEDICATION(S)
NUPLAZID

COVERED USES
Treatment of hallucinations and delusions associated with Parkinson’s disease psychosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Parkinson’s disease psychosis, Reauth: documentation of response

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial: 3 months, Continuation: 1 year

OTHER CRITERIA
Parkinson’s disease psychosis:
Initial – Patient meets the following criteria:
1.Symptoms of psychosis developed after the PD diagnosis
2.Symptoms include at least one of the following: visual hallucinations, auditory hallucinations or delusions
3.Symptoms have been present for at least one month AND individual has experienced symptoms at least once weekly
4.Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium.
Continuation: Individual has experienced a reduction in psychosis symptoms compared to baseline.

NURTEC ODT

MEDICATION(S)
NURTEC ODT

COVERED USES
Acute treatment of migraine with or without aura, Preventative treatment of migraine headaches.

EXCLUSION CRITERIA
For preventative treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For preventative treatment: Initial-3 months; Continuation-12 months
For acute treatment: 1 year

OTHER CRITERIA
Acute treatment: Approve if the patient has trialed and failed or has a contraindication [documentation required] to TWO different triptan medications (must be different active ingredients).

Preventative treatment of episodic migraine: For initial therapy: Approve if the patient meets the following (A and B):
A)Adequate trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil).
B)The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia and phonophobia). For episodic cluster headache: approve if the patient has between one headache every other day and eight headaches per day.

For continuation of therapy: Prescriber confirms that the member had a reduction in migraine days per month from baseline after a 3-month trial.

OCALIVA

MEDICATION(S)
OCALIVA

COVERED USES
N/A

EXCLUSION CRITERIA
Patient does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
New to therapy: 6 months. Continuing patients 3 years.

OTHER CRITERIA
1.Currently receiving therapy prior to joining health plan or started therapy in past 6 months.

2.Diagnosis of primary biliary cholangitis (cirrhosis)(PBC) as defined by TWO of the following

a.Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values
b.Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative
c.Histiologic evidence of PBC from a liver biopsy .

3.Have not achieved an adequate response to an appropriate dosage of ursodiol for at least one year or are intolerant to ursodiol.

4.Used in combination therapy with ursodiol after an inadequate response to ursodiol, unless intolerant to ursodiol

5.Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician

OLUMIANT

MEDICATION(S)
OLUMIANT

COVERED USES
See other criteria

EXCLUSION CRITERIA
Concurrent Use with a Biologic or with a Targeted Synthetic DMARD, Concurrent Use with a Biologic Immunomodulator (examples include Adbry, Cinqair, Dupixent, Fasenra, Nucala, Tezspire and Xolair), Concurrent Use with Topical Janus Kinase Inhibitors, Concurrent use with Other Potent Immunosuppressants, COVID-19 – Non-Hospitalized Patient

REQUIRED MEDICAL INFORMATION
See other criteria.

AGE RESTRICTION
See other criteria.

PRESCRIBER RESTRICTION
See other criteria.

COVERAGE DURATION
See other criteria.

OTHER CRITERIA
1.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 18 years of age or older; AND
ii.The patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor (TNFi), unless intolerant.
NOTE: Conventional synthetic DMARDs such as methotrexate (MTX), leflunomide, hydroxychloroquine, and sulfasalazine do not count; AND
iii.Olumiant is prescribed by or in consultation with a rheumatologist; AND
iv.Patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: Examples of tocilizumab subcutaneous products include Actemra and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of tocilizumab intravenous (Actemra, biosimilars), Cimzia, an infliximab product (e.g., Remicade, biosimilars), Kevzara, Orencia intravenous or subcutaneous, or Simponi Aria or subcutaneous also counts [documentation required].
B)Patients Currently Receiving Olumiant. Approve for 1 year if the patient meets BOTH of the following (i and ii);
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease

Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths
2.COVID-19 (Coronavirus Disease 2019) – Hospitalized Patient. Olumiant is indicated for COVID-19 only in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Note: This includes requests for cytokine release syndrome in a patient hospitalized with COVID-19.
3.Alopecia Areata. Approve for the duration noted if the patient meets one of the following (A or B):
Note: Alopecia universalis and alopecia totalis are subtypes of alopecia areata.
A)Initial Therapy. Approve for 6 months if the patient meets all of the following (i, ii, iii, iv, and v):
i.Patient is 18 years of age or greater; AND
ii.Patient has a current episode of alopecia areata lasting for 6 months or greater; AND
iii.Patient has 50 percent scalp hair loss or greater; AND
iv.Patient has tried at least one of the following for alopecia areata (a or b):
a)Conventional systemic therapy (Note: Examples of systemic therapies include corticosteroids, methotrexate, and cyclosporine. An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried Litfulo); OR
b)Topical corticosteroids; AND
v.The medication is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Olumiant. Approve for 1 year if the patient meets all of the following (i, ii, iii and iv):
i.Patient is 18 years of age or older; AND
ii.Patient has been established on the requested drug for at least 6 months; AND
iii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Olumiant) in extent and density of scalp hair loss; AND
iv.According to the prescriber, the patient continues to require systemic therapy for treatment of alopecia areata (Note: International consensus states that systemic treatment is best discontinued once complete regrowth has been achieved and maintained for 6 months or when regrowth is sufficient to be managed topically.)

CONTINUATION OF THERAPY
1B – RA – Patients Currently Taking Olumiant and new to plan:
A)Approve Olumiant for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a or b):
a)Patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab , Rinvoq, and Xeljanz/XR [documentation required]; OR
Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of Actemra intravenous, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Kevzara, Orencia intravenous or subcutaneous, or Simponi Aria or subcutaneous also counts [documentation required].
b)Patient has been established on Olumiant for at least 90 days and prescription claims history indicates at least a 90-day supply of Olumiant was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Olumiant for at least 90 days AND the patient has been receiving Olumiant via paid claims (e.g., patient has not been receiving samples or coupons or other

types of waivers in order to obtain access to Olumiant).

OMNIPOD

MEDICATION(S)
OMNIPOD, OMNIPOD 5 G6 INTRO KIT (GEN 5), OMNIPOD 5 G6 PODS (GEN 5), OMNIPOD 5 G6-G7 INTRO KT(GEN5), OMNIPOD 5 G6-G7 PODS (GEN 5), OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4), OMNIPOD GO PODS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, insulin therapy regimen

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Patient must meet ALL of the following requirements (A, B, C, and D):

A. Diagnosis of diabetes, as indicated by 1 or more of the following (1 or 2):

(1.) Type 1 diabetes mellitus OR

(2.) Type 2 diabetes mellitus and 1 or more of the following (a. or b.): (a.) Daily insulin requirement of 0.7 to 1.8 units per kg or (b.) Total daily insulin dose is 220 units or less

B. Failure of multiple daily injection insulin administration, as indicated by 1 or more of the following:

(1.) Abnormal early-morning increase in blood glucose (“dawn phenomenon”), unresponsive to management with long-acting insulin analogue (eg, insulin glargine, insulin detemir) regimens

(2.) Child for whom multiple daily insulin injections are impractical or inappropriate

(3.) Diabetes complications (eg, neuropathy, nephropathy, retinopathy), and need for more intensive management

(4.) Extreme insulin sensitivity

(5.) HbA1c greater than 7% (53 mmol/mol), despite intensified multiple daily injection insulin therapy

(6.) Hypoglycemia requiring third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital

(7.) Patient is pregnant or planning pregnancy

(8.) Wide swings in glycemic control

C. Patient or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose 3 or more times per day.

D. Provider team is experienced and expert in management and support of patient with insulin pumps

OMVOH

MEDICATION(S)
OMVOH 100 MG/ML SYRINGE, OMVOH PEN

COVERED USES
Ulcerative colitis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
See Other criteria

AGE RESTRICTION
See Other criteria

PRESCRIBER RESTRICTION
See Other criteria

COVERAGE DURATION
See Other criteria

OTHER CRITERIA
1.Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 18 years of age or older; AND
ii.According to the prescriber, the patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous; AND
iii.Patient meets ONE of the following (a or b):
a)Patient has had a trial of one systemic agent for ulcerative colitis; OR
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.
b)Patient meets BOTH of the following [(1) and (2)]:
(1)Patient has pouchitis; AND
(2)Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.
iv.The medication is prescribed by or in consultation with a gastroenterologist; AND
v.Patient meets one of the following (a or b)
a)Patient has tried one adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, or Zymfentra
Note: A trial of an infliximab intravenous product (e.g., Remicade, biosimilars), Simponi subcutaneous, Skyrizi intravenous

or Stelara intravenous also counts
b)According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Omvah intravenous
B)Patient is Currently Receiving Omvoh Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Therapy criteria.
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

CONTINUATION OF THERAPY:
UC – Patients Currently Taking Omvoh and new to plan.
A)Approve for 1 year if the patient meets one of the following (a or b):
a.Patient has tried one of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, or Zymfentra; OR
Note: A trial of an infliximab intravenous product (for example, Remicade, biosimilars), Simponi subcutaneous, Skyrizi intravenous or Stelara intravenous also counts.
b.Patient has been established on Omvoh subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Omvoh subcutaneous was dispensed within the past 130 days [verification in prescription claims history required], or if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Omvoh subcutaneous for at least 90 days AND the patient has been receiving Omvoh subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Omvoh subcutaneous).

OPFOLDA

MEDICATION(S)
OPFOLDA

COVERED USES
Treatment of adults with late-onset Pompe disease

EXCLUSION CRITERIA
Use in combination with Lumizyme or Nexviazyme

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

COVERAGE DURATION
1 year

OTHER CRITERIA
1.Acid alpha-glucosidase deficiency (Pompe Disease). Approve if the patient meets all of the following (a, b, c and d): a.Patient weighs 40 kg or greater b.Medication will be used in combination with Pombiliti c.Patient has not demonstrated an improvement in objective measures after receiving one of the following for at least one year (i or ii) (Note: examples of objective measures include forced vital capacity [FVC] and six-minute walk test [6MWT]): i.Lumizyme IV infusion (alglucosidase alfa) OR ii.Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion d.Patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) with diagnosis established by one of the following (i or ii): i.Patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue, or ii.Patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation

OPHTHALMIC PROSTAGLANDIN THERAPY

MEDICATION(S)
BIMATOPROST 0.03% EYE DROPS, LUMIGAN, TAFLUPROST, TRAVOPROST, VYZULTA

COVERED USES
All FDA-approved indications.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Latanoprost is the preferred product. The drug must be prescribed within the manufacturer’s published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary alternative for the given diagnosis OR the member has a documented contraindication to the preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary alternative OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

OPSUMIT

MEDICATION(S)
OPSUMIT

COVERED USES
Treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and hospitalization for PAH.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterization

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH-must be prescribed by or in consultation with a cardiologist or a pulmonologist.

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.

OPZELURA

MEDICATION(S)
OPZELURA

COVERED USES
Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

EXCLUSION CRITERIA
Concurrent use with a biologic or with other JAK inhibitors. Concurrent use with other potent immunosuppressants.

REQUIRED MEDICAL INFORMATION
Diagnosis, other medications tried.

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
AD - Prescribed by or in consultation with an allergist, immunologist or dermatologist. Nonsegmental vitiligo – prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
AD - 8 weeks. Vitiligo - 6 months.

OTHER CRITERIA
Atopic Dermatitis, mild to moderate- Approve if the patient meets all of the following (A, B, C and D):
A)Patient has mild to moderate atopic dermatitis, according to the prescriber, AND
B)Patient has atopic dermatitis involvement estimated to affect less than or equal to 20% of the body surface area, AND
C)Patient meets ONE of the following (i or ii):
i.Patient meets ALL of the following criteria (a and b):
a)Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND

Note: Concomitant use of a topical corticosteroid with a topical calcineurin inhibitor would meet the requirement.
b)Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber, OR
ii.Patient is treating atopic dermatitis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia AND
D)Patients meets ALL of the following (i and ii):
i.Patient has tried at least one topical calcineurin inhibitor, AND
Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.

ii.Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber.

Vitiligo – approve if the patient meets all of the following (A, B, and C):
A)Patient has nonsegmental vitiligo
B)Patient has vitiligo involvement estimated to affect less than or equal to 10 percent of the body surface area
C)Patient meets ONE of the following (i or ii):
i. Patient meets ALL of the following criteria (a, b and c):
a.Patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid, AND
b.The duration of this topical corticosteroid therapy was at least 12 weeks (Note: intermittent or continuous use of a topical corticosteroid for at least 12 weeks would meet the requirement), AND
c.Inadequate efficacy was demonstrated with this topical corticosteroid therapy
ii. Patient is treating vitiligo affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia

ORENCIA SQ

MEDICATION(S)
ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic or with a Targeted Synthetic DMARD. Ankylosing Spondylitis (AS), Inflammatory Bowel Disease (i.e., Crohn's Disease (CD), Ulcerative Colitis (UC)), Psoriasis.

