MEDICATION(S)
ORILISSA

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
ORILISSA / ELAGOLIX

Drug Class: LHRH (GnRH) Antagonists

FDA-approved uses: Management of moderate to severe pain associated with endometriosis

Available dosage forms: 150mg tablet, 200mg tablet

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Confirmed diagnosis of moderate to severe endometriosis
?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: Every 6 months, for up to 24 months maximum (200mg twice daily for up to 6 months maximum).
?Prescriber Specialty: Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist,

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
•Patient has current symptoms of moderate to severe pain (not mild)
?90-day trial and failure of the following therapies:
?Non-steroidal anti-inflammatory drugs (NSAIDs), AND
?Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device), AND
?Gonadotropin-releasing hormone (GnRH) agonist [i.e., nafarelin (Synarel), goserelin (Zoladex)], AND
•Pregnancy is excluded prior to treatment, AND
•Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy, AND
•Patient does not have osteoporosis, AND
•Patient does not have severe hepatic impairment (Child Pugh C)
•200mg twice daily is limited dyspareunia diagnosis only
?Age: ? 18 years old

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
•Decrease in pain, or less analgesic medication use
•Attestation that they are being monitored as clinically appropriate (pregnancy tests for women of childbearing age, liver function test, bone mineral density in women with risk factors for bone loss or osteoporosis)

Updated 7/1/20

MEDICATION(S)
ACITRETIN

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
Covered Uses: Severe Psoriasis

Must be prescribed by a Dermatologist

Exclusion Criteria

•Soriatane must not be used by females who are pregnant, or who intend to become pregnant during therapy or at any time for at least 3 years following discontinuation of therapy.
•Soriatane is contraindicated in patients with impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values.
•Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Coverage Duration:

Initial 3-months

Continuation 1-year

Other Criteria:

Initial

1. Documentation of both:
   a. 90 day trial of methotrexate
   b. 90 days trial of high dose topical steroids (betamethasone aug., clobetasol, halobetasol)

Continuation

1. All of the initial criteria.
2. Documentation of a positive response to therapy.
1. Claims documentation supporting compliance with therapy.

Effective 6/1/16

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

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
ACTEMRA-SQ/ TOCILIZUMAB-SQ

Drug Class: Interleukin-6 (IL-6) Receptor Antagonist

FDA-approved uses:
?Rheumatoid arthritis (RA)
?Giant Cell Arteritis (GCA)
?Polyarticular Juvenile Idiopathic Arthritis (PJIA)
?Systemic Juvenile Idiopathic Arthritis (SJIA)

Available dosage forms: Subcutaneous injection: 162mg/0.9ml single-dose prefilled syringe, or single-dose prefilled autoinjector

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approved indications detailed above

?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: 1 year
?Prescriber Specialty: Therapy is prescribed by or in consultation with a rheumatologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

oDocumentation of a negative TB test in the past 12 months
oDocumentation that member has been screened for viral hepatitis (Hep B) prior to starting therapy

oRheumatoid Arthritis (RA): (age 18 years or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate OR
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. Patients less than 100kg weight: 162mg every other week, followed by an increase to every week based on clinical response. Patients at or above 100kg weight: 162mg every week, 4 syringes/28 days

oGiant Cell Arteritis (GCA): (age 18 or older) documentation in the patient's medical record confirming diagnosis
oQuantity: Based on FDA dosing. 162mg every week in combination with tapering course of glucocorticoids, 4 syringes/28 days

oPolyarticular Juvenile Idiopathic Arthritis (PJIA): (age 2 years or older)
?Trial and failure of methotrexate for at least 4 to 6 weeks or contraindication/intolerance to methotrexate OR
?Patient has tried and failed at least one other non-biologic DMARD for 3 months OR
?Provider states that there has been rapid disease progression
oQuantity: Based on FDA dosing. Patients less than 30kg weight: 162mg every three weeks, 1 syringe/21 days. Patients at or above 30kg weight: 162mg every two weeks, 2 syringes/28 days
oSystemic Juvenile Idiopathic Arthritis (SJIA): (age 2 years or older)
oQuantity: Based on FDA dosing. Patients less than 30kg weight: 162mg every two weeks. Patients at or above 30kg weight: 162mg every week, 4 syringes/28 days
?Route of Administration: Subcutaneous injection
?Place of Service: Self-administered

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oThe patient has experienced symptomatic improvement or maintained stable clinical status.
oMember continues to have yearly negative Tb test

Contraindications/Exclusions/Discontinuation:
oTherapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
oPatient receiving additional biologic DMARD therapy.

Other special considerations:
oAdditional information may be required on a case-by-case basis to allow for adequate review. Aminosalicylates, corticosteroids, methotrexate, nonsteroidal anti-inflammatory drugs, analgesics, immunomodulatory agents (e.g., 6-mercaptopurine, azathioprine), and/or other non-biologic DMARDs may be continued during treatment with tocilizumab.

Updated 4/1/20

MEDICATION(S)
ADCIRCA, TADALAFIL 20 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
N/A

OTHER CRITERIA
Clinical Criteria

PULMONARY ARTERIAL HYPERTENSION
- ADCIRCA® / TADALAFIL/ ALYQ
- ADEMPAS® / RIOCIGUAT
- LETAIRIS® / AMBRISENTAN
- REVATIO® / SILDENAFIL
- TRACLEER® / BOSENTAN

Drug Class: Pulmonary Antihypertensive Agents

FDA-approved uses:
- Adcirca: Pulmonary Arterial Hypertension (PAH), WHO Group 1
- Letairis - Pulmonary Hypertension, with WHO Group 1
- Tracleer - Pulmonary Hypertension, with WHO Group 1

Adempas:
o Chronic Thromboembolic Pulmonary Hypertension
o Pulmonary Arterial Hypertension
Sildenafil: Pulmonary Hypertension

Available dosage forms:
*Adcirca: 20 mg tablet
*Adempas: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg,
*Letairis: 5 mg, 10 mg tablet
Revatio: 10 mg/ml Oral Suspension, 10 mg/12.5ml IV solution
*Sildenafil: 20 mg tablet
*Tracleer: 32mg tablet for oral suspension, 62.5 mg, 125 mg tablet
Viagra: 25 mg, 50 mg, 100 mg Tablet
*Covered on the Managed Care Common Formulary

Adcirca is covered for members who meet the following criteria: Drug Class: Pulmonary Antihypertensive Agents - Selective c-GMP PDE Type 5 Inhibitor Coverage Criteria/Limitations for initial authorization:
Diagnoses: Pulmonary Arterial Hypertension (PAH), WHO Group 1 which is symptomatic
Duration of approval:
o Initial Authorization: 1 year
o Continuation of therapy: 1 year
Prescriber Specialty: Pulmonologist or Cardiologist

Adcirca: continued
Documentation Requirements- (e.g. Labs, Medical Record, Special Studies):
(All three bullets must be met)
o PAH defined as WHO Group 1 of pulmonary hypertension
o Diagnosis id confirmed using a right heart catheterization test:
Pretreatment Right heart catheterization results:
MPAP greater than 25mmHg
PCWP less than 15 mmHg
PVR greater than 3 Wood units
o Member has NYHA functional Class II or III symptoms
Quantity: 40 mg taken once daily, dividing the dose over the course of the day is not

recommended.

Age: 18 or older, safety has not been proven in children.

Route of Administration: Oral

Place of Service: Home

Criteria for continuation of therapy:

Documentation of the following is required:

o All initial authorization criteria must be met.

Contraindications/Exclusions/Discontinuation:

- Contraindicated in individuals with known hypersensitivity to tadalafil.
- Concomitant use of organic nitrated or GC stimulators
- Use cautiously with mild to moderate renal insufficiency:

o Mild to moderate renal insufficiency (Cr Clearance 31-80ml/min): Initiate therapy with 20 mg daily, increase to 40 mg once daily based on individual tolerability.

o Severe renal insufficiency (Cr Clearance 30ml/minor less): Avoid use

o End-stage renal disease requiring hemodialysis: Avoid use

- Hepatic function Impairment:

o Mild or moderate hepatic impairment (Child-Pugh class A or B): Use with caution. Consider a starting dosage of 20 mg per day.

o Severe hepatic cirrhosis (Child-Pugh class C): Avoid Use

- Use cautiously with ritonavir

oInitiation of tadalafil in patients currently receiving ritonavir for at least 1 week: Initiate tadalafil at 20 mg once daily, increase to 40 mg once daily based on individual tolerability.

o Initiation of ritonavir in patients currently receiving tadalafil: Discontinue tadalafil at least 24 hours prior to the initiation of ritonavir. After at least 1 week of ritonavir, resume tadalafil at 20 mg once daily, increase to 40 mg once daily based on individual tolerability.

- Do not use if taking rifampin or ketoconazole

•If sudden loss of vision in one or both eyes or sudden decrease of hearing and or dizziness, patient must seek immediate medical attention.

- Prolonged erectile dysfunction, seek medical attention.

Adcirca: continued

Other special considerations:

•Tadalafil has been used off label to Raynaud's phenomenon. It may be used as monotherapy or as adjunctive therapy to vasodilator therapy (e.g., calcium channel blockers, angiotensin receptor blockade)

Effective 7/1/19

MEDICATION(S)
ADEMPAS

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
Clinical Criteria

PULMONARY ARTERIAL HYPERTENSION
- ADCIRCA® / TADALAFIL/ ALYQ
- ADEMPAS® / RIOCIGUAT
- LETAIRIS® / AMBRISENTAN
- REVATIO® / SILDENAFIL
- TRACLEER® / BOSENTAN

Drug Class: Pulmonary Antihypertensive Agents

FDA-approved uses:
- Adcirca: Pulmonary Arterial Hypertension (PAH), WHO Group 1
- Letairis - Pulmonary Hypertension, with WHO Group 1
- Tracleer - Pulmonary Hypertension, with WHO Group 1

Adempas:
o Chronic Thromboembolic Pulmonary Hypertension
o Pulmonary Arterial Hypertension
Sildenafil: Pulmonary Hypertension

Available dosage forms:
*Adcirca: 20 mg tablet
*Adempas: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg,
*Letairis: 5 mg, 10 mg tablet
Revatio: 10 mg/ml Oral Suspension, 10 mg/12.5ml IV solution
*Sildenafil: 20 mg tablet
*Tracleer: 32mg tablet for oral suspension, 62.5 mg, 125 mg tablet
Viagra: 25 mg, 50 mg, 100 mg Tablet
*Covered on the Managed Care Common Formulary

Adempas is covered for members who meet the following criteria: Drug Class: Pulmonary Antihypertensive Agents-Soluble Guanylate Cyclase Stimulator Coverage Criteria/Limitations for initial authorization:
Diagnoses:
o Chronic thromboembolic pulmonary hypertension
o Pulmonary arterial hypertension
Duration of approval:
o Initial Authorization: 1 year
o Continuation of therapy: 1 year
Prescriber Specialty: Pulmonologist or cardiologist

For Chronic Thromboembolic Pulmonary Hypertension (CTEPH):
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Member has CTEPH defined as WHO Group 4 of pulmonary hypertension
o Member has one of the below:
Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA):
Documented date of pulmonary endarterectomy (PEA) for CTEPH only)
OR
Inoperable CTEPH with the diagnosis confirmed by both of the following (I and II):
• Computed tomography (CT)/Magnetic resonance imaging (MRI) angiography or pulmonary angiography
•Pretreatment right heart catheterization with all the of the following results:

o MPAP greater than 25mmHg
o PCWP less than 15 mmHg
o PVR greater than 3 Wood units

For Pulmonary Arterial Hypertension (PAH)
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Member has PAH defined as WHO Group 1 of pulmonary hypertension
o PAH confirmed by right heart catheterization with the following pretreatment results:
- MPAP greater than 25mmHg
- PCWP less than 15 mmHg
- PVR greater than 3 Wood units

oMember has NYHA functional Class II or III symptoms prior to initiation of Adempas therapy.

Adempas: continued
Quantity: 2.5 mg three times daily, maximum. Initial dosage is 1mg TID. Or 0.5mg TID for individuals unable to tolerate the hypotensive effects. Titration may increase by 0.5 mg TID if systolic blood pressure remains greater that 95 mmHG and the patient has no signs or symptoms of hypotension. Dose increase should be no sooner than 2 weeks apart. May decrease the dose by 0.5 mg three times daily if the hypotensive effects are not tolerated
Age: 18 or older, pediatric safety and effectiveness have not been established
Route of Administration: Oral
Place of Service: Outpatient/home

Criteria for continuation of therapy:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oAll members requesting continuation of therapy must meet all initial authorization criteria.