REQUIRED MEDICAL INFORMATION
See Other criteria

AGE RESTRICTION
See Other criteria

PRESCRIBER RESTRICTION
See Other criteria

COVERAGE DURATION
See Other criteria

OTHER CRITERIA
1.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve Orencia SC for 6 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD); AND
ii.Orencia SC is prescribed by or in consultation with a rheumatologist.
iii. The patient meets ONE of the following conditions (a or b):
a. The patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, or Xeljanz/XR [documentation required]. Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of tocilizumab intravenous (Actemra intravenous, biosimilar), Cimzia, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi Aria or SC also counts [documentation required]; OR
b. According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.

B) Patient is Currently Receiving Orencia (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
b)Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

2.Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis {JRA}] (regardless of type of onset). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve Orencia SC for 6 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient meets one of the following conditions (a, b, c, or d):
a)The patient has tried one other agent for this condition (e.g., methotrexate [MTX], sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug [NSAID]).
NOTE: A previous trial of one biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count.; OR
b)The patient will be starting on Orencia SC concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
c)The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
d)The patient has aggressive disease, as determined by the prescribing physician; AND
ii. Orencia SC is prescribed by or in consultation with a rheumatologist. AND
iii. The patient meets ONE of the following conditions (a or b):
a)The patient has tried TWO of Enbrel, an adalimumab product, Rinvoq/Rinvoq LQ, Xeljanz, and a tocilizumab subcutaneous product. Note: A trial of tocilizumab intravenous (Actemra intravenous, biosimilar), Kevzara, Orencia IV, an infliximab product (e.g., Remicade, biosimilars) or Simponi Aria also counts also counts [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz tablets and Xeljanz oral solution) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of multiple tocilizumab products counts as ONE product; OR
b)According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.
B)Patient is Currently Receiving Orencia (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

3.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii)
i. Orencia is prescribed by or in consultation with a rheumatologist or a dermatologist.
ii. The patient meets ONE of the following conditions (a, b, or c):
a)The patient is 18 years of age or older and has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi SC, Stelara SC, Taltz, Tremfya, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria or SC also counts [documentation required]; OR
b)The patient is less than 18 years of age AND has tried ONE of Enbrel, Rinvoq/Rinvoq LQ, or Stelara SC [documentation required]. Note: A trial of another TNFi counts towards a trial of Enbrel. A trial of either or both Rinvoq products (Rinvoq or Rinvoq LQ) collectively counts as ONE product.; OR
c)According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.
B)Patient is Currently Receiving Orencia (IV or SC). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requesting drug). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths).

CONTINUATION OF THERAPY:
1B, 2B, and 3B-RA, JIA, or PsA – Patients Currently Taking Orencia (SC or IV) and new to plan.
A)Approve Orencia SC for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a, b, c, d, e, f or g):

a)The patient has been established on Orencia SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Orencia SC was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Orencia SC for at least 90 days AND the patient has been receiving Orencia SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Orencia SC); OR
b)According to the prescribing physician, the patient has been established on Orencia IV for at least 90 days; OR
c)The patient has RA and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, or Xeljanz/XR [documentation required]. Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of tocilizumab intravenous, Cimzia, an infliximab product (e.g., Remicade,

biosimilars), Kevzara, Simponi (Aria or SC) also counts [documentation required]; OR
d)The patient has JIA and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq/Rinvoq LQ, and Xeljanz tablets or oral solution. Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz tablets and Xeljanz oral solution) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product. A trial of tocilizumab intravenous (Actemra IV, biosimilar), Kevzara, Orencia IV, an infliximab product (e.g., Remicade, biosimilars) or Simponi Aria also counts [documentation required]; OR
e)The patient is 18 years of age or older with PsA and has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi SC, Stelara SC, Taltz, Tremfya, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ). A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria or SC also counts [documentation required]; OR
f)The patient is less than 18 years of age with PsA and has tried ONE of Enbrel, Rinvoq/Rinvoq LQ, or Stelara SC [documentation required]. Note: A trial of another TNFi counts towards a trial of Enbrel. A trial of either or both Rinvoq products (Rinvoq or RInvoq LQ) collectively counts as ONE product.; OR
g)According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.

ORENITRAM

MEDICATION(S)
ORENITRAM ER, ORENITRAM MONTH 1 TITRATION KT, ORENITRAM MONTH 2 TITRATION KT, ORENITRAM MONTH 3 TITRATION KT

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other inhaled or parenteral prostacyclin agents used for pulmonary hypertension

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or pulmonologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.

ORKAMBI

MEDICATION(S)
ORKAMBI

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use with Kalydeco or Symdeko.

REQUIRED MEDICAL INFORMATION
For patients new to therapy, homozygous F508del mutation status in the CFTR gene required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
CFTR gene mutation cnfrmed,lifetime. If cont use from prior to joining plan and mutation unknwn, 3 mo

OTHER CRITERIA
Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

ORLADEYO

MEDICATION(S)
ORLADEYO

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant Use with Other HAE Prophylactic Therapies (e.g., Haegarda, Takhzyro).

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results (C1-INH protein, C4 levels), reauth: number and severity of HAE attacks

AGE RESTRICTION
12 years and older (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values [documentation required] AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].

Continuation of therapy: Patient meets both of the following (1 and 2): 1. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months AND 2. Patient has experienced a reduction in the number of HAE attacks from baseline

OTEZLA

MEDICATION(S)
OTEZLA 10-20 MG STARTER 28 DAY, OTEZLA 10-20-30MG START 28 DAY, OTEZLA 20 MG TABLET, OTEZLA 30 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Ankylosing Spondylitis. Concurrent Use with a Biologic or with a Targeted Synthetic DMARD. Rheumatoid Arthritis (RA).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria below

PRESCRIBER RESTRICTION
See other criteria below

COVERAGE DURATION
See other criteria below

OTHER CRITERIA
1.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 4 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient is an adult greater than or equal to 6 years of age; AND
ii.The patient meets the following conditions (a or b):
a)The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
Note: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.Otezla is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets ALL of the following conditions (i, ii and iii):
i.The patient has already received at least 4 months of therapy with Otezla.
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

2.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of following criteria (i and ii):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.Otezla is prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b)Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

3.Behcet's Disease. Approve for the duration noted if the patient meets the following criteria (A or B):
A)Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.The patient has oral ulcers or other mucocutaneous involvement; AND
iii.The patient has tried at least ONE other systemic therapy.
Note: Examples of systemic therapies include colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors (e.g., adalimumab [Humira, biosimilars], etanercept [Enbrel, biosimilars], certolizumab pegol [Cimzia], golimumab [Simponi/Aria], or infliximab products [Remicade, biosimilars]); AND
iv.Otezla is prescribed by or in consultation with a rheumatologist or dermatologist.
B)Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i. Patient has already received at least 4 months of therapy with Otezla; AND
ii.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); ulcer depth, number, and/or lesion size.
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, or improved visual acuity (if ophthalmic manifestations).

OXERVATE

MEDICATION(S)
OXERVATE

COVERED USES
Treatment of neurotrophic keratitis

EXCLUSION CRITERIA
Treatment duration greater than 16 weeks per affected eye

REQUIRED MEDICAL INFORMATION
Diagnosis, Documentation of decreased or loss of corneal sensitivity and corneal epithelium changes, Documentation of treatment of underlying conditions if appropriate (e.g. herpetic eye disease, diabetes, dry eye, multiple sclerosis, etc.), discontinuation of ophthalmic steroids or avoidance of ophthalmic preservatives

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION
2 months

OTHER CRITERIA
1.Neurotrophic Keratitis. Approve if the patient meets the following criteria (A or B):
A)Initial Therapy in patients who have never received Oxervate: Approve for 8 weeks if patient has diagnosis of neurotrophic keratitis.
B)Patient Who Has Previously Received Oxervate. Approve for 8 weeks if the patient meets the following criteria (i and ii):
i.Patient has previously received less than or equal to 8 weeks of treatment per affected eye(s); AND
ii.Patient has a recurrence of neurotrophic keratitis

PALYNZIQ

MEDICATION(S)
PALYNZIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use with sapropterin (continuation therapy)

REQUIRED MEDICAL INFORMATION
Palynziq is being used to reduce blood phenylalanine concentrations for patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases

COVERAGE DURATION
Initial: 1 year

Continuation: 3 years

OTHER CRITERIA
For initiation of therapy: Approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan).

For continuation of therapy: Approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.

PCSK9 INHIBITORS

MEDICATION(S)
PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use of Juxtapid, Kynamro, or Leqvio. Concurrent use with Praluent, if Repatha is requested. Concurrent use with Repatha, if Praluent is requested.

REQUIRED MEDICAL INFORMATION
Prior therapies tried, medication adverse event history, medical history.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a Cardiologist/lipid/cardiometabolic specialist/endocrinologist.

COVERAGE DURATION
3 years

OTHER CRITERIA
A. Diagnosis/Indication must be one of the following, 1, 2, 3 or 4:
1.Repatha and Repatha Pushtronex only: Diagnosis of homozygous familial hypercholesterolemia
a.Member has one of the following (i, ii, iii, or iv)
i.Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
ii.Untreated LDL greater than 500 mg/dl (prior to treatment)
iii.Treated LDL greater than or equal to 300 mg/dl (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid)
iv.Has clinical manifestations of HoFH (e.g. cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma
b.AND member has tried one high intensity statin (defined below) for 8 weeks or longer and LDL remains 70 mg/dl or higher unless statin intolerant (defined below) OR

2.Diagnosis of heterozygous familial hypercholesterolemia, and the member
a.Must have tried and failed ONE high intensity statin (for example, atorvastatin greater than or equal to 40mg daily or rosuvastatin greater or equal to 20mg daily), UNLESS
b.A physician has diagnosed rhabdomyolysis or the member is determined to be statin intolerant. Statin intolerance is defined by experiencing stating related skeletal-related muscle symptoms while receiving two separate trials of statins and during both trials the skeletal-related symptoms resolved during drug discontinuation. The statin trials may be either
i.A trial of two different statins, or

ii.A rechallenge of the same statin at a lower dose.
(The member need not exceed two trials total to confirm intolerance) OR

3.Diagnosis of Clinical Atherosclerotic Cardiovascular Disease, used for secondary prevention in patients with hyperlipidemia who failed a high intensity statin or are statin intolerant.
a.Secondary prevention requires that the member has a history of one of the following conditions: prior MI, history of acute coronary syndrome, diagnosis of angina, history of stroke or transient ischemic attack, peripheral arterial disease, undergone a coronary or other arterial revascularization procedure, AND the member
b.Must have tried and failed ONE high intensity statin (for example, atorvastatin greater than or equal to 40mg daily or rosuvastatin greater or equal to 20mg daily), UNLESS
c.A physician has diagnosed rhabdomyolysis or the member is determined to be statin intolerant. Statin intolerance is defined by experiencing stating related skeletal-related muscle symptoms while receiving two separate trials of statins and during both trials the skeletal-related symptoms resolved during drug discontinuation. The statin trials may be either
i.A trial of two different statins, or
ii.A rechallenge of the same statin at a lower dose.
(The member need not exceed two trials total to confirm intolerance)

4.For Praluent and Repatha, allow approval for primary hyperlipidemia (not associated with ASCVD, HeFH or HoFH) with the following requirements (a. AND b.)
a.The member tried one high-intensity statin therapy (defined above) (unless member is determined to be statin intolerant (defined above]) and ezetimibe for 8 weeks
b.LDL remains 100 mg/dL or higher unless statin intolerant (defined above)

PEDICULOSIS CAPITIS

MEDICATION(S)
SPINOSAD

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment is for head lice.

AGE RESTRICTION
Spinosad: 4 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days

OTHER CRITERIA
Failed two treatments using any one or more of the following medications: permethrin 1% (Nix), pyrethrins with piperonyl butoxide (Rid, or others), Malathion (Ovide), benzyl alcohol 5% lotion (Ulesfia), lindane (Kwell). Crotamiton 10% lotion (Eurax)

Note: two treatments may be shown as a listed product filled twice, listed product filled once but with a sufficient quantity for 2 treatments, two listed products being filled on separate dates.

PREVYMIS

MEDICATION(S)
PREVYMIS

COVERED USES
N/A

EXCLUSION CRITERIA
Severe hepatic impairment (Child-Pugh C). Members on dialysis or with end-stage renal disease (CrCl <10 ml/min) (unless receiving Prevymis for kidney transplant indication).

REQUIRED MEDICAL INFORMATION
Diagnosis, CMV lab value

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, or transplant specialist (or nephrologist if for kidney transplant indication)

COVERAGE DURATION
4 months

OTHER CRITERIA
CMV prophylaxis in patients who have received an allogeneic hematopoietic stem cell transplant must meet all of the following (1, 2 and 3)
1.Member is CMV-seropositive
2.Medication is started within 28 days post-transplant
3.Patient does not have active CMV infection (CMV PCR level over 250 IU/ml)
CMV prophylaxis in kidney transplant recipients must meet all of the following (1, 2, 3 and 4):
1.Member is a recipient of a kidney transplant
2.Member is CMV-seronegative
3.Donor is CMV-seropositive
4.Provider attests Prevymis will be initiated between Day 0 and 7 post-transplantation

PROCYSBI

MEDICATION(S)
PROCYSBI

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use of Cystagon and Procysbi

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases).

COVERAGE DURATION
1 year

OTHER CRITERIA
Cystinosis, nephropathic – approve if the member meets all of the following (1 and 2):
1.Prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
2.Member has tried and failed Cystagon.

PROMACTA

MEDICATION(S)
ALVAIZ, PROMACTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
A.For Chronic Immune Thrombocytopenia Purpura: Initial duration 90 days, review for renewal. For continuation of therapy, platelet count must demonstrate a positive increase to >50,000/mm3, OR if <50,000/mm3 the member must have a clinically significant improvement in bleeding status; authorization will be for 1 year. If the platelet count does not increase after 4 weeks at the maximum dose, therapy will not be reauthorized. Review annually.
B.For Thrombocytopenia due to HCV or MDS, 12 months. Review for renewal.
C.For aplastic anemia, 12 months. Review for renewal.

OTHER CRITERIA
A. Promacta may be approved if all of the following criteria are met:
1. Patient has a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP). Chronic is defined as greater than 6 months.AND
2. The member must have a baseline platelet count that is either <30,000/mm3 OR 30,000-50,000/mm3 AND in the presence of a clinically significant previous bleeding episode OR at high risk of experiencing a clinically significant bleeding episode (for example, upcoming surgery, if the member is at high risk of falls, etc.) AND
3. Patient must have had an insufficient response to or be intolerant to BOTH of the following (insufficient response is defined as the inability to achieve a platelet count of >50,000/mm3): Corticosteroids AND One of the following: Splenectomy, IVIG, anti-D immunoglobulins

B. Promacta may be approved if all of the following criteria are met:
1.Patient requires treatment of thrombocytopenia associated with hepatitis C virus (HCV) to allow for initiation and maintenance of interferon-based therapy (i.e., the degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy).
AND

2.Must be prescribed by or in consultation with a gastroenterologist, hematologist or infectious disease physician.
AND
3.If the member is currently on interferon based therapy, the member must have attempted and failed to improve platelet levels through interferon dose reduction.

C.Promacta may be approved if all of the following criteria are met:
1.Patient has a diagnosis of severe aplastic anemia, defined as follows based on the criteria of the International Aplastic Anemia Study Group (IAASG). Member must meet both criteria a and b:
a.Any 2 or 3 of the following peripheral blood criteria:
i.Neutrophils less than 0.5 x 10^9/L
ii.Platelets less than 20 x 10^9/L
iii.Reticulocytes less than 1% corrected (percentage of actual hematocrit [Hct] to normal Hct)
AND
b.Any one of the following marrow criteria:
i.Severe hypocellularity
ii.Moderate hypocellularity, with hematopoietic cells representing less than 30% of residual cells
AND
2.The member will use Promacta in combination with standard immunosuppressive therapy or had an insufficient response to immunosuppressive therapy

D.Promacta may be approved if all the following criteria are met:
a.Patient has a diagnosis of thrombocytopenia in myelodysplastic syndrome (MDS)
AND
b.The requested medication is being prescribed by or in consultation with a hematologist or oncologist
AND
c.Patient has low- to intermediate-risk MDS and according to the prescriber the patient has clinically-significant thrombocytopenia (e.g. low platelet counts [pretreatment], is platelet transfusion-dependent, active bleeding, and/or a history of bleeding at low platelet counts.)

PYRUKYND

MEDICATION(S)
PYRUKYND

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with Pyruvate Kinase Deficiency homozygous for the c.1436G A variant/mutation in the pyruvate kinase liver and red blood cell (PKLR) gene or patients with two non-missense variants/mutations (without the presence of other missense variant/mutation) in the PKLR gene.

REQUIRED MEDICAL INFORMATION
Diagnosis, laboratory values

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist

COVERAGE DURATION
Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hemolytic Anemia due to pyruvate kinase deficiency:

Initial Therapy. Approve if the patient meets both of the following (i and ii):

i.Patient meets both of the following (a and b):

a.Presence of at least two variant/mutant alleles in the PKLR gene

b.At least one of the variant/mutant alleles was a missense variant, AND

ii.Patient meets one of the following (a or b):

a.Patient has a current hemoglobin level less than or equal to 10 g/dL, or

b.Patient is currently receiving red blood cell transfusions regularly, defined as at least 6 transfusions within the last year

Continuation of Therapy. Approve if the patient meets the following (i, ii, and iii):

i.Patient meets both of the following (a and b):

a.Presence of at least two variant/mutant alleles in the PKLR gene, AND

b.At least one of the variant/mutant alleles was a missense variant, AND

ii.Patient has current hemoglobin less than or equal to 12.0 g/dL, AND

iii.According to the prescriber, the patient has experienced a benefit from therapy based on one of the following (a, b or c):

a.Increase in or maintenance of hemoglobin levels, OR

b.Improvement in or maintenance of hemolysis laboratory parameters (e.g. indirect bilirubin, lactate dehydrogenase, and haptoglobin), OR

c.Decrease in or maintenance of transfusion requirements

QULIPTA

MEDICATION(S)
QULIPTA

COVERED USES
N/A

EXCLUSION CRITERIA
Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months, Continuation: 12 months

OTHER CRITERIA
Preventative treatment of episodic migraine:
For initial therapy: Approve if the patient meets the following (A and B)
A)Patient has had an adequate trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil).
B)The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia and phonophobia).

Preventative treatment of chronic migraine:
Approve if the patient meets the following (A and B)
A)Patient has had an adequate trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil).
B)The member must have a diagnosis of migraine, as indicated by 15 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or

photophobia and phonophobia).

For continuation therapy: Prescriber confirms that the member had a reduction in migraine days per month from baseline after a 3-month trial.

RADICAVA ORS

MEDICATION(S)
RADICAVA ORS

COVERED USES
Treatment of amyotrophic lateral sclerosis (ALS)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous medication trials, ALSFRS-R score, FVC. For reauth: documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

COVERAGE DURATION
6 months

OTHER CRITERIA
ALS Initial treatment:
1.Approve if patient meets ALL of the following (a, b, c, d, and e)
a.According to the prescriber, the patient has a “definite” or “probable” diagnosis of ALS based on the application of the El Escorial or the revised Airlie House diagnostic criteria; AND
b.Patient has a score of two points or more on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R) as assessed and documented in the past 3 months [i.e. has retained most or all activities of daily living]; AND
c.Patient has a percent-predicted forced vital capacity (FVC) 80% or greater (i.e. has normal respiratory function); AND
d.Patient has been diagnosed with ALS for 2 years or less; AND
e.Patient has received or is currently receiving riluzole (tablets, oral suspension or oral film)
ALS Currently receiving Radicava:
1.Approve if the patient meets both of the following (a, b and c):
a.Member had met initial criteria requirements at time of medication being started; AND
b.According to the prescriber, the patient continues to benefit from therapy; AND
c.The patient is not requiring invasive ventilation

REGRANEX

MEDICATION(S)
REGRANEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of pressure ulcers, venous stasis ulcers or ischemic diabetic ulcers

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 months

OTHER CRITERIA
Diabetic Neuropathic Ulcers – patient meets the following:
1.Treatment will be given in combination with ulcer would care (e.g., debridement, infection control, pressure relief)
2.Treatment is for lower extremity diabetic ulcers
3.Ulcer extends into the subcutaneous tissue or beyond
4.Ulcer has adequate blood supply

REYVOW

MEDICATION(S)
REYVOW

COVERED USES
Acute treatment of migraine

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Acute treatment: Approve if the patient has trialed and failed or has a contraindication [documentation required] to TWO triptans (must be different active ingredients).

REZUROCK

MEDICATION(S)
REZUROCK

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
N/A

RHOPRESSA

MEDICATION(S)
RHOPRESSA

COVERED USES
Treatment of ocular hypertension and open-angle glaucoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prior therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Member must try and fail latanoprost AND one Ophthalmic Beta Blocker (ex. Timolol, betaxolol, levobunolol, metipranolol) prior to Rhopressa therapy

RILUTEK, RILUZOLE, TIGLUTIK, EXSERVAN

MEDICATION(S)
EXSERVAN, TIGLUTIK

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of amyotrophic lateral sclerosis (ALS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Neurologist.

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
Requires documentation of exclusion of other diagnoses by neurologist.

RINVOQ

MEDICATION(S)
RINVOQ, RINVOQ LQ

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. COVID-19. Concurrent use with a biologic immunomodulator. Concurrent use with Other Janus Kinase Inhibitors.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria below.

PRESCRIBER RESTRICTION
See other criteria below.

COVERAGE DURATION
See other criteria below.

OTHER CRITERIA
1.Rheumatoid Arthritis (RA). Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
i.The patient is greater than or equal to 18 years of age; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The agent is prescribed by or in consultation with a rheumatologist.
iv.Patient has tried one of Enbrel or an adalimumab product (Note: a trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.)
B)Patients Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Therapy.
ii.Patient meets at least one of the following (a or b):
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity

Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
b)Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

2.Atopic Dermatitis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets one of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
i.Patient is 12 years of age or older; AND
ii.Patient meets one of the following (a or b):
a)Patient has had a 4-month trial of at least ONE systemic therapy; OR
b)Patient has tried at least ONE systemic therapy but was unable to tolerate a 4-month trial; AND
Note: Examples of systemic therapies include Dupixent (dupilumab subcutaneous injection) and Adbry (tralokinumab-ldrm subcutaneous injection). Methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil also count towards trial of a systemic therapy.
iii.The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
B)Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets the following (i, ii, and iii):
i.Patient has already received at least 90 days of therapy with Rinvoq; AND
Note: A patient who has received less than 90 days of therapy or who is restarting therapy with Rinvoq should be considered under Initial Therapy.
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Rinvoq) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND
iii.Compared with baseline (prior to receiving Rinvoq), patient experienced an improvement in at least one symptom, such as decreased itching.

3.Psoriatic Arthritis. Approve Rinvoq extended-release tablets or Rinvoq LQ oral solution for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 2 years of age or older; AND
ii.Patient meets ONE of the following (a or b):
a)Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b)Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
iv.Patient has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
B)Patient is Currently Receiving Rinvoq/Rinvoq LQ. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq/Rinvoq LQ); OR

Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating Rinvoq/Rinvoq LQ), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function, or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4.Ankylosing Spondylitis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B);
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 18 years of age or older; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The medication is prescribed by or in consultation with a rheumatologist; AND
iv.The patient has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
B)Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Rinvoq), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
5.Ulcerative Colitis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
i.Patient is 18 years of age and older; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The medication is prescribed by or in consultation with a gastroenterologist
iv.Patient has tried one adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars) or Simponi subcutaneous also counts.
B)Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established a therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):

a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq) Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b.Compared with baseline (prior to initiating Rinvoq), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.

6.Non-Radiographic Axial Spondyloarthritis. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i. Patient has objective signs of inflammation, defined as at least one of the following (a or b):
a.C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
b.Sacroiliitis reported on magnetic resonance imaging (MRI); AND
ii. Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii. The medication is prescribed by or in consultation with a rheumatologist.
iv. Patient has tried Cimzia (Note: A trial of an Enbrel, an adalimumab product, an infliximab Product (Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.)
B)Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on the requested drug for at least 6 months; AND
ii. Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
7.Crohn’s Disease. Approve Rinvoq extended-release tablets (not Rinvoq LQ oral solution) for the duration noted if the patient meets ONE of the following criteria (A or B):
A) Approve for 6 months if the patient meets ALL of the following criteria (i, ii, iii and iv):
i.Patient is 18 years of age or older; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The medication is prescribed by or in consultation with a gastroenterologist.
iv.Patient has tried one adalimumab product. Note: a trial of an infliximab product (e.g. Remicade, biosimilars, Zymfentra) or Cimzia also counts.
A)Patient is Currently Receiving Rinvoq extended-release tablets. Approve for 1 year if the patient meets BOTH of the following criteria (i and ii):
i. Patient has been established on therapy for at least 6 months
ii.Patient meets at least one of the following criteria (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior

to initiating Rinvoq). Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.
b.Compared with baseline (prior to initiating Rinvoq), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.
8.Juvenile Idiopathic Arthritis (JIA). Approve Rinvoq extended-release tablets or Rinvoq LQ oral solution for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following (i, ii and iii):
i.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
ii.The medication is prescribed by or in consultation with a rheumatologist
iii.The patient has tried one of Enbrel or an adalimumab product. Note: a trial of an infliximab product (e.g. Remicade, biosimilars) or Simponi Aria also counts.
B)Patient is Currently Receiving Rinvoq/Rinvoq LQ. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least ONE of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Rinvoq/Rinvoq LQ). Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
b.Compared with baseline (prior to initiating Rinvoq/Rinvoq LQ), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

CONTINUATION OF THERAPY: AS, RA, PsA, UC, nr-axSpA – for members new to plan:
Approve for 1 year if the patient meets applicable continuation criteria from above and one of the following:
1.Patient has AS and has tried one of Enbrel or on adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR
2.Patient has CD and has tried one adalimumab product. Note: a trial of an infliximab product (e.g. Remicade, biosimilars, Zymfentra) or Cimzia also counts.
3.Patient has JIA and has tried one of Enbrel or an adalimumab product. Note: a trial of an infliximab product (e.g. Remicade, biosimilars) or Simponi Aria also counts.
4.Patient has nr-axSpA and has tried Cimzia. Note: A trial of Enbrel, an adalimumab product, an infliximab Product (Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR
5.Patient has RA and has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR
6.Patient has PsA and has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR
7.Patient has UC and has tried an adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars, Zymfentra) or Simponi subcutaneous also counts.; OR
8.Patient has been established on Rinvoq for at least 90 days and prescription claims history indicates at least a 90-day supply of Rinvoq was dispensed within the past 130 days [verification in prescription claims history required] if claims history

is not available, according to the prescriber [verification by prescriber required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Rinvoq for at least 90 days AND the patient has been receiving Rinvoq via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Rinvoq).