Contraindications/Exclusions/Discontinuation:
•Boxed Warning: Embryo-fetal toxicity. All female patients obtain Riociguat through a restricted program called the Adempas risk evaluation and mitigation strategy (REMS) program. Obtain pregnancy tests in female patients prior to initiation and monthly during treatment. Category X
- Co-administration with nitrates or nitric oxide donors (e.g., amyl nitrite) in any form

•Co-administration with phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (e.g., sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (e.g., dipyridamole or theophylline)
•Concomitant therapy: Strong cytochrome P450 and P-glycoprotein/breast cancer resistance protein inhibitors (e.g. azole antifungals [such as ketoconazole, itraconazole], or protease inhibitors. [e.g. ritonavir])
- Renal function impairment: No dosage adjustment provided in manufacturer’s labeling.

- Hepatic function impairment: (Child-Pugh A, B, and C) No dosage adjustment provided in the manufacturer's labeling

Other special considerations:

- Smokers:

oConsider titrating to greater than 2.5 mg three times daily, if tolerated. A decreased dose may be necessary in patients who stop smoking during therapy.

REMS program: Call 1-855-423-3672 or visit http://www.AdempasREMS.com for more information.

•Hypotension: Reduces blood pressure. Use with caution in patients at increased risk for symptomatic hypotension or ischemia (eg, patients with hypovolemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction) or concurrent use of antihypertensives or strong CYP-450 and P-glycoprotein/breast cancer resistance protein inhibitors. Consider initiating at a lower dose for patients at risk of hypotension and/or dose reduction if hypotension develops.

Adempas: continued

Other special considerations: continued

- Bleeding: Serious bleeding has been observed.

•Pulmonary veno-occlusive disease: Use is not recommended in patients with pulmonary veno- occlusive disease. Discontinue in any patient with pulmonary edema suggestive of pulmonary veno-occlusive disease.

- CNS effects: Patients must be cautioned about performing tasks that require mental alertness (e.g., operating machinery or driving).

•Hazardous agent: Use appropriate precautions for handling and disposal (meets NIOSH 2014 criteria).

Effective 7/1/19

MEDICATION(S)
AMITIZA

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
AMITIZA® / LUBIPROSTONE ORAL

Drug Class:
Amitiza (lubiprostone): Chloride Channel Activator, GI Agent-miscellaneous

FDA-approved uses:
Amitiza
•Chronic idiopathic constipation in adults (CIC)
•Irritable bowel syndrome with constipation in women ? 18 years of age (IBS-C)
•Opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation

Available dosage forms:
Amitiza (lubiprostone): 8mcg capsule/24mcg capsule

Coverage Criteria/Limitations for initial authorization:

?Diagnoses: FDA Approved Indications as listed above
?Duration of approval:
oInitial authorization: 3 months
oContinuation of Therapy: 6 months
?Prescriber Specialty: Consultation or visit with gastroenterologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies): MUST MEET ALL
oPatient must be ? 18 years old
oPatient must have diagnosis of:
?Chronic idiopathic constipation OR
?Irritable bowel syndrome with constipation (*female only*) OR
?Opioid-induced constipation with chronic non-cancer pain OR
?Opioid-induced constipation with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation
oPatient must have documentation of dietary changes and/or lifestyle modifications. This would include:
?Increase fluid intake
?Increase dietary fiber intake
?Increase mobility or exercise, if possible
oPatient must have inadequate response to standard therapy
?Inadequate response is defined as less than 3 bowel movements per week during the last 3-month period
?Standard therapy is defined as routine, combined use of 2 or more of the following agents with different mechanisms of action (confirmed by chart notes and/or claim history):
•Stool Softeners
•Stimulant laxatives
•Bulk forming laxatives
•Osmotic laxative
•Lubricants

Documentation Requirements, continued

oPatient must have had a trial and failure, contraindication, or intolerance to both polyethylene glycol and lactulose for a minimum period of 14 days.
?Quantity: 2 capsules per day
?Age: 18 years to older
?Route of Administration: oral

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of successful increase in bowel movements
oConfirmation of no opioid dose escalation
Contraindications/Exclusions/Discontinuation:
Amitiza (lubiprostone):
Contraindicated in known or suspected mechanical gastrointestinal (GI) obstruction.

Not approved for use in males with irritable bowel syndrome with constipation.
Safety and effectiveness has not been establish in pediatric patients.
Efficacy lubiprostone in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

Other special considerations:
•Patient is not pregnant or breastfeeding.
•All requests must provide required documentation. No grandfathering.

MEDICATION(S)

ATOVAQUONE

COVERED USES

Documentation of:

1. Acute oral of mild to moderate PCP in adults and adolescents 13 years of age or older. OR
2. Prevention of P. jiroveci pneumonia (PCP) 1n adults and adolescents 13 years of age or older

EXCLUSION CRITERIA

•Patient is noncompliant with medical or pharmacologic therapy.

•No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

•Hypersensitivity to atovaquone or any component of the formulation.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Patient must be 13 years of age or older.

PRESCRIBER RESTRICTION

Must be prescribed by Infectious Disease prescriber.

COVERAGE DURATION

21-days

OTHER CRITERIA

Clinical Criteria

1. Documented failure, contraindication or intolerance to trimethoprim-sulfamethoxazole.

Effective 6/1/16

MEDICATION(S)
AUBAGIO

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
Drug Class: Multiple Sclerosis Agent - Pyrimidine Synthesis Inhibitor

FDA-approved uses: treatment of patients with relapsing forms of multiple sclerosis

Available dosage forms: Tablets 7 mg and 14 mg

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Indicated for the treatment of patients with relapsing forms of multiple sclerosis including:
oRelapsing-remitting multiple sclerosis [RRMS]
oSecondary-progressive multiple sclerosis [SPMS] with relapses
oClinically Isolated Syndrome [CIS]
?Duration of Approval:
oInitial Approval: 1 year
oContinuation of Therapy: 1 year
?Prescriber Specialty:

oBoard-certified Neurologist
oBoard-certified Multiple Sclerosis physician specialist
oConsult with a Board-certified neurologist or physician specialist with experience in prescribing multiple sclerosis therapy (submit consultation notes)
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oA definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria.
oExpanded Disability Status Scale {EDSS) score between O and 5 (disability severe enough to impair full daily activities) OR documentation supporting the disability within this range
oDocumented inadequate response (at least 6 months of therapy) to a non interferon, glatiramer acetate (Copaxone ®)
•NOTE: "Needle phobia" or "needle fatigue" is not considered an intolerance or
contraindication to the first-line disease-modifying therapies (DMT's)
•Inadequate response is defined as meeting TWO of the following three criteria during treatment with one of these agents: [TWO]
•Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses
•Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium- enhancing lesions, T2 hyperintense lesions and/or Tl hypointense lesions)
•Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, or ability to perform activities of daily living

Documentation Requirements: continued
oConfirmation of ONE of the following from the Prescriber AND by verifying in member's prescription profile
?Member is not currently being treated with another disease-modifying agent for MS
?Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent
oDocumentation/Reports/Labs: of the following BASELINE lab reports/exams [ALL]
?CBC
?LFT’s and Bilirubin levels
?Negative pregnancy test, if female
?Negative TB skin test
?Quantity: 30 tablets per month
?Age: Must be greater than 18 years of age
?Gender: Male or Female
?Route of Administration: Oral
?Place of Service: Outpatient

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oConfirmation of ONE of the following from the Prescriber AND by verifying in member's prescription profile

?Member is not currently being treated with another disease-modifying agent for
?MS
?Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent
oAdherence to Therapy
?Member compliance with therapy as verified by Prescriber and member's
?medication fill history (review prescription history for compliance)
•NOTE: Therapy may be discontinued due to compliance issues or poor adherence upon agreement among treating physician, member, and Medical Director.
oStabilization or positive response to Aubagio® (teriflunomide) treatment.
Demonstrated efficacy as evidenced by (including but not limited to the following):
[ALL APPLICABLE]
•Relapses: A decrease in frequency, severity, sequelae relapses from baseline
•Radiologic evidence of disease activity: Beneficial effect on MRI measures of disease severity (decrease in number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or Tl hypointense lesions)
oDisability progression: EDSS score remains less than or equal to 5.5 or stabilization/improvement routine neurological observation, mobility, or ability to perform activities of daily living
o
Criteria for continuation of therapy: Documentation Requirements, continued
oValidated patient reported outcome measure [i.e. Fatigue Impact Scale (FIS), Medical Outcome Study SF-36, etc]
•Fatigue Impact Scale {FIS} is a validated patient reported outcome measure that evaluates the effect of fatigue on the lives of people with MS. The Medical Outcome Study SF-36 is a self-administered health-reported quality of life outcome measure that is validated for several indications and patient populations

Contraindications/Exclusions/Discontinuation:
•Steady progression of disability
•Have had an allergic reaction to Aubagio® or a medicine called leflunomide
•Non-FDA approved indications
• NOTE: "Needle phobia" or "needle fatigue" is not considered a contraindication.
•Concomitant therapy of any two disease modifying agents in MS
•Patient is noncom pliant with medical or pharmacologic therapy
•No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
•If you are a man whose partner plans to become pregnant

Other special considerations:
•For use as monotherapy therapy only:

oPrescriber intends to use teriflunomide (Aubagio®) as a single agent, no other disease-modifying multiple sclerosis medications are being administered concomitantly, including but not limited to: interferon beta-la (Avonex®, Rebif®), interferon beta-lb (Betaseron®, Extavia®), glatiramer acetate (Copaxone®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), fingolimod (Gilenya™), Tecfidera® (dimethyl fumarate)

Updated 4/1/20

MEDICATION(S)
AVONEX, AVONEX PEN

COVERED USES
Documented diagnosis of relapsing forms of Multiple Sclerosis.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patient must be 18 years of age.

PRESCRIBER RESTRICTION
Prescription must be written by or in consultation with a neurologist.

COVERAGE DURATION
Initial 6-months
Continuation 12-months

OTHER CRITERIA
Renewal Requests must include: documentation from the prescribing neurologist that therapy has been effective (i.e. decreased relapses or diminished lesion documented by MRI results.

Effective 6/1/16

MDCH COMMON - CALCIPOTRIENE (DOVONEX)

MEDICATION(S)

CALCIPOTRIENE 0.005% OINTMENT, CALCIPOTRIENE 0.005% SOLUTION

COVERED USES

Documented diagnosis of Psoriasis.

EXCLUSION CRITERIA

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial 3-months

Continuation 12-months

OTHER CRITERIA

Initial

Initial

1. Documented failure of two formulary steroids, at least one must be high pr very high potency.

Continuation

1. Documentation of positive response to therapy required.

Effective 6/1/16

MEDICATION(S)
CAYSTON

COVERED USES
Updated effective 10/1/17
Documented diagnosis of Cystic Fibrosis confirmed by appropriate diagnostic or genetic testing.

EXCLUSION CRITERIA
•Less than 7 years of age
•FEV1 less than 25 percentor greater than 75 percent predicted
•Colonization with Burkholderia cepacia
•Non-FDA approved indications
•Hypersensitivity to aztreonam or any of its components
•Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patient must be 7 years of age or older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist or specialist with experience in treating CF.

COVERAGE DURATION
Initial 6-months
Continuation 6-months

OTHER CRITERIA
Initial Clinical Criteria

Initial

1. Documentation of a positive sputum culture confirming P. aeruginosa in cultures from the airway.
2. Susceptibility test results indicating that aztreoman is the only inhaled antibiotic to which the P.aeruginosa is sensitive.

OR

3. At least one of the following is applicable (documentation required)
   a. Previous use of TOBI inhalation solution and experienced a clinically significant adverse reaction or an unsatisfactory therapeutic response
   b. Contraindication, intolerance of medical condition(s) that prevent the use of TOBI inhalation soln. (pregnancy, allergy to tobramycin)
   c. Sputum culture shows resistance to tobramycins.
   d. Confirmation that the patient is not receiving treatment with other inhaled or nebulized antibiotics, anti-infective agents, including alternating treatment schedules or as part of a cyclic rotation with TOBI.

Continuation Criteria

1. All of the following are met
   a. Patient currently meets ALL intitial coverage criteria.
   b. Adherence to prescribed therapy (confirmed by prescriber and medication history)
   c. Documentation of stabilization or improvement as evaluated by a pulmonologist or specialist experienced in treating CF.

Note: Therapy may be discontinued if patient is noncompliant with medical or pharmacological therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 6/1/16
Update 10/1/16

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

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
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS
AIMOVIG® / ERENUMAB-AOOE,
AJOV® / FREMANEZUMAB-VFRM,
EMGALIT® / GALCANEZUMAB-GNLM

Drug Class: Anti-migraine Agents, CGRP Inhibitors
These agents are human monoclonal antibodies that antagonize calcitonin gene-related peptide (CGRP) receptor function.