SAMSCA

MEDICATION(S)
TOLVAPTAN

COVERED USES
N/A

EXCLUSION CRITERIA
Patients requiring urgent intervention to raise serum sodium acutely. Patients unable to sense or appropriately respond to thirst. Patients with hypovolemic hyponatremia. Concomitant use of strong CYP 3A inhibitors (ketoconazole, clarithromycin, itraconazole, ritonavir, indinavir, nelfinadir, saquinavir, nefazodone, telithromycin). Patients who are anuric. Liver disease.

REQUIRED MEDICAL INFORMATION
The diagnosis must be clinically significant hyponatremia, hypervolemic or euvolemic, defined as serum sodium less than 125meq/l or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, and the patient must be symptomatic (symptoms may include nausea/vomiting, headache, confusion, lethargy, fatigue, loss of appetite, restlessness and irritability, muscle weakness, spasm, cramps, seizures, decreased consciousness, or coma), including patients with heart failure, cirrhosis, and SIADH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 4 days. With positive response, then may approve for 30 days. Review for renewal every 30 days.

OTHER CRITERIA
Therapy must be initiated or re-initiated in a hospital setting. The patient must have failed or resisted correction with one other means of treatment, such as loop diuretics, hypertonic saline, or salt tablets. The patient has been discontinued from any other possible cases of drug-induced hyponatremia or SIADH (such as carbamazepine, oxcarbazepine, chlorpropamide, fluoxetine, sertraline, vincristine, vinblastine, cisplatin, cyclophosphamide, thiothixene, thioridazine, haloperidol, amitriptyline, MAO inhibitors, methotrexate, NSAIDs, interferon alpha and gamma, amiodarone, ciprofloxacin, and opiates).

SAPROPTERIN

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with Palynziq (continuation only)

REQUIRED MEDICAL INFORMATION
Diagnosis of hyperphenylalaninemia (HPA) due to Phenylketonuria (PKU). Member must first try and fail a specialized phenylalanine restricted diet alone OR the member is pregnant.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial 3 months. Continuation 1 year. If member is pregnant coverage is through term.

OTHER CRITERIA
Member must continue to receive a specialized phenylalanine restricted diet in conjunction with sapropterin. For continuation of therapy, a positive response is defined as showing a 30% or greater reduction in blood phenylalanine level after initial 3 months of therapy. If approved for pregnancy, the coverage duration is limited through the term of the pregnancy only. Coverage after delivery is dependent upon the member meeting the requirements set forth in the standard criteria.

SGLT-2 INHIBITORS

MEDICATION(S)
BRENZAVVY, DAPAGLIFLOZIN, DAPAGLIFLOZIN-METFORMIN ER, INVOKAMET, INVOKAMET XR, INVOKANA, SEGLUROMET, STEGLATRO, STEGLUJAN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Authorization requires that all of the following criteria be met:

1.The requested drug is being prescribed for an FDA – approved indication, AND

2.The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3.One of the following:

Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. For authorization of Invokamet, Invokana, Segluromet or Steglatro, the preferred product (Farxiga, Jardiance, Synjardy, Synjardy XR, or Xigduo XR) must be referenced in the

following assessment:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

SIGNIFOR

MEDICATION(S)
SIGNIFOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medication history. Acromegaly. Cushing's disease for whom pituitary surgery is not an option or has not been curative. Endogenous Cushing's Syndrome, awaiting surgery or therapeutic response after radiotherapy.

AGE RESTRICTION
18 years and older (initial therapy)

PRESCRIBER RESTRICTION
Cushing's disease/syndrome: Prescribed by, or in consultation with, an endocrinologist or a physician that specializes in the treatment of Cushing's syndrome. Acromegaly: prescribed by, or in consultation with, an endocrinologist.

COVERAGE DURATION
Cushing's disease/syndrome: initial therapy – 4 months. Continuation – 1 year. Patient awaiting surgery or response after radiotherapy – 4 months. Acromegaly – 1 year.

OTHER CRITERIA
For Cushing's disease/syndrome – Approve Signifor or Signifor LAR if the following criteria are met: Initial therapy: Approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Continuation therapy: Approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.

For Acromegaly – approve Signifor LAR if the following criteria are met (1 and 2) : 1) Patient has pre-treatment (baseline) insulin-like growth factor-1 (IGH-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND 2) Patients meets one of the following (a, b or c): a) Has had an inadequate response to surgery and/or radiotherapy OR b) Is not an appropriate candidate for surgery and/or radiotherapy OR c) The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression).

SILIQ

MEDICATION(S)
SILIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs). Crohn's Disease. Rheumatoid Arthritis.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
i.The patient is 18 years of age or greater; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, or acitretin tablets) for at least 3 months, unless intolerant.
NOTE: A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.Siliq is prescribed by or in consultation with a dermatologist.
iv.The patient has tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, and Tremfya [documentation required]. Note: A trial of multiple adalimumab products counts as ONE product.
B)Patient is Currently Receiving Siliq. Approve Siliq for 1 year if the patient meets ALL of the following conditions (i, ii and iii):
i.Patient has been established on therapy for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Siliq) in at least

one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving Siliq), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

CONTINUATION OF THERAPY – Patients new to the plan and currently taking Siliq:
A)Approve for 1 year if the patient meets applicable continuation criteria from above and ONE of the following conditions (a or b):
a.Patient has tried TWO of Enbrel, an adalimumab product, Otezla, Skyrizi subcutaneous, Sotyktu, Stelara subcutaneous, Taltz, or Tremfya [documentation required]. Note: A trial of multiple adalimumab products counts as ONE product.; OR
b.Patient has been established on Siliq for at least 90 days and prescription claims history indicates at least a 90-day supply of Siliq was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required].

SIMPONI SC

MEDICATION(S)
SIMPONI

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. Plaque Psoriasis without Psoriatic Arthritis.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Ankylosing Spondylitis (AS). Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 6 months if both of the following are met (i and ii):
i. Prescribed by or in consultation with a rheumatologist.
ii. The patient has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz and Xeljanz/XR [documentation required]. Note: a trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product.
B)Patients Currently Receiving Simponi (SC or Aria). Approve Simponi SC for 1 year if the patient Meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2.Psoriatic Arthritis (PsA). Approve for the duration noted if the patient meets ONE of the following conditions (A or B):

A)Initial Therapy. Approve for 6 months if the following are met (i and ii):
i. Simponi SC is prescribed by or in consultation with a rheumatologist or a dermatologist.
ii. The patient has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi SC, Stelara SC, Taltz, Tremfya and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.
B)Patients Currently Receiving Simponi (SC or Aria). Approve Simponi SC for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi. Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

3.Rheumatoid Arthritis (RA). Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following criteria (i, ii, and iii):
i.The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD; AND
ii.Simponi SC is prescribed by or in consultation with a rheumatologist.
iii. The patient has tried TWO of tocilizumab subcutaneous products, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]. Note: Examples of tocilizumab products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product.
B)Patients Currently Receiving Simponi (SC or Aria). Approve Simponi SC for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4.Ulcerative Colitis (UC) in an Adult. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
i.The patient is 18 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)Patient has had a trial of one systemic therapy (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus) or a corticosteroid such as prednisone or methylprednisolone.
NOTE: An exception to this criterion can be made if the patient has already tried a biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.; OR
b)The patient has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, hydrocortisone enema], or Rowasa® (mesalamine) enema; AND
iii.Simponi SC is prescribed by or in consultation with a gastroenterologist.
iv.The patient has tried one adalimumab product.
B)Patients Currently Receiving Simponi (SC or Aria). Approve Simponi SC for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patients meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi). Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b.Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

Other Uses with Supportive Evidence

5.Spondyloarthritis (SpA), Other Subtypes (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter's disease]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications]. Approve for the duration noted if ONE of the following conditions are met (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following conditions (i and ii):
i.The patient meets ONE of the following (a or b):
a)The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD (e.g., methotrexate [MTX], leflunomide, sulfasalazine) has been tried; OR
b)The patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following [(1) or (2)]:
(1)C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
(2)Sacroiliitis reported on magnetic resonance imaging (MRI); AND
ii.Simponi SC is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving Simponi (SC or Aria). Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior

to initiating Simponi). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b)Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

CONTINUATION OF THERAPY for patients new to plan.
1B, 2B, 3B, 4B – AS, PsA, RA, UC
A)Approve Simponi SC for 1 year if the patient also meets applicable continuation criteria from above and ONE of the following conditions (a, b, c, d, e, or f):
a)Patient has Rheumatoid Arthritis and has tried TWO of tocilizumab subcutaneous products, Enbrel, an adalimumab product, Rinvoq, and Xeljanz/XR [documentation required]; OR
Note: A trial of multiple tocilizumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product.
b)Patient has Ankylosing Spondylitis and has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR. [documentation required]; OR
Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product.
c)Patient has Psoriatic Arthritis and has tried TWO of Enbrel, adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR [documentation required]; OR
Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.
d)Patient has Ulcerative Colitis and has tried one adalimumab product; OR
e)According to the prescriber, the patient has been established on Simponi Aria for at least 90 days; OR
f)Patient has been established on Simponi subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi subcutaneous was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Simponi subcutaneous for at least 90 days AND the patient has been receiving Simponi subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi subcutaneous).

SKYCLARYS

MEDICATION(S)
SKYCLARYS

COVERED USES
Treatment of Friedreich's ataxia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
16 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist or a physician who specializes in ataxias and/or neuromuscular disorders

COVERAGE DURATION
1 year

OTHER CRITERIA
Friedreich's Ataxia:
Initial Therapy – approve if patient meets all of the following (1, 2, 3, and 4):
1.Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia [documentation required]
2.Patient has all of the following in the past year (a, b and c)
a.Patient has a B-type natriuretic peptide (BNP) less than or equal to 200 pg/mL [documentation required], AND
b.Patient has a left ventricular ejection fraction greater than or equal to 40% [documentation required], AND
c.Patient has a hemoglobin A1c (HbA1c) less than or equal to 11 percent [documentation required]
3.Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score greater than or equal to 20, but less than or equal to 80 [documentation required]
4.Patient is ambulatory
Continuation Therapy – approve if patient meets all of the following (1 and 2):
1.Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia [documentation required]
2.Patient continues to benefit from therapy, as demonstrated by a slowed progression on the modified Friedreich's Ataxia Rating Scale [documentation required]

SKYRIZI

MEDICATION(S)
SKYRIZI 150 MG/ML SYRINGE, SKYRIZI ON-BODY, SKYRIZI PEN

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
See other Criteria

AGE RESTRICTION
See other Criteria

PRESCRIBER RESTRICTION
See other Criteria

COVERAGE DURATION
See other Criteria

OTHER CRITERIA
1.Plaque Psoriasis. Approve Skyrizi subcutaneous (pens or syringes) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient is an adult 18 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, or acitretin tablets) for at least 3 months, unless intolerant.
NOTE: A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis; OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.The agent is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Skyrizi Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):
i.Patient has been established on the requested drug for at least 3 months; AND
Note: A patient who has received less than 3 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Therapy.
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested

drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

2.Psoriatic Arthritis. Approve Skyrizi subcutaneous (pens or syringes) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patient is Currently Receiving Skyrizi. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy with Skyrizi is reviewed under Initial Therapy.
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi); OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortuium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating Skyrizi), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

3.Crohn’s Disease. Approve Skyrizi subcutaneous (on-body injector) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii and iv):
i.Patient meets ONE of the following conditions (a, b, c or d):
a)Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient (Note: examples of corticosteroids are prednisone or methylprednisolone)
b)Patient has tried one other conventional systemic therapy for Crohn’s disease (Note: Examples include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn’s disease.
c)Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
d)Patient had ileocolonic resection (to reduce the chance of Crohn’s disease recurrence); AND
ii.According to the prescriber, the patient will receive induction dosing with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous; AND
iii.The medication is prescribed by or in consultation with a gastroenterologist
B)Patient is Currently Receiving Skyrizi Subcutenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
NOTE: A patient who has received less than 6 months of therapy or who is restarting therapy is reviewed under criterion A.
ii.Patient meets at least one of the following (a or b):

a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi) (Note: examples of objective measures include fecal markers [e.g. fecal lactoferrin, fecal calprotectin], serum markers [e.g., C-reactive protein], imaging studies [magnetic resonance enterography, computed tomography enterography], endoscopic assessment, and/or reduced dose of corticosteroids.)
b)Compared with baseline (prior to initiating Skyrizi), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.
4.Ulcerative Colitis. Approve Skyrizi Subcutaneous (on-body injector) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 18 years of age or older; AND
ii.According to the prescriber, the patient will receive three induction doses with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous; and
iii.Patient meets ONE of the following (a or b):
a)Patient has had a trial of one systemic agent for ulcerative colitis; OR
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.
b)Patient meets BOTH of the following (1 and 2):
1.Patient has pouchitis; AND
2.Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.
iv.The medication is prescribed by or in consultation with a gastroenterologist; OR
B)Patient is Currently Receiving Skyrizi Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii. Patient meets at least ONE of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

SKYTROFA

MEDICATION(S)
SKYTROFA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, test results

AGE RESTRICTION
Greater than or equal to 1 year of age and less than 18 years old

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Growth Hormone Deficiency in pediatric patients, initial-Approve if the patient meets A and B:

A)Patient has tried a short-acting somatropin and experienced inadequate efficacy or significant intolerance (Examples of short-acting somatropins include Omnitrope, Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ, Saizen, Serostim, Zomacton, or Zorbtive) AND

B)Patient meets one of the following (i, ii, iii, iv, or v):

i.Patient meets one of the following (1 or 2):

(1)Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR

(2)Patient meets BOTH of the following criteria (a and b):

(i)Patient has had at least one growth hormone stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory AND

(ii)Patient has at least one risk factor for growth hormone deficiency (for example, the height for age curve has deviated downward across two major height percentiles [e.g., from above the 25th percentile to below the 10th percentile], the child's growth rate is less than the expected normal growth rate based on age and gender, low insulin-like growth factor (IGF)-1 and/or IGFBP-3 levels, the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician, the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile], the patient is status post craniopharyngioma resection, the patient has optic nerve hypoplasia, the patient has a growth hormone gene deletion)

ii.Patient has undergone brain radiation or tumor resection AND patient meets at least one of the following (1 or 2):

(1)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR

(2)Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin)

iii.Patient has congenital hypopituitarism AND meets one of the following (1 or 2):

(1)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR

(2)Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin) and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk

iv.Patient has panhypopituitarism and meets one of the following (1, 2, or 3):

(1)Patient has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary "bright spot" on magnetic resonance imaging or computed tomography, OR

(2)Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin, OR

(3)Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced

hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory

v.Patient has had a hypophysectomy (surgical removal of pituitary gland)-approve.

SOGROYA

MEDICATION(S)
SOGROYA

COVERED USES
Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH) and replacement of endogenous GH in adults with growth hormone deficiency (GHD)

EXCLUSION CRITERIA
For GHD in adult: Use as anti-aging therapy, to enhance athletic ability, or for body building

REQUIRED MEDICAL INFORMATION
Diagnosis, test results (e.g., growth hormone stimulation test results)

AGE RESTRICTION
Greater than or equal to 2.5 years of age

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist (all diagnoses except hypophysectomy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Growth hormone deficiency in child, initial – approve if the patient meets one of the following (1, 2, 3, 4 or 5) 1.Patient meets one of the following (a or b): a.Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR b.Patient meets BOTH of the following criteria (i and ii): i.Patient has had at least one growth hormone stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory AND
ii.Patient has at least one risk factor for growth hormone deficiency (for example, the height for age curve has deviated downward across two major height percentiles [e.g., from above the 25th percentile to below the 10th percentile], the child's growth rate is less than the expected normal growth rate based on age and gender, low insulin-like growth factor (IGF)-1 and/or IGFBP-3 levels, the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician, the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile], the patient is status post craniopharyngioma resection, the patient has optic nerve hypoplasia, the patient has a growth hormone gene deletion) 2.Patient has undergone brain radiation or tumor resection AND patient meets at least one of the following (a or b): a.Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR b.Patient has a deficiency in at least one other pituitary hormone (i.e.,

adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin) 3.Patient has congenital hypopituitarism AND meets one of the following (1, 2 or 3): a.Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory OR b.Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin) OR c.Patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.Patient has multiple pituitary hormone deficiencies and meets one of the following (a, b or c): Note: Growth hormone deficiency may occur in combination with other pituitary hormone deficiencies and is referred to as hypopituitarism, panhypopituitarism, or multiple pituitary hormone deficiency. a.Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin, OR b.Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory 5.Patient has had a hypophysectomy (surgical removal of pituitary gland)-approve. Growth Hormone Deficiency in child, continuation – approve if the patient is responding to therapy. Growth Hormone Deficiency in an Adult-Approve if the patient meets ALL of the following (1 and 2): 1.Patient must have a diagnosis of growth hormone deficiency that is ONE of the following (i or ii): [documentation required for all elements] a.Childhood onset, OR b.Adult onset that results from one of the following: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage, AND 2.Patient meets at least ONE of the following (a, b, or c): a.Patient has known perinatal insults OR congenital or genetic defects, [documentation required] OR b.Patient meets ALL of the following (i, ii, and iii): i.Patient has three or more of the following pituitary hormone deficiencies: Adrenocorticotropic hormone, thyroid-stimulation hormone, gonadotropin deficiency (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin [documentation required], AND

ii.The age and gender adjusted serum insulin-like growth factor-1 is below the lower limit of the normal reference range for the reporting laboratory [documentation required], AND iii.Other causes of low serum insulin-like growth factor-1 have been excluded (e.g., malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy), OR c. Patient has had a negative response to at least ONE of the following standard growth hormone stimulation tests (1, 2, 3, 4, 5, or 6) [documentation required for all elements]: Note: If the patient has had a previous trial of an arginine test with a peak response of less than or equal to 0.4 mcg/L, this would meet the criteria for a negative response to a growth hormone stimulation test. 1.Insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with peak response less than or equal to 5.0 mcg/L, OR 2.Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response less than or equal to 3.0 mcg/L AND the patient's body mass index (BMI) is less than 25 kg/m2, OR 3.Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response less than or equal to 3.0 mcg/L AND the patient's BMI is greater than or equal to 25 kg/m2 and less than or equal to 30 kg/m2 with a high pretest probability of growth hormone deficiency, OR 4.Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response less than or equal to 1.0 mcg/L AND the patient's BMI is greater than or equal to 25 kg/m2 and less than or equal to 30 kg/m2 with a low pretest probability of growth hormone deficiency, OR 5.Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response less than or equal to

1.0 mcg/L AND the patient’s BMI is greater than 30 kg/m2, OR 6.Macrilen (macimorelin oral solution) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with peak responses less than 2.8 ng/mL (2.8 mcg/L) AND the patient’s BMI is less than or equal to 40 kg/m2.

SOHONOS

MEDICATION(S)
SOHONOS

COVERED USES
Reduction in volume of new heterotopic ossification in patients with fibrodysplasia ossificans progressive

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Female: 8 years or older, Male: 10 years or older (Female/Male are defined as an individual with the biological traits of a female/male, regardless of the individual's gender identity or gender expression)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist, rheumatologist, orthopedist or physician who specializes in bone disease.

COVERAGE DURATION
1 year

OTHER CRITERIA
Fibrodysplasia ossificans progressive 1.Initial: Approve if the patient meets A and B: A)Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)R206H consistent with a diagnosis of fibrodysplasia ossificans progressive, AND B)Patient has heterotopic ossification as confirmed by radiologic testing Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan. 2.Continuation: Approve if the patient meets the current criteria and the medication is providing clinical benefit, as attested by the provider

SOMAVERT

MEDICATION(S)
SOMAVERT

COVERED USES
Treatment of acromegaly

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Acromegaly – approve if patient meets has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory and ONE of the following (1, 2 or 3):
1.Patient has had an inadequate response to surgery and/or radiotherapy OR
2.The patient is not an appropriate candidate for surgery and/or radiotherapy OR
3.The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression)

SOTYKTU

MEDICATION(S)
SOTYKTU

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
Concurrent use with other potent immunosuppressants, including methotrexate.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Plaque psoriasis (PP). Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.Patient is 18 years of age or older; AND
ii.Patient meets ONE of the following (a or b):
a)Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of one traditional systemic agent include methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
b)Patient has a contraindication to methotrexate, as determined by the prescriber; AND
iii.The medication is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Sotyktu. Approve for 1 year if patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received less than 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

iii.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

SOVALDI

MEDICATION(S)
SOVALDI

COVERED USES
The drug is being prescribed for the treatment of chronic hepatitis C (CHC) infection where chronic is defined as disease lasting at least 6 months

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years or older. 3 and older in Genotype 2 and 3

PRESCRIBER RESTRICTION
Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD

COVERAGE DURATION
Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA
Sofosbuvir (Sovaldi) may be approved if all of the following criteria are met:

Mavyret AND Harvoni are the preferred medication to be tried first (Must attempt BOTH preferred products): UNLESS one of the following are satisfied:

a.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required

Criteria will be applied consistent with current AASLD/IDSA guidance.

STELARA

MEDICATION(S)
STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthesis DMARD. Akylosing Spondylitis (AS).

REQUIRED MEDICAL INFORMATION
See Other Criteria

AGE RESTRICTION
See Other Criteria

PRESCRIBER RESTRICTION
See Other Criteria

COVERAGE DURATION
See Other Criteria

OTHER CRITERIA
1.Crohn's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i.The patient meets one of the following conditions (a, b, c or d):
a)The patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
b)The patient has tried one conventional systemic therapy for Crohn's disease.
Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate (MTX). An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested drug does not count. These patients who have already received a biologic are not required to "step back" and try another agent);
c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
d) Patient has ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
ii.According to the prescriber, the patient will receive a single induction dose with Stelara IV within 2 months of initiating therapy with Stelara SC; AND
iii.Stelara SC is prescribed by or in consultation with a gastroenterologist.
B)Patients Currently Receiving Stelara SC. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on the requested drug for at least 6 months; AND
ii. Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal

calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

2.Plaque Psoriasis. Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):
Note: If the 90 mg syringe is requested, approve if the patient meets one of the following:
•patient weighs greater than 100 kg; OR
•patient is currently receiving the 90 mg syringe; OR
•patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.

A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient is 6 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant. Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, or acitretin. Note: A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.Stelara is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Stelara SC. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on the requested drug for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3.Psoriatic Arthritis (PsA). Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):
Note: If the 90 mg syringe is requested, approve if the patient meets one of the following:
•patient has moderate to severe plaque psoriasis AND weighs greater than 100 kg; OR
•patient is currently receiving the 90 mg syringe; OR
•patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.
A)Initial Therapy. Approve for 6 months if Stelara is prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patient is Currently Receiving Stelara SC. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease

Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4.Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
i.Patient meets ONE of the following (a or b):
a.The patient has had a trial of one systemic agent for ulcerative colitis; Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.
b.Patient meets BOTH of the following (1 and 2);
1.Patient has pouchitis; AND
2.Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema (Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.)
ii.According to the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous; AND
iii.The agent is prescribed by or in consultation with a gastroenterologist.
B)Patient is Currently Receiving Stelara Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

STRENSIQ

MEDICATION(S)
STRENSIQ

COVERED USES
Treatment of perinatal/infantile- and juvenile-onset hypophosphatasia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values, radiographic reports

AGE RESTRICTION
Disease onset-less than or equal to 18

PRESCRIBER RESTRICTION
Prescribed by an endocrinologist or specialist experienced in treatment of metabolic bone disorders

COVERAGE DURATION
Initial – 6 months. Continuation – 12 months.

OTHER CRITERIA
Initial Coverage – member meets all of the following requirements (1, 2 and 3): 1. Documented diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) AND diagnosis supported by one of the following (a or b): a. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR b. Documentation of ALL of the following (i, ii and iii): i. An elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi] level), ii. Findings on radiographic imaging support diagnosis of hypophosphatasia (e.g. infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age [as detected by DXA scan]), iii. Low baseline ALP activity (age adjusted), 2. Member is 18 years or less at age of disease onset, 3. Member has clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures). Continuation of coverage – member meets the following (1, 2 and 3): 1. Member meets criteria for initial approval, 2. Documentation of positive clinical response to Strensiq (e.g. improvement in clinical symptoms, improvement in Radiographic Global Impression of Change), 3. Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi] level).