FDA-approved uses:
Brand Name (generic name)ManufacturerIndicationFDA Approval
Aimovig®
(erenumab-aooe)AmgenPreventive treatment of migraine in adults.5/17/2018
Ajovy®
(fremananezumab-vfrm)TevaPreventive treatment of migraine in adults. 9/14/2018

Emgality®
(galcanezumab-gnlm)LillyPreventive treatment of migraine in adults.
Preventative treatment of cluster headache during cluster episodes in adults. 9/27/2018

Available products:
Brand Name (generic name)Aimovig®
(erenumab-aooe)Ajovy®
(fremananezumab-vfrm)Emgality®
(galcanezumab-gnlm)
ManufacturerAmgenTevaLilly
Strength 70 mg/mL 1mL, 140mg/ml 1ml SureClick® auto-injector225mg/1.5mL, single dose prefilled syringe120mg/mL 1mL,
autoinjector or prefilled syringe
100mg/ml 1ml, prefilled syringe
Dosing70mg or 140mg SC once monthly225mg SC monthly OR
675mg (3x225) SC every 3 months120mg SC once monthly (240mg as loading dose) for migraine prophylaxis,
300mg SC once monthly for episodic cluster headache

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-3) diagnostic criteria
?Chronic Migraine
?15 or more headache days per month for more than three months, which has the features of migraine headache on at least eight days per month
?Episodic Migraine
?4 to 14 migraine days per month for at least 3 months
?Episodic Cluster Headache (Emgality Only)
?At least 2 cluster periods lasting 7 to 365 days, separated by pain-free periods lasting at least three months
?Age: ? 18
?Route of Administration: SC
?Place of Service: Self-administered
?Duration of approval:
?Initial authorization: Six months
?Continuation of Therapy: up to 12 months
?Prescriber Specialty: Requested by or in consultation with neurologist or pain specialist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
Migraine: CGRPs will be approved based on meeting all of the following criteria.

oMedication over-use headache (MOH) is ruled out OR documentation of trial and failure of titrating down on acute migraine treatments.
oUtilization of non-pharmacologic prophylactic intervention modalities (behavior therapy, lifestyle modifications, physical therapy, and triggers) documented.
oSubmission of headache log or confirmation in progress notes of baseline headache frequency
oPatient has tried and failed ? one-month trial of any two of the following oral medications:
•Antidepressants (e.g., amitriptyline, venlafaxine)
•Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol)
•Anti-epileptics (e.g., valproate, topiramate)
•Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
Episodic cluster headache: Emgality® will be approved based on provision of:
oDocumentation of at least 2 cluster periods lasting 7 to 365 days, separated by pain-free periods lasting at least three months

?Quantity:
Brand Name
(generic name)
ManufacturerDosage FormQuantity
Aimovig®
(erenumab-aooe)

Amgen70mg/ml 1ml single-dose auto-injector
1 per 30 days
140mg/ml 1ml single-dose auto-injector
1 per 30 days
Ajovy®
(fremananezumab-vfrm)
Teva225mg/1.5mL 225mg SC monthly
OR
675mg (3x225mg) SC every 3 months
Prefilled syringe3 every 90 days
Emgality®
(galcanezumab-gnlm)

LillyMigraine Prophylaxis:
Initial dose: 240mg (two 120mg injections) SC
Usual dosage: 120mg/mL 1mL SC monthly
Auto-injector or prefilled syringeInitial dose:
2 per 30 days Continuation:1 per 30 days
Cluster Headache:

300mg (Three 100mg injections) SC every 30 days3 per 30 days
Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
CGRP renewal will be based on meeting all of the following criteria. Must provide documentation of a positive response to therapy and other requirements as noted below:
oChange from baseline in mean monthly migraine days over 4 to 6 months as evidenced by a 50% reduction from baseline, AND
oSignificant decrease in frequency, and/or intensity of headaches, AND
oDecrease in acute migraine and/or opioids medication use, AND
oDocumentation of an overall improvement in function with therapy, AND
oUtilization of non-pharmacologic prophylactic intervention modalities (behavior therapy, lifestyle modifications, physical therapy, triggers) continue to be evaluated, AND
oWomen of childbearing age continue to be monitored for pregnancy status

Contraindications/Exclusions/Discontinuation:
?Women of childbearing age have had a pregnancy test at baseline
?CGRP is NOT being used in combination with Botulinum toxin (e.g., Botox, Dysport, Myobloc, Xeomin)
?Not used in combination with another CGRP inhibitor

Other special considerations:
•Limited literature is available to support combination therapy in combination with Botox, therefore, this treatment option will only be considered on medical necessity review and when ordered or assessed by a neurologist.
•Safety and efficacy in pediatric or geriatric patients has not been sufficiently studied.
•Treatment should only be continued if clinically meaningful treatment benefit can be documented.

Updated 4/1/20

MEDICATION(S)
CIMZIA

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
CIMZIA/ CERTOLIZUMAB

Drug Class: Tumor Necrosis Factor (TNF) inhibiting agent

FDA-approved uses:
?Crohn’s Disease (CD)
?Rheumatoid Arthritis (RA)
?Psoriatic Arthritis (PsA)
?Ankylosing Spondylitis (AS)
?Non-radiographic Axial Spondyloarthritis
?Plaque Psoriasis

Available dosage forms: Subcutaneous injection: 200mg/ml solution in a single-dose prefilled syringe

Coverage Criteria/Limitations for initial authorization:
?Diagnoses:

oCrohn’s Disease (CD)
oRheumatoid Arthritis (RA)
oPsoriatic Arthritis (PsA)
oAnkylosing Spondylitis (AS)
oNon-radiographic Axial Spondyloarthritis
?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: 1 year
?Prescriber Specialty: Therapy is prescribed by or in consultation with a gastroenterologist, rheumatologist or dermatologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of a negative TB test in the last 12 months

Crohn’s Disease (CD): (age 18 years or older)
?The patient has had a previous trial, contraindication or intolerance of one or more conventional agents such as: corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
?Trial and failure of a 90-day trial infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 400mg initially and at weeks 2 and 4, #3(six 200mg syringes)/28 days. If response occurs, follow with 400mg every four weeks, #1 (two 200mg syringes)/28 days
oInitial authorization: 6 months
oContinuation of Therapy: 6 months

oRheumatoid Arthritis (RA): (age 18 years or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120 day period, or contraindication/intolerance to methotrexate AND
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 400mg initially and at weeks 2 and 4, #3(six 200mg syringes)/28 days followed by 200mg every other week #1(two 200mg syringes)/28 days, for maintenance dosing, 400mg every 4 weeks can be considered

oPsoriatic Arthritis (PsA): (age 18 or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120 day period, or

contraindication/intolerance to methotrexate AND
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 400mg initially and at weeks 2 and 4 #3(six 200mg syringes)/28 days, followed by 200mg every other week, #1(two 200mg syringes)/28 days, for maintenance dosing, 400mg every 4 weeks can be considered

oAnkylosing Spondylitis: (age 18 years or older)
?The patient has had a previous trial, contraindication, or intolerance of BOTH of the following: two different NSAIDs within the previous 60 days, AND sulfasalazine
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 400mg initially and at weeks 2 and 4, #3(six 200mg syringes)/28 days, followed by 200mg every other week or 400mg every 4 weeks, #1(2 200mg syringes)/28 days

oNon-radiographic Axial Spondyloarthritis
?The patient has had a previous trial, contraindication, or intolerance of BOTH of the following: two different NSAIDs within the previous 60 days, AND sulfasalazine
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 400mg initially and at weeks 2 and 4, #3(six 200mg syringes)/28 days, followed by 200mg every other week or 400mg every 4 weeks, #1(2 200mg syringes)/28 days
?Route of Administration: Subcutaneous injection
?Place of Service: Self-administered

Criteria for continuation of therapy: Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oThe patient has experienced symptomatic improvement or maintained stable clinical status.
oMember continues to have yearly negative Tb test

Contraindications/Exclusions/Discontinuation:
oTherapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
oPatient receiving additional biologic DMARD therapy.

oFor plaque psoriasis please refer to other Common Formulary covered products.

MEDICATION(S)

CLOBETASOL 0.05% CREAM, CLOBETASOL 0.05% OINTMENT, CLOBETASOL 0.05% SOLUTION

COVERED USES

Documented diagnosis of inflammatory or pruritic corticosteroid responsive dermatoses.

EXCLUSION CRITERIA

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Patient must be 12 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

N/A

OTHER CRITERIA

1. Documented failure of betamethasone dipropionate.

Effective 6/1/16

MEDICATION(S)
RESTASIS, RESTASIS MULTIDOSE

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
CYCLOSPORINE/RESTASIS®, RESTASIS MULTIDOSE®

Drug Class (ETC_Name): Calcineurin Inhibitor, Immunosuppressant Agent, Lymphocyte Function-Associated Antigen 1 (LFA-1) Antagonist

FDA-approved uses:
1.Keratoconjunctivitis Sicca – Increase tear production when suppressed tear production is presumed to be due to keratoconjunctivitis sicca-associated ocular inflammation (in patients not already using topical anti-inflammatory drugs or punctal plugs) 16 years of age and older.
2.Dry Eye Disease – Treatment of signs and symptoms of dry eye disease (DED)

Available dosage forms: Single-Use Ampules, Multi-Dose Vial

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approve use as detailed above
?Duration of approval:

oInitial Authorization: 3 months
oContinuation of Therapy: for up to 1 year
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of use of artificial tear drops, lubricants, preservative free lubricants, or ointments for at least 90 days without resolution of symptoms, OR physician attestation of rapid disease progression
?Quantity:
oRestasis – 60 Ampules per 30 days
oRestasis Multi-Dose – 5.5mL per 30 days
?Age: 16 years of age and older

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation that patient has experienced symptomatic improvement of diagnosis
oPatient is tolerating and adequately responding to medication

Contraindications/Exclusions/Discontinuation:
•Hypersensitivity to the medication or any component of the formulation
•No demonstrable improvement in clinical condition has occurred after initiation of therapy

Updated 7/1/20

MEDICATION(S)

DARAPRIM

COVERED USES

Documented diagnosis of:

a. Treatment for toxoplasmosis
b. Secondary prevention of toxoplasmosis in patients with HIV
c. Prevention of pneumocystis pneumonia in patients with HIV

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation by an infectious disease specialist.

COVERAGE DURATION

Toxoplasmosis 6-weeks initial, 6-months continuatio
Pneumocystis prophylaxis 3-months

OTHER CRITERIA

1. Prescribed by an infectious disease specialist.
2. Additional documentation requirements:
   a. One of the following for a Dx of Pneumocystis prophylaxis
      i. CD4 count less than 200 cells per microL
      ii. Oropharyngeal candidiasis
      iii. CD4 count percentage less than 14 percent
      iv. CD4 cell count between 200-250 cells per microL (if frequent monitoring e.g. every 3 months) of CD4 counts is not possible)

Continuation Criteria

1. Required documentation:

a. For Toxoplasmosis prophylaxis, after initial 6 weeks of induction treatment (ONE of the following):

i. Patient remains symptomatic

ii. Patient is NOT receiving antiretroviral therapy (ART)

iii. Patient has a detectable HIV viral load

? iv. Patient has maintained a CD4 count GT 200 cells per microL for less than six months

b. For Pneumocystis prophylaxis (ONE of the following):

i. CD4 count LT 200 cells per microL

ii. Oropharyngeal candidiasis

iii. CD4 count percentage LT14 percent

iv. CD4 cell count between 200 and 250 cells per microL IF frequent monitoring (eg, every three months) of CD4 cell counts is not possible

Quantity Limit:

- Toxoplasmosis (induction-dose): 90 tablets per 30 days
- Toxoplasmosis (maintenance-dose): 60 tablets per 30 days
- Pneumocystis prophylaxis: 12 tablets per 28 days

Effective 6/1/16

MEDICATION(S)
DESMOPRESSIN 0.01% SOLUTION, DESMOPRESSIN 0.01% SPRAY, DESMOPRESSIN 10 MCG/0.1 ML SPR, STIMATE

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
DESMOPRESSIN / STIMATE NASAL SPRAY

Drug Class: Antidiuretic and vasopressor hormones

FDA-approved uses:
Hemophilia A - Stimate only
von Willebrands disease type I - Stimate only
Diabetes Insipidus – Desmopressin Nasal Spray

Available dosage forms:
Desmopressin Nasal Spray – 0.1 mg/ml solution, 10 mcg/0.1 ml spray,
Stimate – 150 mcg/spray (0.1ml)

Coverage Criteria/Limitations for initial authorization

Diagnoses:

o Hemophilia

o von Willebrands disease

o Diabetes Insipidus

o

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

o Documentation of any of the following diagnoses:

Diabetes insipidus

Hemophilia

von Willebrands disease (Type 1)

Diabetes Insipidus:

•Documented inadequate response to a 3-month trial of a maximum tolerated dose or clinical contraindication of Desmopressin tablets

Route of Administration: various

Contraindications/Exclusions/Discontinuation:

•Contraindicated in individuals with known hypersensitivity to desmopressin acetate or to any of its components.