SUNOSI

MEDICATION(S)
SUNOSI

COVERED USES
Treatment for patients with excessive somnolence-Narcolepsy OR excessive somnolence-Obstructive Sleep Apnea.

EXCLUSION CRITERIA
Concurrent treatment with monoamine oxidase inhibitor (MAOI) or use of an MAOI with the preceding 14 days. Concurrent use with Xyrem, Xywav and/or Wakix.

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, prior therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, a pulmonologist, or a sleep specialist

COVERAGE DURATION
1 year

OTHER CRITERIA
A.For Narcolepsy-One of the following (1 and 2):
1.The member tried and failed or has a contraindication to two first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dexmethylphenidate, Dextroamphetamine, Methamphetamine, Methylphenidate (or their branded products: Adderall, Adderall XR, Focalin, Focalin XR, Dexedrine Spansules, Procentra, Zenzedi, Desoxyn, Methylin, Concerta, Daytrana, Metadate CD, Metadate ER, Quillivant, Ritalin, Ritalin LA, Ritalin SR) OR the member has a history of substance abuse AND
2.Patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed.

B.Excessive sleepiness associated with Obstructive Sleep Apnea
a. Member must have made a maximal effort and failed treatment with CPAP for an adequate period of time AND medication must be used in conjunction with CPAP or the patient must be unable to tolerate CPAP. Patient has tried generic modafinil or armodafinil.

SYMDEKO

MEDICATION(S)
SYMDEKO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystic fibrosis diagnosis. Homozygous for F508 del mutation or Tezacaftor/Ivacaftor-responsive mutation in CFTR gene.

AGE RESTRICTION
6 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
N/A

SYMPROIC

MEDICATION(S)
SYMPROIC

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Note: Criteria and documentation requires reference to 1 alternative product in a class where at least 1 alternative is available, or 2 or more in a class with at least 2 alternatives. For authorization of Symproic, the preferred product (Movantik) must be referenced in the following assessment:

Authorization requires that all the following criteria be met:

1. The requested drug is being prescribed for an FDA – approved indication, AND

2. The drug is being prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature (e.g. package insert, AHFS, Micromedex, current accepted clinical guidelines, etc…), AND

3. One of the following: a. The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

b. The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

c. The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

d. The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

TAFAMIDIS

MEDICATION(S)
VYNDAMAX, VYNDAQEL

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax.

REQUIRED MEDICAL INFORMATION
Diagnosis of cardiomyopathy of wild-type or hereditary TTR-mediated amyloidosis (ATTR-CM). Genetic tests.

AGE RESTRICTION
18 years and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

COVERAGE DURATION
1 year.

OTHER CRITERIA
For cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis: approve if the patient meets all of the following:

A. The patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND

B. The diagnosis was confirmed by one of the following (i or ii):

i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR

ii. Amyloid deposits are identified on cardiac biopsy AND

C. Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

TAKHZYRO

MEDICATION(S)
TAKHZYRO

COVERED USES
Preventing attacks of hereditary angioedema (HAE).

EXCLUSION CRITERIA
Concomitant use with other HAE prophylactic therapies (e.g. Orladeyo, Haegarda)

REQUIRED MEDICAL INFORMATION
Diagnosis. Lab values (C1-INH protein, C4 levels), reauth: number and severity of HAE attacks

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of hereditary angioedema (HAE) or related disorders (initial and continuation).

COVERAGE DURATION
Coverage Duration: Initial: 6 months, Continuation: 1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis
Initial Therapy: Approve if the patient meets all of the below:
1.The patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b):
a.The patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values [documentation required] AND
b.The patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required].
Continuation of therapy: Patient meets both of the following (1 and 2):
1.Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months
2.Patient has experienced a reduction in the number of HAE attacks from baseline

TALTZ

MEDICATION(S)
TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Inflammatory Bowel Diease (i.e., Crohn's Disease, Ulcerative Colitis).

REQUIRED MEDICAL INFORMATION
See other criteria below.

AGE RESTRICTION
See other criteria below.

PRESCRIBER RESTRICTION
See other criteria below.

COVERAGE DURATION
See other criteria below.

OTHER CRITERIA
1.Ankylosing Spondylitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist
B)Patient is Currently Receiving Taltz: Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2.Non-Radiographic Axial Spondyloarthritis: Approve for the duration noted if the patient meets One of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i.The patient has objective signs of inflammation, defined as at least one of the following (a or b):
a)C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR

b)Sacroiliitis reported on magnetic resonance imaging; AND
ii. The agent is prescribed by or in consultation with a rheumatologist.
B)Patients Currently Receiving Taltz. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patients have been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b);
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

3.Plaque Psoriasis. Approve Taltz for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
i.The patient is 6 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant. Note: Examples include methotrexate (MTX), cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
iii.The agent is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Taltz. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on the requested drug for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

4.Psoriatic Arthritis (PsA). Approve Taltz for the duration noted if the patient meets ONE of the following conditions (A or B):
A)Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
B)Patient is Currently Receiving Taltz. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortuium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR

b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

TARPEYO

MEDICATION(S)
TARPEYO

COVERED USES
N/A

EXCLUSION CRITERIA
eGFR less than 30 ml/min/1.73m^2

REQUIRED MEDICAL INFORMATION
Diagnosis, laboratory values, medication history

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist

COVERAGE DURATION
10 months

OTHER CRITERIA
For Primary IgAN:

Initial therapy. Approve if patient meets the following (i and ii):

i.Diagnosis has been confirmed by biopsy, AND

ii.Patient is at high risk of disease progression, defined by meeting the following criteria (a and b):

a.Patient meets ONE of the following (1 or 2):

1.Proteinuria greater than 0.75 g/day, OR

2.Urine protein-to-creatinine ratio equal to or greater than 0.8 g/g, AND

b.Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2):

i.Angiotensin converting enzyme inhibitor, OR

ii.Angiotensin receptor blocker

c.Patient has not previously been treated with Tarpeyo

Continuation of therapy. Approve for up to 10 months (total) if the patient meets the following criteria (i and ii)::

i.Diagnosis has been confirmed by biopsy, AND

ii.Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2):

i.Angiotensin converting enzyme inhibitor, OR

ii.Angiotensin receptor blocker

TAVALISSE

MEDICATION(S)
TAVALISSE

COVERED USES
Chronic Immune thrombocytopenia with insufficient response to previous treatment.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried. Pre-treatment platelet count of less than 50,000/microL.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist.

COVERAGE DURATION
Initial - 4 months. Continuation - 3 years.

OTHER CRITERIA
Chronic Immune thrombocytopenia - Initial: Approve if the patient has tried two other therapies or the patient has undergone splenectomy. For continuation of therapy: Platelet count must increase to a level sufficient to avoid clinically important bleeding after 12 weeks of Tavalisse therapy.

TAVNEOS

MEDICATION(S)
TAVNEOS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older (initial and continuation therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist

COVERAGE DURATION
Initial – 6 months, Continuation – 1 year

OTHER CRITERIA
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has granulomatosis with polyangiitis or microscopic polyangiitis, AND Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis. ii. Patient has active disease, AND Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission. iii. Patient is positive for proteinase 3 antibodies, anti-neutrophil cytoplasmic autoantibodies (ANCA) or myeloperoxidase antibodies, AND iv. Patient is using this medication in combination with at least one immunosuppressant Note: Examples of immunosuppressants include cyclophosphamide, rituximab, azathioprine, or mycophenolate mofetil. Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS]. b)

Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, abdominal pain, or improvement in function or activities of daily living.

TAZAROTENE, TAZORAC, FABIOR, DUOBRII

MEDICATION(S)
TAZAROTENE 0.05% GEL, TAZAROTENE 0.1% CREAM, TAZAROTENE 0.1% GEL

COVERED USES
N/A

EXCLUSION CRITERIA
Pregnancy. Fine wrinkle disorder/fine wrinkles on face. Hyper- and hypo-pigmentation.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
1.Member must not be pregnant and will utilize adequate measures to prevent pregnancy.
AND
2.Patient has a diagnosis of stable plaque psoriasis.
OR
3.Patient has a diagnosis of acne vulgaris and has failed on a least two
other formulary anti-acne preparations (e.g., topical retinoid products, topical antibacterial products).

TEGSEDI

MEDICATION(S)
TEGSEDI

COVERED USES
Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis.

EXCLUSION CRITERIA
Concomitant use with Onpattro or a tafamidis product

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic testing, biopsy results.. PND, FAP or NIS score.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial: Approve if the patient meets all of the following (1, 2, 3 and 4):
1.Patient has a documented transthyretin (TTR) mutation verified by genetic testing
2.Patient has documentation of biopsy proven amyloid deposits
3.Patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperate, vibration, touch]).
4.Patient meets one of the following (a, b or c)
a.Baseline polyneuropathy disability (PND) score less than or equal to IIIb
b.Baseline familial amyloidotic polyneuropathy (FAP) stage 1 or 2
c.Baseline neuropathy impairment score (NIS) between 10 and 130

Continuation: Approve if the patient meets all of the following:
1.Patient has demonstrated a benefit from therapy (e.g. improved neurological impairment, slowing of disease progression, quality of life assessment)
2.Patient meets one of the following (a, b or c):
a.Patient continues to have a PND score less than or equal to IIIb
b.Patient continues to have a FAP stage 1 or 2
c.Patient continues to have a NIS between 10 and 130

TESTOSTERONE

MEDICATION(S)
ANDRODERM, JATENZO, KYZATREX, TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 50 MG/5 GRAM GEL, TESTOSTERONE 50 MG/5 GRAM PKT, TLANDO

COVERED USES
N/A

EXCLUSION CRITERIA
Erectile dysfunction. Decreased Libido.

REQUIRED MEDICAL INFORMATION
Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Male is defined as an individual with the biological traits of a male, regardless of the individual's gender identity or gender expression.]

Gender dysphoria in transgender male patients (Note: this is an off-label indication).

AGE RESTRICTION
Aged 18 years or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Lifetime.

OTHER CRITERIA
Hypogonadism (primary or secondary) in males – initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males – continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a male, regardless of the individual's gender identity or gender expression.]

TETRABENAZINE

MEDICATION(S)
TETRABENAZINE

COVERED USES
1.Chorea (involuntary movements) associated with Huntington’s disease
2.Tardive dyskinesia
3.Tourette syndrome and related tic disorders
4.Hyperkinetic dystonia
5.Hemiballism

EXCLUSION CRITERIA
Impaired hepatic function, Concomitant use of MAOIs (minimum of 14 days should elapse after stopping MAOI and before starting tetrabenazine) or Reserpine (minimum of 20 days should elapse after stopping reserpine and before starting tetrabenazine), Non-Huntington's related chorea.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
For treatment of chorea associated with Huntingtons disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism must be prescribed by or in consultation with a neurologist. For Tardive Dyskinesia, must be prescribed by or in consultation with a neurologist or psychiatrist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Chorea associated with Huntington’s disease – approve if the diagnosis of Huntington’s Disease is confirmed by genetic testing.

TIOPRONIN

MEDICATION(S)
TIOPRONIN 100 MG TABLET, TIOPRONIN DR 100 MG TABLET, TIOPRONIN DR 300 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of severe homozygous cystinuria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a nephrologist or urologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Initiation of therapy: patient has urinary cysteine concentration greater than 250 mg/L.

TRANSDERM SCOPALAMINE PATCH

MEDICATION(S)
SCOPOLAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
The product is not being used for the prevention of nausea and/or vomiting while traveling (for example: seasickness, car motion sickness, air motion sickness, etc.).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Review for renewal.

OTHER CRITERIA
N/A

TREMFYA

MEDICATION(S)
TREMFYA

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Plaque Psoriasis.
A)Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
i.The patient is an adult 18 years of age or older; AND
ii.The patient meets ONE of the following conditions (a or b):
a)The patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant. Note: Examples include methotrexate (MTX), cyclosporine, acitretin [Soriatane®, generics], or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic for the other than the requested drug. A biosimilar of the requested biologic does not count. These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis; OR
b)The patient has a contraindication to methotrexate (MTX), as determined by the prescriber; AND
iii.The requested agent is prescribed by or in consultation with a dermatologist.
B)Patient is Currently Receiving Tremfya. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
i.Patient has been established on the requested drug for at least 3 months; AND
ii.Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
iii.Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning
iv.

2.Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if Tremfya is prescribed by or in consultation with a rheumatologist or a dermatologist.
B) Patient is Currently Receiving Tremfya. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths).

TRIKAFTA

MEDICATION(S)
TRIKAFTA

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with Orkambi, Kalydeco or Symdeko. Patients with unknown CFTR gene mutations

REQUIRED MEDICAL INFORMATION
Treatment is for cystic fibrosis in patients who have at least one F508del mutation in the CFTR gene. Diagnosis, specific CFTR gene mutations, concurrent medications

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF.

COVERAGE DURATION
3 years

OTHER CRITERIA
CF - approve if the patient has at least one copy of the F508del mutation in the cystic fibrosis conductance regulator gene.

TYVASO

MEDICATION(S)
TYVASO, TYVASO DPI 16 MCG CARTRIDGE, TYVASO DPI 16-32 MCG TITR KIT, TYVASO DPI 16-32-48 MCG TITRAT, TYVASO DPI 32 MCG CARTRIDGE, TYVASO DPI 48 MCG CARTRIDGE, TYVASO DPI 64 MCG CARTRIDGE, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other oral or parenteral prostacyclin agents used for pulmonary hypertension

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by appropriate test

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II, III or IV symptoms
Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD) WHO Group 3 (this involves diagnoses such as idiopathic interstitial pneumonia, combined pulmonary fibrosis and emphysema, WHO Group 3 connective disease and chronic hypersensitivity pneumonitis): Patient meets all of the following (1, 2 and 3):
1.Patient has had right heart catheterization to confirm diagnosis
2.Patient has connective tissue disease with a baseline FVC less than 70%
3.Patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest

UBRELVY

MEDICATION(S)
UBRELVY

COVERED USES
Acute treatment of migraine with or without aura.

EXCLUSION CRITERIA
For acute treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for acute treatment.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Approve if the patient has trialed and failed or has a contraindication [documentation required] to TWO triptans (must be different active ingredients).

UPTRAVI

MEDICATION(S)
UPTRAVI

COVERED USES
Treatment of pulmonary arterial hypertension

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of right heart catheterization, medication history as referenced in other criteria

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or pulmonologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1, 2 and 3):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class II-IV symptoms.
3. Meet one of the following (i or ii):
i.Tried one or is currently taking one oral therapy for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (e.g., sildenafil, Revatio), endothelin receptor antagonist (ERA) [e.g., Tracleer, Letairis or Opsumit], or Adempas OR
ii.Receiving or has received in the past one prostacyclin therapy for PAH (e.g., Orenitram, Ventavis, or epoprostenol injection)

VELSIPITY

MEDICATION(S)
VELSIPITY

COVERED USES
Ulcerative Colitis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.Patient is 18 years of age or greater; AND
ii.Patient has had a trial of ONE systemic agent for ulcerative colitis; AND
Note: Examples of systemic agents for ulcerative colitis include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of one biologic also counts as a trial of one systemic agent for ulcerative colitis.
iii.The medication is prescribed by or in consultation with a gastroenterologist.
i.Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Omvoh subcutaneous, Rinvoq, Simponi subcutaneous, Xeljanz/XR [documentation required]; AND
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Entyvio intravenous or subcutaneous, Omvoh intravenous, Skyrizi subcutaneous or Stelara intravenous also counts [documentation required].
iv.Patient has tried Zeposia [documentation required].
B)Continuation of Therapy. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received less than 6 months of therapy or who is restarting therapy with the requested drug is

reviewed under Initial Therapy criteria.
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b)Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

CONTINUATION OF THERAPY:
UC – Patients Currently Taking Velsipity and new to plan.
A)Approve for 1 year if the patient meets one of the following (a or b):
a.Patient meets ONE of the following conditions (i or ii)
i.Patient meets BOTH of the following [(1) and (2)]:
(1)Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, Omvoh subcutaneous, Rinvoq, Simponi subcutaneous, Xeljanz/XR [documentation required]; AND
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Entyvio intravenous or subcutaneous, Omvoh intravenous, Skyrizi intravenous or Stelara intravenous also counts [documentation required].
(2)Patient has tried Zeposia [documentation required]; OR
b)Patient has been established on Velsipity for at least 90 days and prescription claims history indicates at least a 90-day supply of Velsipity was dispensed within the past 130 days [verification in prescription claims history required], or if claims history is not available, according to the prescriber [verification by prescriber required].
Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Velsipity for at least 90 days AND the patient has been receiving Velsipity via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Velsipity).

VENTAVIS

MEDICATION(S)
VENTAVIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis as confirmed by right heart catheterizations

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2):
1.Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c):
a.Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest
b.Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg
c.Pulmonary vascular resistance (PVR) greater than 3 Wood units
2.Individual has WHO functional class III or IV symptoms.
Part B vs D determination will be made based on location of administration.

VEOZAH

MEDICATION(S)
VEOZAH

COVERED USES
Treatment of moderate to severe vasomotor symptoms due to menopause

EXCLUSION CRITERIA
Use in patients with cirrhosis, severe renal impairment (eGFR <30 ml/min/1.73m2) or end-stage renal disease, concomitant use with CYP1A2 inhibitors (e.g. allopurinol, acyclovir, fluvoxamine, mexiletine, cimeditine)

REQUIRED MEDICAL INFORMATION
Continuation of therapy: documentation of a positive clinical response to therapy (e.g. decreased frequency and severity of vasomotor symptoms from baseline)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Vasomotor symptoms due to menopause - Initial: Member meets all of the following (1, 2 and 3): 1.History of failure (following minimum 1-month trial), contraindication or intolerance to a hormonal therapy (e.g., estradiol, Premarin, Prempro) 2.History of failure (following minimum 1-month trial), contraindication or intolerance to a non-hormonal therapy (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin and norepinephrine reuptake inhibitors [SNRIs], gabapentin, clonidine) 3.Diagnosis of moderate to severe vasomotor symptoms due to menopause

VIJOICE

MEDICATION(S)
VIJOICE

COVERED USES
PIK3CA-Related Overgrowth Spectrum (PROS)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has laboratory confirmation of PIK3CA mutation

AGE RESTRICTION
2 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Patient has severe or life-threatening clinical manifestations of PROS, as assessed by the treating physician, that necessitates use of systemic treatment.

VOSEVI

MEDICATION(S)
VOSEVI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Previous therapy. Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment of Vosevi.

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

COVERAGE DURATION
12 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA
Mavyret and Harvoni is the preferred medication for Hepatitis C Treatment: Unless one of the following are satisfied:

1.The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternatives for the given diagnosis. Documentation of the medications, including dates of trial and reason for failure is required, OR

2.The member has a documented contraindication to the preferred formulary/preferred drug list alternatives. Documentation including the medication name(s) and contraindication is required, OR

3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary/preferred drug list alternatives for the requested indication. Documentation of the medication name and adverse reaction is required, OR

4.The member has a clinical condition for which there is no listed formulary agent to treat the condition based on published guidelines or clinical literature. Documentation of the clinical condition is required.

Criteria will be applied consistent with current AASLD/IDSA guidance.

VOXZOGO

MEDICATION(S)
VOXZOGO

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent treatment with growth hormone (e.g., somatropin), long acting growth hormone (e.g., lonapegsomatropin), or insulin-like growth factor-1 (IGF-1) (e.g., Increlex).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Less than 18 years old (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pediatric endocrinologist (initial and continuation)

COVERAGE DURATION
1 year

OTHER CRITERIA
Achondroplasia-approve if the patient meets ONE of the following criteria (A or B):

A)Initial Therapy or Patient Has Been on Voxzogo less than 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, and iv):

i.The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND

ii.Patient meets both of the following (a and b):

a)Patient’s epiphyses are open, AND

b)There is evidence of annualized growth velocity greater than or equal to 1.5 cm/year, AND

iii.Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND

iv.The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration

B)Patient Has Been Receiving Voxzogo for greater than or equal to 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):

i.The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND

ii.Patient meets both of the following (a and b):

a)Patient's epiphyses are open, AND

b)There is evidence of annualized growth velocity greater than or equal to 1.5 cm/year, AND

iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND

iv.The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration, AND

v.Patient's most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Voxzogo).

VTAMA

MEDICATION(S)
VTAMA

COVERED USES
Topical treatment of plaque psoriasis in adults

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Plaque psoriasis:
Patients meets all of the following criteria (1, 2 and 3):
1.Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area
2.Patient meets one of the following criteria (a or b):
a.Patient meets all of the following criteria (i and ii):
i.Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid
ii.Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber
b.Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia
3.Patient meets all of the following criteria (a and b):
a.Patient has tried at least one topical vitamin D analog (e.g. calcipotriene cream, ointment or foam, calcitriol ointment)
b.Inadequate efficacy was demonstrated with the topical Vitamin D analog

WAKIX

MEDICATION(S)
WAKIX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Treatment of excessive daytime sleepiness (EDS) in adults with narcolepsy. Cataplexy treatment in patients with narcolepsy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a sleep specialist physician or neurologist

COVERAGE DURATION
N/A

OTHER CRITERIA
Excessive daytime sleepiness associated with Narcolepsy-Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) AND the patient has tried generic modafinil or generic armodafinil (Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil) OR patient has a history of substance use disorder and a wakefulness-promoting agent that is not a controlled substance is necessary, per the prescriber. Cataplexy tx in patients with narcolepsy-approve if the patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed.

XELJANZ

MEDICATION(S)
XELJANZ, XELJANZ XR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent Use with a Biologic or with a Targeted Synthetic DMARD. Concurrent use with Other Potent Immunosuppressants (e.g., azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil). COVID-19. Renal Transplantation

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See Other Criteria

PRESCRIBER RESTRICTION
See Other Criteria

COVERAGE DURATION
See Other Criteria

OTHER CRITERIA
1.Psoriatic Arthritis (PsA). Approve Xeljanz or Xeljanz XR (not oral solution) for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv and v):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.The medication will be used concomitantly with methotrexate or another conventional synthetic DMARD, unless contraindicated.
Note: Examples of other conventional synthetic DMARDs include leflunomide and sulfasalazine; AND
iv.The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
v.Patient has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
B)Patient is Currently Receiving Xeljanz/XR. Approve for 1 year if the patient meets BOTH of the following (i, ii and iii):
i.Patient has been established on therapy for at least 6 months; AND
ii.The medication will be used concomitantly with methotrexate or another conventional synthetic DMARD, unless contraindicated;
Note: Examples of other conventional synthetic DMARDs include leflunomide and sulfasalazine AND

iii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Xeljanz/XR). Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortuium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR
b.Compared with baseline (prior to initiating Xeljanz/XR), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

2.Rheumatoid Arthritis (RA). Approve Xeljanz or Xeljanz XR (not oral solution) for the duration noted if the patient meets ONE of the following criteria (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii iii, and iv):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.The patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
iii.Xeljanz is prescribed by or in consultation with a rheumatologist; AND
iv.Patient has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
B)Patients Currently Receiving Xeljanz/Xeljanz XR. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).; OR
b.Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.
3.Ulcerative Colitis. Approve Xeljanz /Xeljanz XR (not oral solution) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
i.The patient is an adult greater than or equal to 18 years of age; AND
ii.The patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis OR was unable to tolerate a 3-month trial. AND
iii.Xeljanz is prescribed by or in consultation with a gastroenterologist. AND
iv.Patient has tried one adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars, Zymfentra) or Simponi subcutaneous also counts.
B)Patients is Currently Receiving Xeljanz/Xeljanz XR. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a)When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Xeljanz/XR). Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal

calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b)Compared with baseline (prior to initiating Xeljanz/XR), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.
4.Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes a patient with juvenile spondyloarthropathy/active sacroiliac arthritis]. Approve Xeljanz tablets (not the Xeljanz XR formulation) or oral solution for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii and iii):
i.Patient meets ONE of the following conditions (a or b):
a)Patient has had a 3-month trial of at least one tumor necrosis factor inhibitor; OR
b)Patient has tried at least one tumor necrosis inhibitor but was unable to tolerate a 3-month trial; AND
ii.The medication is prescribed by or in consultation with a rheumatologist.
iii.Patient has tried one of Enbrel or an adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars) or Simponi Aria also counts.
B)Patient is Currently Receiving Xeljanz. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Xeljanz). Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.; OR
b.Compared with baseline (prior to initiating Xeljanz), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.
5.Ankylosing Spondylitis. Approve Xeljanz/XR tablets (not oral solution) for the duration noted if the patient meets ONE of the following (A or B):
A)Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
i.Patient is 18 years of age or older; AND
ii.Patient meets ONE of the following (a or b):
a.Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
b.Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial.; AND
iii.The medication is prescribed by or in consultation with a rheumatologist.
iv.The patient has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
B)Patient is Currently Receiving Xeljanz/XR. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Xeljanz/XR). Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).; OR

b.Compared with baseline (prior to initiating Xeljanz/XR), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

CONTINUATION OF THERAPY

3B – AS, RA, JIA, PsA or UC – Patients Currently Taking Xeljanz/Xeljanz XR and new to plan:

A)Approve Xeljanz or Xeljanz oral solution (not Xeljanz XR) for 1 year if the patient meets applicable continuation criteria from above and ONE of the following (a, b, c, d, e or f):

a.Patient has AS and has tried Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts. OR

b.Patient has RA and has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR

c.Patient has JIA and has tried one of Enbrel or an adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars) or Simponi Aria also counts.; OR

d.Patient has PsA and has tried one of Enbrel or an adalimumab product. Note: A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.; OR

e.Patient has UC and has tried an adalimumab product. Note: A trial of an infliximab product (e.g., Remicade, biosimilars, Zymfentra) or Simponi subcutaneous also counts.; OR

f.Patient has been established on Xeljanz/Xeljanz XR for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz/Xeljanz XR was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Xeljanz/Xeljanz XR for at least 90 days AND the patient has been receiving Xeljanz/Xeljanz XR via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Xeljanz/Xeljanz XR).