•Contraindicated in patients with moderate to severe renal impairment (defined as a creatinine clearance below 50ml/min).

• Contraindicated in patients with hyponatremia or a history of hyponatremia.

•Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

•As of 2007, the intranasal formulation is no longer FDA-approved for the treatment of primary nocturnal enuresis.

MEDICATION(S)
DICLOFENAC SODIUM 3% GEL

COVERED USES
Documented diagnosis of Actinic Keratoses

EXCLUSION CRITERIA
Contraindications/Exclusions/Discontinuation:

a. Solaraze is contraindicated in patients with a known hypersensitivity to diclofenac. Solaraze should be used with caution in patients with active GI ulceration or bleeding and severe renal or hepatic impairments.

b. In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
a. An inadequate response or intolerance to office-based treatments (liquid nitrogen cryotherapy, surgical curettage) OR have been considered and ruled out due to nature/number of lesions or limited resources to provide such treatments, AND
b. An inadequate response to a full treatment or intolerance/contraindication to a trial of 5-fluorouracil, AND
c. An inadequate response to a full treatment or intolerance/contraindication to a trial of imiquimod

Criteria for Continuation of Therapy - Documentation of positive response to therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial and continuation: 3 months

OTHER CRITERIA
Quantity Limit: 100gm

Effective 6/1/16

MEDICATION(S)
JANUMET, JANUMET XR, JENTADUETO

COVERED USES
Single Ingredient DPP-4 Inhibitor
Type 2 diabetes mellitus: Treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control

Combination DPP-4 Inhibitor
Type 2 diabetes mellitus: As an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus when treatment with combination therapy is appropriate

EXCLUSION CRITERIA
Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
Single Ingredient DPP-4 Inhibitor
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
1. Tried and failed Metformin
2. Tried and failed alogliptin (for Januvia and Tradjenta only)
3. A1c must be less than or equal to 9

Combination DPP-4 Inhibitor
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
1. Clinically demonstrated successful treatment with individual components for 60 of the most recent 120 days
2. Tried and failed alogliptin-metformin (for Janumet, Janumet XR, Jentadueto only)
3. A1c must be less than or equal to 9

AGE RESTRICTION
Age Greater than or Equal to 18 years

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial Authorization: 6 months

Continuation of Therapy: 6 months

OTHER CRITERIA

Criteria for continuation of therapy:

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

1. Patient responding to treatment
2. Patient tolerating treatment

Effective 6/1/2016

Update 7/1/2017

MEDICATION(S)
JANUVIA, TRADJENTA

COVERED USES
Documented diagnosis of Type 2 Diabetes Mellitus

EXCLUSION CRITERIA
Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patient must be 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6-months

OTHER CRITERIA
Initial

1. Documented trial and failure of Metformin.
2. Documented trial and failure of Alogliptin (eff. 4/1/17)
3. Documented A1C less than or equal to 9.

Continuation of Therapy:
1. Documented response to therapy.

Effective 6/1/16

MEDICATION(S)
DRONABINOL

COVERED USES
Documented diagnosis of:
a. chemotherapy-induced nausea and vomiting
b. appetite stimulation in AIDS patients

EXCLUSION CRITERIA
•Hypersensitivity to dronabinol, cannabinoids, sesame oil, or any component of the formulation
•In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist.

COVERAGE DURATION
Initial: duration of chemotherapy treatment.
Continuation: determined based on the plan of care

OTHER CRITERIA
1. Documentation that the patient is receiving chemotherapy and meets the following:
   a. Intolerant or refractory to first line agents such as ondansetron.
   b. First dose must be under close supervision during the initial use and during dose adjustments due to its potential for altered mental
   status.
2. Not to exceed 30 days per fill

MEDICATION(S)
ELIQUIS

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
Clinical Criteria

Initial

1. Patient must be 18 years of age or older.
2. Patient was stated on Eliquis therapy in the hospital and was discharged while on therapy. OR
3. Patient has A-fib and Eliquis therapy is being used for stroke prevention (For 5mg oral BID dosing) AND
   a. Documented diagnosis of non-valvular atrial fibrillation.
   b. Documented trial, failure or intolerance to warfarin therapy.
   c. Must have moderate to high risk of stroke as determined by the following:
      i. Either history or stroke, TIA or systemic embolism OR
      ii. Two of the following:
         1. Age greater than or equal to 75 years
         2. Arterial hypertension requiring treatment
         3. Diabetes Mellitus
         4. Heart Failure greater than or equal to NYHA Class 2

5. Left Ventricular Ejection Fraction less than or equal to 40%

In addition to the above criteria, if the member has at least 2 of the following characteristics the recommended dose is 2.5 mg orally BID

a. Age greater than or equal to 80 years old
b. Body weight less than or equal to 60 kg
c. Serum Creatinine greater than or equal to 1.5 mg/dL

OR

4. Treatment of DVT or PE
   a. Documented DVT or PE
   b. Trial, failure or intolerance to warfarin therapy.

OR

5. DVT prophylaxis
   a. Documentation that the patient has undergone elective total hip or knee arthoplasty.

Quantity-Duration

Non-valvular Afib, DVT or PE - as determined by prescriber
DVT Prophylaxis
- hip replacement surgery - 35 days recommended
- knee replacement surgery - 12 days recommended

Treatment of DVT and PE to be determined by prescriber

Quantity for Starter Pack: 1 Starter Pack per 90 days

Continuation Criteria (Documentation requirements)

Member is tolerating and responding to medication and there continues to be a medical need for the medication

CrCL is being monitored

Contraindication/Exclusions/Discontinuation

•Box Warning:

oDiscontinuing Eliquis can lead to higher risk of stroke. If discontinuation is warranted for reasons other than pathological bleeding, consider use of another anticoagulation agent.

oAdministration of Eliquis while also receiving neuraxial anesthesia or undergoing spinal puncture can lead to epidural or spinal hematomas, which can result in long term or permanent paralysis.

•Eliquis should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. Eliquis should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled. Restart after the procedure once adequate

hemostasis has been established.

•Per the Beers Criteria, Geriatric patients greater than or equal to 65 years old should avoid Eliquis if CrCl less than 25 ml/min

•The safety and efficacy of Eliquis has not been studied in patients with prosthetic heart valves. Therefore, Eliquis is not recommended in these patients.

•Severe hepatic impairment (child Pugh Class C)

•Eliquis is not recommended in pregnancy

•Eliquis is not recommended if nursing – discontinue drug or discontinue nursing

•Avoid use with P-gp and strong CYP3A4 inhibitors/inducers in patients who require the 2.5mg BID dose.

•Active pathological bleeding

•Hypersensitivity reaction to Eliquis

•Patient is noncompliant with medical or pharmacologic therapy

•No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 7/1/17, updated 1/1/2019

MEDICATION(S)
ELMIRON

COVERED USES
Indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

EXCLUSION CRITERIA
Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REQUIRED MEDICAL INFORMATION
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Diagnosis of interstitial cystitis confirmed

Criteria for continuation of therapy
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
• If pain has not improved after 3 months of therapy and if limiting adverse events have not occurred, pentosan may be continued for an additional 3 months. The clinical benefit of treatment beyond 6 months for patients whose pain has not improved is not known.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Duration of therapy:
o Initial Approval: 3 months
o Continuation of Therapy: 3 months

OTHER CRITERIA
Effective 6/1/16
Last Updated 10/1/2018

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

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
ENBREL® / ETANERCEPT

Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).

*Please refer to the continuation criteria section for members that are already established on Enbrel prior to the 07/01/2019 prior authorization changes.

Drug Class: Anti-inflammatory Tumor Necrosis Factor Inhibiting agents, Non-Selective
FDA-approved uses:
?Ankylosing spondylitis
?Plaque psoriasis
?Polyarticular juvenile idiopathic arthritis (JIA)
?Psoriatic arthritis
?Rheumatoid arthritis

Available dosage forms: 25 mg subcutaneous kit, 25mg/0.5ml and 50mg/ml subcutaneous solution, prefilled syringes, Enbrel 50mg/ml Sure Click, a subcutaneous solution auto-injector

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approved indications detailed above
?Duration of Approval:
For Plaque Psoriasis:
oInitial Authorization: 6 months
?Starting Dose: 50mg twice weekly: 3 months
?Maintenance Dose: 50mg once weekly: 3 months
oContinuation of Therapy: 1 year

For all other diagnoses:
oInitial Authorization: 6 months
?Enbrel 50mg once weekly:
oContinuation of Therapy: 1 year
?Prescriber Specialty: Rheumatologist, dermatologist, or provider in consultation with specialist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of a current negative TB test
oAdditional criteria based on the diagnosis (unless contraindications are documented):
?Ankylosing Spondylitis (Enbrel):
•Trial and failure of 2 different NSAIDs within the last 60 days
•Trial and failure of sulfasalazine
•Trial and failure of a 90-day trial of Infliximab (medical benefit) unless there are transportation or other access issues documented
•Trial and failure of a 90-day trial of Cimzia
?Plaque Psoriasis (Enbrel):
•Clinically diagnosed with moderate to severe chronic plaque psoriasis
•Involvement of greater than 10% of body surface area (unless hands, feet, head, neck, or genitalia are involved)
•Trial and failure of at least one topical agent
•Trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate
•Trial and failure of at least one additional systemic treatment (acitretin, cyclosporine) or contraindication/intolerance to systemic treatment
•Trial and failure of UVB or PUVA therapy or contraindication to therapy
•Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
•Trial and failure of a 90-day trial of Otezla

•Dose for plaque psoriasis should be reduced to 50mg per week after the initial 3-month approval
?Psoriatic Arthritis:
•Trial and failure of methotrexate for at least 3 months
•Trial and failure of one additional non-biologic DMARD (sulfasalazine, hydroxychloroquine or leflunomide)
•Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
•Trial and failure of a 90-day trial of one of the following: Orencia, Cimzia, or Xeljanz
?Rheumatoid Arthritis (Adults)
•Trial and failure of methotrexate or at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
•Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
•Trial and failure of a 90-day trial of one of the following: Actemra, Xeljanz, Cimzia, or Orencia.

?JIA (age ? 2 years for Enbrel):
•Trial and failure of methotrexate for at least 4 to 6 weeks or contraindication/intolerance to methotrexate AND
•Trial and failure of a 90-day trial of SQ Actemra or SQ Orencia, unless provider states that there has been rapid disease progression during trial

?Age: 18 years of age or older, except for JIA (?2 years of age), and plaque psoriasis (?4 years of age)
?Route of Administration: Subcutaneous

Criteria for continuation of therapy:
?Documentation Requirements:
oPlans must continue to cover Enbrel, etanercept, or available biosimilar for established patients when continuation criteria is met.
oDocumentation by respective specialty that the patient continues to have a beneficial response to therapy.

Contraindications/Exclusions/Discontinuation:
•Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 6/1/16
Update 1/1/17, 7/1/19, 10/1/19, 1/1/20, 4/1/20

MEDICATION(S)
ENDARI

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
ENDARI / L-GLUTAMINE

Drug Class: Sickle Cell Anemia Agents (N1H)

FDA-approved uses:
Endari is an amino acid indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

Available dosage forms:
Oral Powder: 5 grams of L-glutamine powder per paper-foil-plastic laminate packet.

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Sickle Cell Disease
?Duration of approval:
oInitial authorization: 6 month duration upon approval
?Documented diagnosis of sickle cell disease AND

?Request is for an FDA approved dose AND
?Patient has had 2 or more crises in the last 12 months AND
?Patient has had an inadequate response to an adherent, maximally tolerated dose of hydroxyurea for the past 180 days OR
? Justification provided regarding intolerance or contraindication to the use of hydroxyurea
oContinuation of Therapy: 6 month approval
?Member has had a reduction in the number of sickle cell crises AND
?Member continues on an FDA approved dose.
?Prescriber Specialty: Hematology
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMedical Record indicating
?Sickle Cell Disease
?Number of crises reported in the past 12 months
?History of Hydroxyurea use and documentation regarding 80% adherence or intolerance/contraindication to Hydroxyurea
?Quantity: Maximum of 180 packets/30 days
?Age: 5 years of age and older
?Route of Administration: Oral
?Place of Service: Outpatient pharmacy

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMedical record justifying continuation through positive outcomes in the past 6.
Contraindications/Exclusions/Discontinuation:
•No contraindications to report at this time.
•Warnings/Precautions: Use with caution in patients with hepatic and/or renal impairment. No specific dosage adjustments are documented.
•Safety has not been established in patients younger than 5 years old.
•No clinical benefit observed as measured by a reduction in the number of sickle cell crises or maintained improvement when compared history before initiation of Endari.

Updated 1/1/20

MDCH COMMON - ENOXAPARIN (LOVENOX)

MEDICATION(S)

ENOXAPARIN 100 MG/ML SYRINGE, ENOXAPARIN 120 MG/0.8 ML SYR, ENOXAPARIN 150 MG/ML SYRINGE, ENOXAPARIN 30 MG/0.3 ML SYR, ENOXAPARIN 40 MG/0.4 ML SYR, ENOXAPARIN 60 MG/0.6 ML SYR, ENOXAPARIN 80 MG/0.8 ML SYR

COVERED USES

Documented diagnosis of a DVT or PE

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

See other criteria for duration of coverage

OTHER CRITERIA

Note: Prior Authorization on necessary for Day Supply exceeding 10 days per fill.

Diagnosis

a. DVT or PE prophylaxis
    i. hip fracture or replacement surgery - up to 5 weeks allowed
    ii. all other indications - up to 10 days without Prior Authorization
    iii. Treatment or bridge therapy - up to 10 days without Prior Authorization
b. Thrombosis prophylaxis cancer patients - 3-6 months or as requested

Effective 6/1/16

MEDICATION(S)
ARANELLE, ARANESP, EPOGEN, PROCRIT, RETACRIT

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
ERYTHROPOIESIS STIMULATING AGENTS
ARANESP® / DARBEPOETIN ALFA
EPOGEN® / EPOETIN ALFA
RETACRIT® / EPOETIN ALFA-EPBX
PROCRIT® / EPOETIN ALFA

Drug Class: Erythropoietins (Aranesp), Erythropoiesis-Stimulating Agents (Epogen & Procrit)
FDA-approved uses:
?Aranesp: Anemia due to chronic kidney disease or chemotherapy in patients with cancer
?Epogen & Procrit:
oAnemia due to the following:
?Chronic kidney disease
?Chemotherapy in patients with cancer
?Anemia caused by zidovudine in HIV-infected patients
?Reduction of allogeneic RBC transfusion in patients undergoing elective, non-cardiac, non-vascular

surgery
Available dosage forms:
?Aranesp:
oVials of 25 mcg/ml, 40 mcg/ml, 60 mcg/ml, 100 mcg/ml, 150 mcg/0.75ml, 200 mcg/ml, 300 mcg/ml
oSyringes of 10 mcg/0.4 ml, 25 mcg/0.42 ml, 40 mcg/0.4 ml, 60 mcg/0.3 ml,
100 mcg/0.5 ml, 150 mcg/0.3 ml, 200 mcg/0.4 ml, 300 mcg/0.6 ml, 500 mcg/1 ml
?Epogen:
oVials of 2,000 units/ml, 3,000 units/ml, 4,000 units/ml, 10,000 units/ml, 20,000 units/ml
?Procrit:
oVials of 2,000 units/ml, 3,000 units/ml, 4,000 units/ml, 10,000 units/ml, 20,000 units/ml, 40,000 units/ml
?Retacrit:
oVials of 2,000 units/ml, 3,000 units/ml, 4,000 units/ml, 10,000 units/ml, 40,000 units/ml

Aranesp
Coverage Criteria/Limitations for initial authorization:
Diagnosis: Anemia Due to CKD
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oHemoglobin less than 10 g/dL within the last 2 weeks
oIron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin greater than 100, transferrin saturation greater than 20%)
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.

Aranesp, continued
Diagnosis: Anemia Due to Chemotherapy in Patients with Cancer
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient is currently receiving chemotherapy
oPatient meets all of the following:
?Hemoglobin less than 10 g/dL within the 2 weeks prior to starting therapy
?Documentation to support anemia is due to concomitant myelosuppressive chemotherapy
?Diagnosis of non-myeloid malignancy (e.g., solid tumor)
?Patient has a minimum of 2 additional months of planned chemotherapy upon initiation of therapy
oAdditional information may be required on a case-by-case basis to allow for adequate review.
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.
?Duration of approval:
oInitial Authorization: 3 months
oContinuation of therapy: 3 months

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oApproved diagnosis continues

oHb less than 11 g/dL within the last 2 weeks
oFollow up iron studies showing member has adequate iron to support erythropoiesis
Contraindications/Exclusions/Discontinuation:
•Anemia in patients with cancer who are not receiving chemotherapy
•Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers
•Anemia associated with radiotherapy (as monotherapy) in cancer
•To enhance athletic performance
•Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e. acute blood loss)

Epogen, Retacrit & Procrit
Coverage Criteria/Limitations for initial authorization:
Diagnosis: Anemia Due to CKD
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oHemoglobin less than 10 g/dL within the last 2 weeks
oIron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin greater than 100, transferrin saturation greater than 20%)
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.

Epogen, Retacrit & Procrit, continued
Diagnosis: Anemia Due to Chemotherapy in Patients with Cancer
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient is currently receiving chemotherapy
oPatient meets all of the following:
?Hemoglobin less than 10 g/dL within the 2 weeks prior to starting therapy
?Documentation to support anemia is due to concomitant myelosuppressive chemotherapy
?Diagnosis of non-myeloid malignancy (e.g., solid tumor)
?Patient has a minimum of 2 additional months of planned chemotherapy upon initiation of therapy
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.

Diagnosis: Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Non-cardiac, Non-vascular Surgery
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient will be undergoing elective, non-cardiac, non-vascular surgery
oHemoglobin level greater than 10 and less than 13 g/dL within 30 days prior to the planned surgery date
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.

Diagnosis: Anemia due to Zidovudine in HIV-infected Patients
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient is receiving treatment with zidovudine at a dose less than 4200 mg/week
oPatient meets both of the following:
?Endogenous erythropoietin levels less than 500 mUnits/mL
?Hemoglobin less than 10 g/dL within the last two weeks
oAdditional information may be required on a case-by-case basis to allow for adequate review
oDocumented trial and failure or inability to utilize therapy with preferred Retacrit.

?Duration of approval:
oInitial Authorization: 3 months
?Exception- Reduction of perioperative RBC infusion: Up to 21 days of therapy per surgery
oContinuation of therapy: 3 months
Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oApproved diagnosis continues
oHb less than 11 g/dL within the last 2 weeks
oFollow up iron studies showing member has adequate iron to support erythropoiesis

Epogen, Retacrit & Procrit, continued
Contraindications/Exclusions/Discontinuation:
•Anemia in patients with cancer who are not receiving chemotherapy
•Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers
•Anemia associated with radiotherapy (as monotherapy) in cancer
•To enhance athletic performance
•Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e. acute blood loss)
•Uncontrolled hypertension, pure red cell aplasia (PRCA) that begins after treatment with epoetin alfa or other erythropoietin protein drugs, serious allergic reactions to epoetin alfa
•Increased mortality, myocardial infarction, stroke, and thromboembolism

MDCH COMMON - FENTANYL TRANSDERMAL

MEDICATION(S)

FENTANYL 100 MCG/HR PATCH, FENTANYL 12 MCG/HR PATCH, FENTANYL 50 MCG/HR PATCH, FENTANYL 75 MCG/HR PATCH

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial

1. Documentation of a trial and failure of formulary long acting opioid analgesics (30-day trial of at least 200mg per day of morphine sulfate
   ER or equivalent
2. Documentation of chronic pain condition must be present and documented.
3. Documentation that medication is intended for regular, round the clock use (not PRN)
4. Documentation that based upon the patient's narcotic history, the use of this medication is deemed safe.

Continuation

1. All of the initial clinical criteria remains the same.
2. Documentation that patient is responsive to treatment.

AGE RESTRICTION

Patient must be 2 years of age or older

PRESCRIBER RESTRICTION

Prescription must be written by a board certified pain management physician

COVERAGE DURATION

3-months for initial authorization.

1 year for continuation of therapy.

OTHER CRITERIA

Effective 6/1/16

MEDICATION(S)
FLUOROURACIL 0.5% CREAM, FLUOROURACIL 5% CREAM

COVERED USES
Documented Diagnosis of:
Actinic keratosis OR
Superficial basal cell carcinoma

EXCLUSION CRITERIA
Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

An inadequate response or intolerance to office-based treatments (liquid nitrogen cryotherapy, surgical curettage) OR have been considered and ruled out due to nature/number of lesions or limited resources to provide such treatments,
AND
An inadequate response to a full treatment or intolerance/contraindication to a trial of imiquimod

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial Authorization: 3 months
Continuation of Therapy: 3 months

OTHER CRITERIA
Quantity Limits:
0.5% cream: 30 grams
5% cream: 40 grams

Criteria for continuation of therapy:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

There is a recurrence of active lesions and treatment with another course of therapy is required
Effective 4/1/2018

MEDICATION(S)
FORTEO

COVERED USES
Documented diagnosis (Dx) of one of the following:
a. Glucocorticoid-induced osteoporosis
b. Osteoporosis in men
c. Osteoporosis in postmenopausal women
d. Treatment of hypoparathyroidism (off-label)

EXCLUSION CRITERIA
Contraindications/Exclusions/Discontinuation:
1. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
2. Box Warning: Potential risk of osteosarcoma: In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20 mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe teriparatide only to patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide should not be prescribed for patients who are at increased baseline risk for osteosarcoma (e.g., those with Paget disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with prior external beam or implant radiation therapy involving the skeleton).

REQUIRED MEDICAL INFORMATION
Initial
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
i. Dx of osteoporosis in postmenopausal women and men
1. T-score less than or equal to -3 with a previous vertebral fracture AND
2. Documented failure of oral bisphosphonates (or documented intolerance or contraindication to the medication) despite compliance for at least 2 years, AND
3. Documented failure or intolerance to a compliant (at least 12 months) regimen of zoledronic acid (generic Reclast)
4. FOR DX of OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN ONLY: Documented failure of Tymlos (requires a prior authorization)

NOTE: Failure is defined by new fracture while on treatment or reduction in BMD per recent DEXA scan. If

member has a new fracture while on a bisphosphonate, we will only require a clinical trial of one bisphosphonate (oral or IV)

ii. Dx of corticosteroid treatment induced osteoporisis

1. T-score less than or equal to -1 AND
2. Documented failure of an oral bisphosphonate (or documented intolerance or contraindication to the medication) despite compliance for at least 2 years, AND
3. Documented failure or intolerance to a compliant (at least 12 months) regimen of zoledronic acid (generic Reclast)

NOTE: Failure is defined by new fracture while on treatment or reduction in BMD per recent DEXA scan. If member has a new fracture while on a bisphosphonate, we will only require a clinical trial of one bisphosphonate (oral or IV)

iii. Dx of hypoparathyroidism

1. Parathyroid Hormone level (PTH) checked to rule out hyperparathyroidism
2. Trial and failure/intolerance to a compliant (at least 2 months) regimen of formulary medications used to treat hypoparathyroidism (Calcijex/ Rocaltrol, ergocalciferol)

AGE RESTRICTION

Patient must be 18 years of age or older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial:

Osteoporosis-1 year (need baseline DEXA T-Score)

Hypoparathyroidism-3 months

OTHER CRITERIA

Continuation Duration:

Osteoporosis-1 year, Use or teriparatide or other parathyroid hormone analogs for more than 2 years is not recommended

Hypoparathyroidism-1 year

Continuation Criteria

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

1. Osteoporosis:
   a) continue to meet qualifying criteria
   b) responding to treatment with evidence of maintenance or improved T-Score on DEXA scan

2. Hypoparathyroidism:
   a. Patient is tolerating and responding to treatment

Effective 6/1/16
Updated 4/1/2018

MEDICATION(S)
LANTHANUM CARBONATE

COVERED USES
Indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis

EXCLUSION CRITERIA
Bowel obstruction.

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Not indicated in pediatric use

PRESCRIBER RESTRICTION
Must be written by or in consultation with a nephrologist.

COVERAGE DURATION
12-months

OTHER CRITERIA
1. Documentation of hyperphosphatemia.
2. Trial and failure of calcium acetate (elevated phosphorus or calcium levels for consecutive measurements).
3. Inability to swallow.