XIFAXAN

MEDICATION(S)
XIFAXAN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Travelers diarrhea: 12 years of age or older. HE, IBS-D: 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Hepatic encephalopathy: 1 year, IBS-D: 14 days, Travelers' diarrhea: 3 days

OTHER CRITERIA
1.Hepatic encephalopathy: trial/failure, intolerance or contraindication to lactulose.
2.Travelers' diarrhea: trial/failure, intolerance or contraindication to ciprofloxacin, levofloxacin, ofloxacin or azithromycin
3.IBS-D:
a.Moderate to severe disease, including bloating without constipation
b.Inadequate response to and antispasmodic (e.g. dicyclomine) AND an antidiarrheal agent (e.g. loperamide, diphenoxylate/atropine)

XOLAIR

MEDICATION(S)
XOLAIR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For asthma, diagnosis must be moderate to severe persistent asthma, baseline IgE level of at least 30 IU/ml, and member must have a positive skin test or in vitro testing (blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay [for example, immunoCAP, ELISA]) or the radioallergosorbent test (RAST) for one or more perennial aeroallergens or for one or more seasonal aeroallergens. For urticaria, diagnosis must be Chronic Idiopathic Urticaria. IgE-mediated food allergy: Baseline IgE, positive skin prick test, positive in vitro test for IgE to one or more foods.

AGE RESTRICTION
Asthma: 6 years or greater. Chronic Idiopathic Urticaria: 12 years or greater. Nasal polyps: 18 years or greater. IgE-mediated food allergy: 1 year of age or greater.

PRESCRIBER RESTRICTION
Asthma: prescribed by or in consultation with an allergist, immunologist, or pulmonologist. Urticaria: prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal polyps: prescribed by or in consultation with an allergist, immunologist, or otolaryngologist. IgE-mediated food allergy: Prescribed by or in consultation with an allergist or immunologist.

COVERAGE DURATION
Asthma/CIU initial: 4 months, Nasal polyps initial: 6 months. IgE-mediated food allergy: 1 year. Continuation: 12 months.

OTHER CRITERIA
For Asthma (Initial): Patient has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one of the following: long-acting beta agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, AND patient's asthma is uncontrolled or was prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) as defined by ONE of the following (a, b, c, d, or e): a. The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b. The patient experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c. Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d. Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e. The patients asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months. For Asthma (Continuation): Patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For

Chronic Idiopathic Urticaria (Initial): Urticaria must be for more than 6 weeks (prior to treatment with Xolair), requires the that member remains symptomatic (symptoms present more than 3 days/week) despite H1 antihistamine treatment. For Chronic Idiopathic Urticaria (Continuation): Patient has responded to therapy as determined by the prescribing physician. Pharmacy Benefit Criteria Only: Additional medical drug benefit criteria may be required if the patient is receiving the medication at the hospital or clinic.

For Nasal polyps (Initial): Patient has baseline IgE level greater than or equal to 30 IU/ml, AND patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell, AND patient is currently receiving therapy with an intranasal corticosteroid, AND patient has received treatment with a systemic corticosteroid for chronic rhinosinusitis with nasal polyps within the previous 2 years OR has a contraindication to systemic corticosteroid therapy OR patient has had prior surgery for nasal polyps. For Nasal polyps (continuation): Approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy. For IgE-mediated food allergy: Baseline IgE greater than or equal to 30 IU/ml, Positive skin prick test to one or more foods and positive in vitro test for IgE to one or more foods, History of allergic reaction that met all of the following: pt demonstrated signs and symptoms of a significant systemic allergic reaction, and reaction occurred within a short period of time following a known ingestion of the food, and prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector and Patient has been prescribed an epinephrine auto-injector.

XOPENEX/LEVALBUTEROL

MEDICATION(S)
LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Indefinite

OTHER CRITERIA
Levalbuterol authorization may be approved if the required following criteria is met:

The patient tried and was intolerant to albuterol secondary to clinically significant adverse cardiovascular effects (increased pulse rate, increased blood pressure, and/or other sympathetic nervous symptom symptoms)

XYREM

MEDICATION(S)
LUMRYZ, SODIUM OXYBATE, XYWAV

COVERED USES
N/A

EXCLUSION CRITERIA
Exclusions: Concomitant use of sodium oxybate, Xywav, Wakix, Sunosi, modafinil and/or armodafinil

REQUIRED MEDICAL INFORMATION
Diagnosis of cataplexy and narcolepsy OR narcolepsy, with excessive daytime sleepiness.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a sleep specialist physician or a Neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
A.For Excessive Daytime Sleepiness (EDS) in patients with narcolepsy-approve if the patient has tried two CNS stimulants (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil AND narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT)

B.Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT)

C.For Xywav only: Idiopathic hypersomnia – approve if the patient has tried two CNS stimulants (e.g., methylphenidate, dexmethylphenidate, dextroamphetamine) AND diagnosis has been confirmed using polysomnography and a multiple sleep latency test.

ZEPATIER

MEDICATION(S)
ZEPATIER

COVERED USES
N/A

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding Sovaldi and ribavirin.

REQUIRED MEDICAL INFORMATION
Hep C genotype, concurrent medications, medication history, NS5A polymorphism

AGE RESTRICTION
18 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.

COVERAGE DURATION
12 weeks or 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

OTHER CRITERIA
Criteria will be applied consistent with current AASLD/IDSA guidance. Harvoni and Mavyret are the preferred products. Authorization for Zepatier requires that the member must have confirmation of one of the following: A documented failure to both of the preferred products, OR A documented intolerance to both the preferred products, OR A documented contraindication to both of the preferred products, OR A documented adverse reaction to both of the preferred products.

ZEPOSIA

MEDICATION(S)
ZEPOSIA 0.92 MG CAPSULE, ZEPOSIA STARTER KIT (28-DAY), ZEPOSIA STARTER PACK (7-DAY)

COVERED USES
See other criteria

EXCLUSION CRITERIA
•Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.

•Non-Relapsing Forms of Multiple Sclerosis

•Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis.

REQUIRED MEDICAL INFORMATION
See other criteria

AGE RESTRICTION
See other criteria

PRESCRIBER RESTRICTION
See other criteria

COVERAGE DURATION
See other criteria

OTHER CRITERIA
1.Multiple Sclerosis – approve for the following duration if the patient meets ONE of the following (a or b):
a.Initial Therapy. Approve for 1 year if the patient meets the following (i and ii):
i.Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
ii.Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
b. Patient is Currently Receiving Zeposia for 1 year or longer. Approve for 1 year if the patient meets the following (i, ii and iii):
i.Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
ii.Patient meets one of the following (1 or 2):
1.Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging

(MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.
2.Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND
iii.Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

2.Ulcerative Colitis. Approve for the following duration if the patient meets ONE of the following (a or b):
a.Initial therapy. Approve for 6 months if the patient meets the following (i ii, iii and iv):
i.Patient is 18 years of age or older; AND
ii.Patient has had a trial of ONE systemic agent for ulcerative colitis; AND
Note: Examples of systemic agents for ulcerative colitis include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a biologic also counts as a trial of one systemic agent for ulcerative colitis.
iii.The medication is prescribed by or in consultation with a gastroenterologist.
iv. Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, Stelara subcutaneous, and Zymfentra. Note: A trial of an infliximab intravenous product (e.g., Remicade, biosimilar), Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, Skyrizi intravenous or Stelara intravenous also counts.
b.Patient is Currently Receiving Zeposia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i.Patient has been established on therapy for at least 6 months; AND
ii.Patient meets at least one of the following (a or b):
a.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug). Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.; OR
b.Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

CONTINUATION OF THERAPY
UC – Patients Currently Taking Zeposia and new to plan:
A)Approve Zeposia for 1 year if the patient meets applicable continuation criteria from above and ONE of the following conditions (i or ii):
i.Patient has TWO of an adalimumab product, Skyrizi subcutaneous Stelara subcutaneous or Zymfentra. Note: A trial of an infliximab product (e.g., Remicade, biosimilars), Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, Skyrizi intravenous or Stelara intravenous also counts.
ii.Patient has been established on Zeposia for at least 90 days and prescription claims history indicates at least a 90-day supply of Zeposia was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescriber required]. Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Zeposia for at least 90 days AND the patient has been receiving Zeposia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain

access to Zeposia).

ZOKINVY

MEDICATION(S)
ZOKINVY

COVERED USES
The member has a diagnosis of Hutchinson-Gilford Progeria Syndrome (HGPS) or Processing-Deficient Progeroid Laminopathies (PL)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, gene mutations as described in other criteria

AGE RESTRICTION
12 months and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist or cardiologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Hutchinson-Gilford Progeria Syndrome, approve if the patient meets (A and B):
A)Patient has a body surface area greater than or equal to 0.39 m2
B)Genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome

Progeroid laminopathies, approve if the patient meets (A and B):
A)Patient has a body surface area greater than or equal to 0.39 m2
B)Patient has Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.

ZTALMY

MEDICATION(S)
ZTALMY

COVERED USES
Treatment of seizures associated with cyclin-dependent kinase-like (CDKL5) deficiency disorder (CDD)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Seizures associated with CDKL5 deficiency disorder – approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.

ZURZUVAE

MEDICATION(S)
ZURZUVAE

COVERED USES
Treatment of postpartum depression (PPD) in adults

EXCLUSION CRITERIA
Prior use of Zulresso or Zurzuvae for the current pregnancy

REQUIRED MEDICAL INFORMATION
Depression score or documentation of severe depression (as referenced in other criteria)

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a psychiatrist or a Perinatal Psychiatry Access Program

COVERAGE DURATION
30 days

OTHER CRITERIA
Postpartum depression: Member must meet all of the following (1, 2 and 3): 1.Diagnosis of major depressive episode that began no earlier than the third trimester and no later than the first 4 weeks following delivery, as diagnosed by Structured Clinical Interview for DSM-5 2.Meets one of the following criteria: a.HAMD score 24 or greater (severe depression) b.MADRS score 35 or greater (severe depression) c.PHQ-9 score 20 or greater (severe depression) d.If member does not have severe depression as demonstrated by one of the depression scores (a, b or c), documentation of severe depression as evidenced by a psychiatrist clinical interview 3.No more than 12 months have passed since member has given birth

ZYMFENTRA

MEDICATION(S)
ZYMFENTRA

COVERED USES
Crohn's disease, Ulcerative Colitis

EXCLUSION CRITERIA
Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD)

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
See other criteria section

PRESCRIBER RESTRICTION
See other criteria section

COVERAGE DURATION
See other criteria section

OTHER CRITERIA
1. Crohn’s Disease. Approve for the duration noted if the patient meets ONE of the following (a or b):
a.Initial Therapy. Approve for 6 months if the patient meets all of the following (i, ii, iii and iv):
i.Patient is 18 years of age or older, ii.According to the prescriber, the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra, iii.Patient meets ONE of the following (1, 2, 3 or 4): 1.Patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated in this patient (Note: Examples of corticosteroids are prednisone and methylprednisolone), 2.Patient has tried one conventional systemic therapy for Crohn’s disease (Note: Examples of conventional systemic therapy for Crohn’s disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic therapy for Crohn’s disease, 3.Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, 4.Patient had ileocolonic resection (to reduce the chance of Crohn’s disease recurrence, iv.The medication is prescribed by or in consultation with a gastroenterologist. b.Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): i.Patient has been established on therapy for at least 6 months, ii.Patient meets at least one of the following (1 or 2): 1.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested product). Note: Examples Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids. 2.Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement

in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool. 2.Ulcerative Colitis. Approve for the duration noted if the patient meets one of the following (a or b): a.Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv) i.Patient is 18 years of age or older, ii.According to the prescriber, the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra, iii.Patient meets one of the following (1 or 2): 1.Patient had a trial of one systemic agent or was intolerant to one of these agents for ulcerative colitis. Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. 2. Patient meets BOTH of the following (a and b): a.Patient has pouchitis, b. Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa (mesalamine enema). Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema (Cortenema, generics), iv.The medication is prescribed by or in consultation with a gastroenterologist.

b. Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months. ii.Patient meets at least one of the following (1 or 2): 1.When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product). Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids. 2.Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.