Effective 6/1/16

MEDICATION(S)
GILENYA 0.5 MG CAPSULE

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
GILENYA® / FINGOLIMOD

Drug Class: Multiple Sclerosis Agent - Sphingosine 1-phosphate receptor modulator

FDA-approved uses: Gilenya is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Available dosage forms: 0.25 mg and 0.5mg Capsules

Coverage Criteria/Limitations for initial authorization:
Diagnoses: Indicated for the treatment of patients with relapsing forms of multiple sclerosis including:
o Relapsing-remitting multiple sclerosis [RRMS]
o Secondary-progressive multiple sclerosis [SPMS] with relapses

o Progressive-relapsing multiple sclerosis [PRMS]

Duration of Approval:

o Initial Authorization: 6 months

o Continuation of Therapy: 1 year

Prescriber Specialty:

o Board-certified Neurologist

o Board-certified Multiple Sclerosis physician specialist

oConsult with a Board-certified neurologist or physician specialist with experience in prescribing multiple sclerosis therapy (submit consultation notes)

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

o A definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria.

oExpanded Disability Status Scale (EDSS) score between 0 and 5 (disability severe enough to impair full daily activities) OR documentation supporting the disability within this range

oFor members age 18 and older: Documented inadequate response (at least 6 months of therapy) to a non-interferon, glatiramer acetate (Copaxone®)

NOTE: “Needle phobia” or “needle fatigue” is not considered an intolerance or contraindication to the first-line disease-modifying therapies (DMT's)

Inadequate response is defined as meeting TWO of the following three criteria during treatment with one of these agents:

•Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses

•Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)

Documentation Requirements, continued (e.g. Labs, Medical Record, Special Studies):

•Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, or ability to perform activities of daily living

o For members 10-17 years of age:

Weight reported as greater than 40kg for 0.5mg dose.

NOTE: Manufacturer reports that the 0.25mg dose, indicated for pediatric patients ? 40kg, will not be released on the market. Instead, it will be available through the manufacturer’s Gilenya® Go Program®.

o Confirmation of ONE of the following from the Prescriber AND by verifying in member’s prescription profile.

Member is not currently being treated with another disease-modifying agent for

MS
Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent
o All of the following labs or exams within the last 6 months
CBC
LFT's and bilirubin levels
Negative pregnancy if female
EKG evaluation
Ophthalmic examination
oPatient has documented history of chicken pox OR has had the varicella zoster vaccination OR has evidence of immunity (positive antibodies)
Quantity: 30 capsules per month
Age: 10 years of age or older
Gender: male or female
Route of Administration: Oral
Place of Service: Outpatient

Criteria for continuation of therapy:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Confirmation of ONE of the following from the Prescriber AND by verifying in member's prescription profile.
Member is not currently being treated with another disease-modifying agent for MS
Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent

Criteria for continuation of therapy: (continued)
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Adherence to Therapy
Member compliance with therapy as verified by Prescriber and member's medication fill history (review prescription history for compliance)
•NOTE: Therapy may be discontinued due to compliance issues or poor adherence upon agreement among treating physician, member, and Medical Director.
o Labs/Reports/Documentation required [ALL]
CBC
LFT's and bilirubin levels
Negative pregnancy test, if female
EKG evaluation (if Gilenya discontinued for more than 14 days after the first month of treatment)
Ophthalmic examination (3 to 4 months after starting treatment, then any time visual disturbances are

reported or annually if member has diabetes or history of uveitis)
oStabilization or positive response to Gilenya® (fingolimod) treatment. Demonstrated efficacy as evidenced by (including but not limited to the following): [ALL APPLICABLE]
Relapses: A decrease in frequency, severity, sequelae relapses from baseline
Radiologic evidence of disease activity: Beneficial effect on MRI measures of disease severity (decrease in number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
oDisability progression: EDSS score remains less than or equal to 5.5 or stabilization/improvement routine neurological observation, mobility, or ability to perform activities of daily living
o Validated patient reported outcome measure [i.e. Fatigue Impact Scale (FIS), Medical Outcome Study SF-36, etc]
Fatigue Impact Scale (FIS) is a validated patient reported outcome measure that evaluates the effect of fatigue on the lives of people with MS. The Medical Outcome Study SF-36 is a self-administered health-reported quality of life outcome measure that is validated for several indications and patient populations

Contraindications/Exclusions/Discontinuation:
- Steady progression of disability
- Drug toxicity or serious adverse reaction
- Non-FDA approved indications
- Authorization will not be granted if ANY of the following contraindications/exclusions to Gilenya® (fingolimod) therapy apply:

oMyocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure experienced within the past 6 months
o History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker
o Baseline QTc interval ?500 msec
o Treatment with Class Ia or Class III anti-arrhythmic drugs
o NOTE: “Needle phobia” or “needle fatigue” is not considered a contraindication.

Contraindications/Exclusions/Discontinuation: (continued)
•In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:
- For use as monotherapy therapy only:

oPrescriber intends to use Gilenya as a single agent, no other disease-modifying multiple sclerosis medications are being administered concomitantly, including but not limited to: interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), glatiramer acetate (Copaxone®),

mitoxantrone (Novantrone®), natalizumab (Tysabri®), teriflunomide (Aubagio®), or dimethyl fumerate (Tecfidera®)

Effective 4/1/2019

MEDICATION(S)

GLATIRAMER ACETATE, GLATOPA 20 MG/ML SYRINGE

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

Clinical Criteria

1. Patient must be 18 years of age or older.
2. Must be prescribed by a neurologist.
3. Documented diagnosis of relapsing forms of multiple sclerosis

Duration of Authorization: 6 months

Effective 6/1/16
Update 1/1/18

MEDICATION(S)
OZEMPIC, TRULICITY 0.75 MG/0.5 ML PEN, TRULICITY 1.5 MG/0.5 ML PEN, VICTOZA 2-PAK, VICTOZA 3-PAK

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
GLP1-AGONIST
VICTOZA® / LIRAGLUTIDE
OZEMPIC® / SEMAGLUTIDE
TRULICITY® / DULAGLUTIDE

Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).

Drug Class: Antihyperglycemic – Incretin Mimetic, GLP-1 Receptor Agonist Analog
FDA-approved uses: Type 2 diabetes mellitus: Indicated as adjuvant therapy to improve glycemic control in patients with Type 2 diabetes mellitus.
To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.
Available dosage forms:
Victoza 2-Pak 18 mg/3ml pen

Victoza 3-Pak 18 mg/3mL pen
Ozempic 0.25 mg or 0.5 mg/dose Pre-filled pen solution for injection
Ozempic 1 mg/dose Pre-filled pen solution for injection
Trulicity 0.75mg/0.5ml Pre-filled Pen Solution for Injection
Trulicity 1.5mg/0.5ml Pre-filled Pen Solution for Injection

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA Approved Indication as listed above
?Duration of Approval
oInitial Approval: 6 months
oContinuation of Therapy: 6 months
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oTrial, failure or intolerance to at least two (2) antidiabetic agents such as:
?metformin
?sulfonylurea
?TZD
?DPP-4 Inhibitor
?SGLT-2 inhibitor, OR
?insulin and has not achieved adequate glycemic control (HbA1c greater than 7% after 3 continuous months of receiving maximal daily doses) despite current treatment
oChart notes confirming all previous antidiabetic therapy, medications tried, dates of trial, response to therapy.
oA1c lab less than or equal to 9%.
?Quantity:
oVictoza 2-Pak: 6 mL per 30 days
oVictoza 3-Pak: 9 mL per 30 days
oOzempic 0.25 or 0.5 mg/dose Pen: 1.5 mL per 28 days
oOzempic 1 mg/dose Pen: 3 mL per 28 days
oTrulicity 0.75mg/0.5mL Pen: 2 ml per 28 days
oTrulicity 1.5mg/0.5mL Pen: 2 ml per 28 days

?Age: ? 18 years of age, Victoza ? 10 years of age
?Route of Administration: Subcutaneous

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient tolerating and responding to treatment

Contraindications/Exclusions/Discontinuation:

•Not approved for convenience or if noncompliant with therapies
•HbA1c less than 7.0%
•Type 1 diabetes
•Hypersensitivity or contraindications to the use of liraglutide, semaglutide or dulaglutide
•Presence of medullary thyroid carcinoma, personal or family history
•Presence of multiple endocrine neoplasia syndrome type2
•Excluded if primarily being used for weight loss

Contraindications/Exclusions/Discontinuation, continued:
•Boxed Warning: Thyroid C-cell tumor risk:
Liraglutide, semaglutide and dulaglutide cause dose-dependent and treatment duration–dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether these agents cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, because the human relevance of liraglutide, semaglutide or dulaglutide-induced rodent thyroid C-cell tumors has not been determined.
Liraglutide, semaglutide and dulaglutide are contraindicated in patients with a personal or family history of MTC and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of liraglutide, semaglutide, and dulaglutide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with liraglutide, semaglutide or dulaglutide
•In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:
•Prescriber requirements: Prescribers are encouraged to review the Dear healthcare Provider letter that provides safety information and prescribing recommendations for (Victoza) liraglutide: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM202063.pdf.

Updated 7/1/20

MEDICATION(S)
FULPHILA, GRANIX, NEUPOGEN, NIVESTYM 300 MCG/0.5 ML SYRING, NIVESTYM 480 MCG/0.8 ML SYRING, ZARXIO

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
GRANULOCYTE COLONY-STIMULATING FACTOR (G-CSF)
GRANIX® (TBO-FILGRASTIM)
NEUPOGEN® (FILGRASTIM) ZARXIO™ (FILGRASTIM-SDZ)
FULPHILA™ (PEGFILGRASTIM-JMDB)
NIVESTYM ™ (FILGRASTIM-AAFI)

Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).

Drug Class: Granulocyte Colony-Stimulating Factor (G-CSF)
FDA-approved uses:

?Granix:
oReduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving

myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

?Neupogen & Zarxio:
oTo decrease the duration of neutropenia in patients undergoing myeloablative chemotherapy followed by marrow transplantation for non-myeloid malignancies
oTo decrease the incidence of infections from febrile neutropenia in patients with non-myeloid malignancies who are receiving myelosuppressive chemotherapy
oTo reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia
oTo reduce the incidence and duration of neutropenia sequelae, including fever, infections, or oropharyngeal ulcers, in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
oMobilization of hematopoietic progenitor cells before autologous stem cell transplant
oMobilization of hematopoietic progenitor cells in the donor before allogenic stem cell transplant
oTreatment of acute radiation exposure, to increase survival, in patients who receive myelosuppressive doses of radiation at a dose of 2 gray (Gy)

?Fulphila:
oTo decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
?Nivestym:
oDecrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
oReduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
oReduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
oMobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
oReduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Available dosage forms:

Granix:
?Injection: 300 mcg/mL solution in single-dose vials
?Injection: 480 mcg/1.6 mL solution in single-dose vials

?Injection: 300 mcg/0.5 mL solution in single-use prefilled syringe
?Injection: 480 mcg/0.8 mL solution in single-use prefilled syringe

Neupogen
?Injection: 300 mcg/mL in a single-use vial
?Injection: 480 mcg/1.6 mL in a single-use vial
?Injection: 300 mcg/0.5 mL in a single-use prefilled syringe
?Injection: 480 mcg/0.8 mL in a single-use prefilled syringe

Zarxio:
?Injection: 300 mcg/0.5 mL in a single-use prefilled syringe
?Injection: 480 mcg/0.8 mL in a single-use prefilled syringe

Fulphila:
?Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe

Nivestym:
?Injection: 300 mcg/ml solution in single-dose vials
?Injection: 480 mcg/1.6ml solution in single-dose vials
?Injection: 300 mcg/0.5ml solution in a prefilled syringe
?Injection: 480 mcg/0.8ml solution in a prefilled syringe

Coverage Criteria/Limitations for initial authorization:
•Diagnoses:
FDA approved indications detailed above

oChemotherapy-induced neutropenia
?Chemotherapy regimen is identified as having a high overall risk (over 20%) of febrile neutropenia#
OR
?Chemotherapy regimen is identified as having an intermediate overall risk (10% - 20%) of febrile neutropenia# AND
?Member is at high-risk for neutropenic complications (e.g., age over 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities) OR
oChemotherapy-induced neutropenia, contined
?Patient experienced a neutropenic complication from a prior cycle of the same chemotherapeutic regimen
?Administered 24 – 72 hours after completion of chemotherapy
?Patient is not receiving concurrent chemotherapy and radiation therapy

#National Comprehensive Cancer Network. Myeloid Growth Factors (Version 2.2018 – August 3, 2018) Pages MGF-A.1 (Regimens with High Risk) and MGF-A.2 (Regimens with Intermediate Risk)

https://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf

Agent Coverage for Diagnosis 1
Filgrastim-aafi (Nivestym®) is considered medically necessary as first line therapy

Second line therapy of Tbo-filgrastim (Granix®) may be covered when:
•First line Filgrastim-aafi (Nivestym®) has been tried and failed, OR
•There is a contraindication to the use of Filgrastim-aafi (Nivestym®) OR
•Patient issues related to geographic challenges and an inability to self-administer GCSF may be considered for coverage of the longer acting second line agents on a case by case basis

Third line therapy of Filgrastim-sndz (Zarxio™) may be covered when:
•Second line therapy of Tbo-filgrastim (Granix®) has been tried and failed, OR
•There is a contraindication to the use of Tbo-filgrastim (Granix®)
Fourth line therapy of filgrastim (Neupogen®) may be covered when:
•Third line therapy of Filgrastim-sndz (Zarxio™) has been tried and failed, OR
•There is a contraindication to the use of Filgrastim-sndz (Zarxio™)
Pegylated Filgrastim Requests:

Fulphila™ (Pegfilgrastim-jmdb) – Formulary (preferred)
Neulasta® (Pegfilgrastim) – Non-formulary
Udenyca™ (Pegfilgrastim-cbqv) – Non-formulary

•Trial and failure of, or contraindication to, one preferred filgrastim product
oFilgrastim-aafi (Nivestym®)
oTbo-filgrastim (Granix®)
oFilgrastim-sndz (Zarxio™)

•If Fulphila™ is approved, the following dosing and administration recommendations apply:
oThe recommended dosage of Fulphila is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
oFor dosing in pediatric patients weighing less than 45kg, the following weight based dosing is recommended:
?less than 10 kg = 0.1 mg/kg
?10-20 kg = 1.5 mg (0.15 mL)
?21-30 kg = 2.5 mg (0.25 mL)
?31-44 kg = 4mgg (0.4 mL)
oNot to be administered within 14 days before and 24 hours after administration of cytotoxic chemotherapy.
oTreatment of neutropenia
?Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

?Drug-induced neutropenia in immunosuppressed patients
•Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR
•Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR
•Patient has a documented bacterial infection
?Myeloid reconstitution after autologous or allogenic or autologous bone marrow transplant
•Patient has a non-myeloid malignancy
?Following reinfusion of peripheral blood stem cells (PBSCs)

oPeripheral blood stem cell (PBSC) mobilization
?Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation

Agent Coverage for Diagnoses 2-3

Filgrastim-aafi (Nivestym®) is considered medically necessary as first line therapy for patients at risk of severe febrile neutropenia

Second line therapy of Filgrastim-sndz (Zarxio™) may be covered when:

•First line Filgrastim-aafi (Nivestym®) has been tried and failed, OR
•There is a contraindication to the use of Filgrastim-aafi (Nivestym®)
Third line therapy of filgrastim (Neupogen®) may be covered when:

•Second line Filgrastim-sndz (Zarxio™) has been tried and failed, OR
•There is a contraindication to the use of Filgrastim-sndz (Zarxio™)

oAcute radiation exposure
?Following exposure to myelosuppressive doses of radiation at a dose of 2gray (GY)

Agent Coverage for Diagnoses 4

Filgrastim-sndz (Zarxio™) is considered medically necessary as first line therapy for patients at risk of severe febrile neutropenia

Second line therapy of Filgrastim (Neupogen®) may be covered when:
o First line Filgrastim-sndz (Zarxio™) has been tried and failed, OR
o Member requires a does less than 0.3 ml (180mcg) OR
    o There is a contraindication to the use of Filgrastim-sndz (Zarxio™)

?CSFs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMedical Record which documents the FDA approved indication and Absolute neutrophil count (ANC)
•Prescriber Specialty: Prescribed by hematologist and/or oncologist, or other specialist per associated diagnosis/indication
•Quantity:
oChemotherapy-induced neutropenia (primary or secondary prophylaxis):
?Approve per cycle of chemotherapy up to a 14 day supply
?Include refills if number of cycles is provided
oTreatment of neutropenia (e.g., congenital, cyclic, or idiopathic, or after chemo + BMT):
?Approve for 3 months
•Gender: Male or Female
•Route of Administration: Subcutaneous
•Place of Service: Outpatient

Criteria for continuation of therapy:
•Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oChemotherapy-induced neutropenia (primary or secondary prophylaxis):
?Recent ANC showing a response to therapy
?Approve per cycle of chemotherapy up to a 14 day supply
?Include refills if number of cycles is provided
oAll other indications:
?Recent ANC
?Approve every 30 days.

MEDICATION(S)
NORDITROPIN FLEXPRO

COVERED USES
The FDA has approved the use of rhGH for treatment of children with short stature associated with GHD, chronic renal insufficiency, Turner's syndrome, Prader-Willi syndrome, children who are small for gestational age and who do not manifest catch-up growth by age 2, and, most recently, for idiopathic short stature (ISS). Although one rhGH product is approved for treatment of acquired immunodeficiency syndrome (AIDS) wasting and cachexia in adults, it has not yet been approved for use in children. The FDA-approved indications for rhGH products are as follows:
o Pediatrics:
• Growth hormone deficiency causing slow growth
• Growth hormone deficiency causing infantile hypoglycemia
• Short stature or growth failure due to:
? Turner syndrome
? Prader-Willi syndrome
? Chronic renal insufficiency prior to transplantation
? Noonan's syndrome
? SHOX (short stature homeobox-containing gene) deficiency
? Idiopathic short stature
? Small for gestational age
? Central nervous system tumor treated with radiation (requires medical clearance from the treating oncologist)

o Adults:
• Growth hormone deficiency due to hypothalamic or pituitary condition
• Child onset growth hormone deficiency continuing into adulthood
• Short-bowel syndrome
• HIV Wasting (refer to Serostim prior authorization guidelines)

NOTE: Human growth hormone products currently available in the United States are exclusively produced from recombinant technology in the form of somatropin. Although recombinant human growth hormone (rhGH) products are produced by different manufacturers, the molecular structure is the same for each brand name for somatropin, hence there are no expected differences in efficacy between products. Growth hormone products used in GHD (and other indications) are all approved as containing the identical sequence of 191 amino acids constituting the naturally occurring pituitary human growth hormone

EXCLUSION CRITERIA

Contraindications/Exclusions/Discontinuation:

? Active malignancy

? Critical illness (e.g., after complications following open heart or abdominal surgery, multiple trauma, acute respiratory failure or similar conditions)

? Known hypersensitivity to growth hormone or to any of its excipients

? Intracranial hypertension

? Diabetic retinopathy, proliferative or pre-proliferative (Note: Diabetes mellitus is not a contraindication, however GH therapy might impede the control of type 2 diabetes)

? Pregnancy or lactation: Pregnancy is not an absolute contraindication, but GH therapy during pregnancy is recommended if clearly needed. Category B (Genotropin, Omnitrope, Saizen, Serostim, and Zorbtive). Category C (Accretropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, and Tev-Tropin).

? In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION

? Prescriber Specialty: Prescribed by a specialist based on the condition treated (e.g. endocrinologist (for adults) or pediatric endocrinologist (for children), HIV specialist, nephrologist)

? Neonates/Infants:

o Random GH level less than20ng/ml (by RIA test).

o Abnormal IGFBP-3 (in infants)

o Other causes have been ruled out or treated (hypothyroidism, metabolic disorders)

? Children:

o Not used for idiopathic short stature (not considered medically necessary)

o Not used for growth promotion in pediatric patients with epiphyseal closure (linear growth can no longer occur. i.e., bone age greater than 14 yrs old). The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.

o Other factors contributing to growth failure have been ruled out, or are being treated (e.g., inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism ? patients need normal TSH, T4)

o Recent (within the last 3 months) height more than 2 SDS below the mean (less than 3rd percentile) for age and sex

o Recent (within the last 3 months) weight

o Pretreatment growth velocity below normal for age and sex

ADDITIONAL INFORMATION REQUIRED (BASED ON DIAGNOSIS):

Pediatric Treatments:

Diagnosis: Child – Growth Hormone Deficiency (GHD):

(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin)

? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

o Fasting Growth Hormone Stimulation testing with arginine (ARG), clonidine, glucagon, insulin tolerance test (ITT) and/or levodopa
o Peak levels less than 10 mcg/L from 2 different agents are required if the cause of growth failure is unknown
o If cause of GHD is known, only 1 peak level less than 10 mcg/L will be required:
• Structural or developmental abnormalities: e.g. anencephaly, pituitary aplasia
• Genetic disorders: e.g., PROP1 and PIT1 mutations, septo-optic dysplasia
• Acquired causes: e.g., craniopharyngeomas*, cranial irradiation, brain surgery, head trauma, CNS infections

Diagnosis: Child – Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency or Noonan Syndrome: (Prader-Willi Syndrome: Genotropin, Tev-Tropin, Omnitrope) (Turner Syndrome: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope) (SHOX: Humatrope) (Noonan Syndrome: Norditropin)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documentation to support the diagnosis (e.g., Turner Syndrome confirmed by karyotype studies, Prader-Willi Syndrome confirmed by genetic testing)

Diagnosis: Child – Chronic Renal Insufficiency (CRI): (Nutropin)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documented diagnosis of CRI
o Patient has not received a renal transplant
o Existing metabolic abnormalities (e.g., malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia -correct phosphorus to less than 1.5 times the upper limit for age) have been corrected

Diagnosis: Child – Small for Gestational Age (SGA) with failure to catch-up by 2 years of age: (Genotropin, Humatrope, Norditropin, Omnitrope)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o At least 2 years of age
o Birth length or weight less than 3rd percentile for gestational age, or
o Birth weight less than 2500 grams at a gestational age of more than 37 weeks

Adult Treatments
Diagnosis: Adult – Idiopathic GH deficiency (Childhood-onset): (Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documented diagnosis of idiopathic childhood-onset GHD
o Growth hormone must not be taken for 1-3 months before repeat GH stimulation test and IGF-1 were drawn
o Growth hormone stimulation testing:
• Insulin Tolerance Test (ITT):

? Considered Gold standard test
? Peak ? 5 mcg/L indicative of GHD
• Glucagon (for patients who are unable to take ITT):
? Alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD, or cerebrovascular disease)
? ?Peak ? 3 mcg/L indicative of GHD
• Note: Levodopa and clonidine tests are not recommended
o Baseline serum IGF-1

Diagnosis: Adult – GH deficiency due to a known cause (Childhood-onset):
(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documented diagnosis of childhood-onset GHD due to a known cause (structural lesions, genetic disorders, acquired causes)
o Baseline serum IGF-1
o Note: for conditions other than GHD, such as Turner Syndrome and small for gestational age, there is no proven benefit to continuing GH treatment into adulthood once final height is achieved.

Diagnosis: Adult – Onset GH deficiency: (Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documented diagnosis of GHD acquired as an adult due to a known cause (e.g. surgery, cranial irradiation, panhypopituitarism)
o Baseline IGF-1
o Growth hormone stimulation test:
• Insulin Tolerance Test (ITT):
? Considered Gold standard test
? Peak ? 5 mcg/L indicative of GHD
• Glucagon (for patients who are unable to take ITT):
? Alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD, or cerebrovascular disease)
? Peak ? 3 mcg/L indicative of GHD
• Note: Levodopa and clonidine tests are not recommended
o If GH deficiency is due to traumatic brain injury and aneurysmal subarachnoid hemorrhage, GHD may be transient, therefore, GH stimulation testing should be performed at least 12 months after the event

Diagnosis: Adult – HIV Wasting/cachexia: (Serostim)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Documented height, weight, and ideal body weight
o Patient had progressive weight loss below IBW over the last year which cannot be explained by a

concurrent illness other than HIV infection
o Documented adequate caloric intake
o Failure of megestrol and dronabinol
o On antiretroviral therapy

Diagnosis: Adult – Short Bowel Syndrome: (Zorbtive)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Age greater than 18 years of age
o Patient is receiving specialized nutrition (e.g. TPN or PPN)

Diagnosis: Adult – Treatment of excess abdominal fat in HIV-infected patients with lipodystrophy: (Egrifta)
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o 18-65 years of age
o Men: waist circumference ? 95 cm (37.4") and waist-to-hip-ration ? 0.94
o Women: ? 94 cm (37.0") and waist-to-hip ration ? 0.88
o On antiretroviral therapy
o Patient is at risk for medical complications due to excess abdominal fat
o Contraindications: No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma, active malignancy, known hypersensitivity to tesamorelin and/or mannitol, and pregnancy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
? Duration of Approval (Pediatric GHD):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• Documentation to support final height has not been achieved
• No evidence of epiphyseal closure AND
• Growth velocity is greater than 5cm/year on current dose or less than 5 cm/year with intended dose increase (Note: Growth velocity will typically decrease as final height is approached (growth velocity less than 2 cm/year).
• For Chronic Renal Insufficiency: there is insufficient data regarding the benefit of treatment beyond three years.

? Duration of Approval (Child-Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, or Noonan Syndrome):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• Documentation to support final height has not been achieved
• No evidence of epiphyseal closure AND
• Growth velocity is greater than 5cm/year on current dose or less than 5 cm/year with intended dose increase (Note: Growth velocity will typically decrease as final height is approached (growth velocity less than 2 cm/year).
• For Chronic Renal Insufficiency: there is insufficient data regarding the benefit of treatment beyond three years.

? Duration of Approval (Child-Chronic Renal Insufficiency):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• Documentation to support final height has not been achieved
• No evidence of epiphyseal closure AND
• Growth velocity is greater than 5cm/year on current dose or less than 5 cm/year with intended dose increase (Note: Growth velocity will typically decrease as final height is approached (growth velocity less than 2 cm/year).
• For Chronic Renal Insufficiency: there is insufficient data regarding the benefit of treatment beyond three years.

? Duration of Approval (Child-Small for Gestational Age):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• Documentation to support final height has not been achieved
• No evidence of epiphyseal closure AND
• Growth velocity is greater than 5cm/year on current dose or less than 5 cm/year with intended dose increase (Note:Growth velocity will typically decrease as final height is approached (growth velocity less than 2 cm/year).
• For Chronic Renal Insufficiency: there is insufficient data regarding the benefit of treatment beyond three years.

? Duration of Approval (Adult-Idiopathic GH deficiency (childhood-onset):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range

? Duration of Approval (Adult-GH deficiency due to a known cause (childhood-onset):

o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range

? Duration of Approval (Adult - Onset GH deficiency):
o Initial Authorization: 6 months
o Continuation of Approval: 6 months
• if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range

? Duration of Approval (Adult - HIV Wasting/cahexia):
o Initial Authorization: 3 months
o Continuation of Approval: 12 weeks (maximum 48 weeks)
• Requires: documentation to support response to therapy

? Duration of Approval (Adult-Short Bowel Syndrome):
o Initial Authorization: One 4-week course
o Continuation of Approval: Approve 4 weeks, No renewals

? Duration of Approval (Adult - Treatment of excess abdominal fat in HIV-infected patients with lipodystrophy):
o Initial Authorization: 3 months
o Continuation of Approval: Initial Renewal: 6 months
• Requires: documentation to support response to therapy, decrease in baseline waist circumference, and documentation that IGF-1, and A1C is being monitored

OTHER CRITERIA
Recommended Dosage:
DOSAGE RECOMMENDATIONS FOR GH
Clinical Condition/Dose
GHD Children/25-50 mcg/kg/day
GHD Adolescents/25-100 mcg/kg/day
GHD Adults/6-25 mcg/kg/day
Chronic Renal Insufficiency/50 mcg/kg/day
Turner Syndrome/50 mcg/kg/day
PWS 35-50 mcg/kg/day

Reference: Lawson Wilkins Pediatric Endocrinology Society

Dosage prescribed is within the FDA-approved labeling based on member's confirmed diagnosis. Dosage should be 0.1-0.3 mg/day subcutaneously, and titrate monthly to effect. Adult dosage greater than 0.3

mg/day will not be authorized.

Available dosage forms:

? * Norditropin FlexPro - 5 mg/1.5ml, 10 mg/1.5ml, 15 mg/1.5ml, 30 mg/3ml

? Genotropin ? Cartridge 5 mg, 12 mg

? Genotropin MiniQuick - Solution 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, 2 mg

? Humatrope - Vial 5 mg, Cartridge 6 mg, 12 mg, 24 mg

? Norditropin NordiFlex Pen - 30 mg/3ml

? Nutropin AQ - NuSpin 5 mg/2 ml, 10 mg/1ml, 20 mg/2ml, Pen 10 mg/2ml, 20 mg/2ml

? Omnitrope - Vial 5.8 mg, Cartridge 5 mg/1.5ml, 10 mg/1.5ml

? Saizen - Vial 5 mg, 8.8 mg, Click Easy Cartridge 8.8 mg

? Zomactin - Vial 5 mg, 10 mg

? Zorbtive - Vial 8.8 mg

* Covered on the Managed Care Common Formulary

MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT

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
HEMATOPOIETIC AGENTS

Drug Class: Hematopoietic Agents

Preferred Agents: Clinical Prior Authorization below

Aranesp®
Procrit®
Retacrit®

Non-Preferred Agents: Prior Authorization Criteria below

Epogen®

Non-Preferred Agent PA Criteria:
•Allergy to the preferred medications

•Contraindication or drug to drug interaction with the preferred medications
•History of unacceptable side effects
•Therapeutic failure after one-month trial with one preferred medication
•See additional medication/diagnoses-specific criteria below:

CHRONIC KIDNEY DISEASE STAGE 3, STAGE 4 [CRF - CHRONIC RENAL FAILURE] AND STAGE 5 [ESRD END STAGE RENAL DISEASE] (EPOGEN®, PROCRIT®, AND ARANESP®):
•Hemoglobin level less than 10 g/dL before treatment with Epogen®, Procrit®, Aranesp® or transfusions
•RENEWAL: CURRENT hemoglobin level less than 12 g/Dl

KIDNEY TRANSPLANT PATIENTS - TRANSPLANTED KIDNEY IS NOTED AS NOT YET FUNCTIONING TO ANTICIPATED POTENTIAL (EPOGEN®, PROCRIT®, AND ARANESP®):
•Less than 1-year post transplant
•CURRENT hemoglobin level less than 12 g/dL
•Length of Authorization: 6 months

CHEMOTHERAPY OR RADIATION THERAPY CONFIRMED AS CURRENT (EPOGEN® PROCRIT® AND ARANESP® ONLY):
•Hemoglobin level less than 10 g/dL before beginning treatment with Epogen® or Procrit® or transfusions
•RENEWAL: CURRENT hemoglobin level less than 12 g/dL

ANEMIA IN AIDS PATIENTS: (EPOGEN® AND PROCRIT® ONLY)
•Hemoglobin level less than 10 g/dL

ANEMIC PATIENTS SCHEDULED TO UNDERGO NON-CARDIAC, NON-VASCULAR SURGERY TO DECREASE NEED FOR TRANSFUSIONS: (EPOGEN® & PROCRIT® ONLY).
•Clinical rationale why alternative approaches such as donating own blood prior or transfusion is not an option.
•CURRENT hemoglobin level less than 10 g/dL

MYELODYSPLASIA AND MYELODYSPLASTIC SYNDROME (EPOGEN® AND PROCRIT® ONLY):
•CURRENT hemoglobin level less than 10 g/dL

HEPATITIS C WITH CURRENT INTERFERON TREATMENT (EPOGEN® AND PROCRIT® ONLY):
•Beginning hemoglobin level less than 10 g/dL
•RENEWAL: CURRENT hemoglobin level less than 12 g/dL

?Duration of Approval: For the duration of the prescription up to 6 months, unless otherwise noted in Medication/Diagnoses-Specific Information

MEDICATION(S)
HUMALOG 100 UNIT/ML VIAL

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
HUMALOG® U-100 VIAL / INSULIN LISPRO

Drug Class: Rapid acting insulin
FDA-approved uses:
?To improve glycemic control in adults and children with diabetes mellitus.

Available dosage forms: guideline only applies to U-100 vial dosage form

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA-approved uses as listed above
?Duration of therapy:
oInitial Approval: 12 months
oContinuation of Therapy: 12 months
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient is currently utilizing an insulin pump delivery system

?Quantity/Duration: According to FDA-approved use
o30 mL (3 vials) per 30 days
?Age: No restriction

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient is tolerating and responding to medication and there continues to be a medical need for the medication.
oPatient's insulin continues to be delivered by an insulin pump

Contraindications/Exclusions/Discontinuation:
•Risk of hypoglycemia. Severe hypoglycemia can cause seizure, may be life-threatening or cause death. Hypoglycemia can impair concentration ability and reaction time.
•Risk of hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia and death. Monitor potassium levels in patients at risk for hypokalemia (patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations.

Other special considerations:
•Patients with renal or hepatic impairment may be at increased risk of hypoglycemia and may require more frequent HUMALOG dose adjustment and more frequent blood glucose monitoring.

Effective 4/1/19

MEDICATION(S)
HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN 40 MG/0.4 ML, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS

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
HUMIRA® / ADALIMUMAB

Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).

*Please refer to the continuation criteria section for members that are already established on Humira prior to the 07/01/2019 prior authorization changes.

Drug Class: Anti-Inflammatory Tumor Necrosis Factor Inhibiting Agents, TNF=alpha set

FDA-approved uses:
?Ankylosing spondylitis (AS): For reducing signs and symptoms in adults with active ankylosing spondylitis.
?Crohn disease: For reducing signs and symptoms, as well as inducing and maintaining clinical remission, in adult and pediatric patients 6 years and older with moderately to severely active Crohn disease who have

had an inadequate response to conventional therapy, for reducing signs and symptoms, as well as inducing clinical remission, in these patients if they have also lost response to or are intolerant to infliximab (adults) or corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate (6 years and older).
?Hidradenitis suppurativa: Treatment of moderate to severe hidradenitis suppurativa.
?Juvenile idiopathic arthritis (JIA): For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years and older, alone or in combination with methotrexate.
?Plaque psoriasis (PsO): For the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
?Psoriatic arthritis (PsA): For reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adults with active psoriatic arthritis, alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs).
?Rheumatoid arthritis (RA): For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active rheumatoid arthritis (RA), alone or in combination with methotrexate or other non-biologic DMARDs.
?Ulcerative colitis (UC): For inducing and sustaining clinical remission in adults with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine.
?Uveitis (adults)
?Uveitis (children/adolescents)

Available dosage forms:
?Humira Prefilled Syringe Kit 10 mg/0.2ml, 20 mg/0.4ml, 40 mg/0.8ml
?Humira Pediatric Crohn’s prefilled syringe kit 40 mg/0.8ml
?Humira Pen Injector Kit 40 mg/0.8ml
?Humira Pen-Crohn’s starter pen injector kit 40 mg/0.8ml
?Humira Pen-Psoriasis starter pen injector kit 40 mg/0.8ml
?Humira Pen-Psoriasis-Uveitis starter pen injector kit 40 mg/0.8ml
?Humira Citrate Free Prefilled Syringe Kit 10mg/0.1ml, 20mg/0.2ml, 40mg/0.4ml
?Humira Citrate Free Pen Kit 40mg/0.4ml
?Humira Citrate Free Prefilled Syringe Kit 80mg/0.8ml & 40mg/0.4ml Pediatric Crohn’s Starter Package
?Humira Citrate Free Prefilled Syringe Kit 80mg/0.8ml Pediatric Crohn’s Starter Package (3 count)
?Humira Citrate Free 80mg/0.8ml Starter Pack for Crohn’s, UC or HS
?Humira Citrate Free Pen 80mg/0.8ml & 40mg/0.4ml Kit for Psoriasis, Uveitis or Adolescent HS Starter Pack

Coverage Criteria/Limitations for initial authorization
?Diagnoses: FDA approved use as listed above

?Prescriber Specialty: Prescribed by, or in consultation with a specialist (based on indication-rheumatologist, dermatologist, gastroenterologist, ophthalmologist)

ADDITIONAL INFORMATION REQUIRED (BASED ON DIAGNOSIS)
Diagnosis: Ankylosing Spondylitis (AS):
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oPresence of active disease for at least 4 weeks
oBASDAI score of 4 or more
oTrial and failure of 2 different NSAIDS totaling 90 consecutive days
oTrial and failure of steroid products, sulfasalazine or methotrexate for at least 90 consecutive days in the previous 120-day period.
oTrial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oTrial and failure of a 90-day trial of Cimzia
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
?Quantity: Based on FDA dosing. Partial Fill Restrictions may apply
o40mg subcutaneously every other week
?Age: At least 18 years of age
?Route of Administration: Injection

Diagnosis: Hidradenitis suppurativa:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oClinically diagnosed with severe and refractory hidradenitis suppurativa
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oDocumentation of use of general measures:
?Education and support
?Avoidance of skin trauma
Diagnosis: Hidradenitis suppurativa, continued
oDocumentation of inadequate response to intralesional corticosteroids
oDocumentation of inadequate response to procedural interventions (punch debridement) in combination with pharmacologic therapies
oDocumentation of trial and failure of systemic and topical antibiotic therapy
?3 months of topical antibiotics
?3 months of doxycycline

?3 months of clindamycin plus rifampin
oDocumentation of adequate trial and failure of Infliximab (medical benefit) unless there are transportation or other access issues documented
?Trial and failure of Infliximab does not apply to members less than 18 years old
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
oQuantity:
•Day 1: 160 mg or 80 mg for two consecutive days
•Day 15: 80 mg
•Day 29/Maintenance: 40 mg every week
?Based on FDA dosing. Partial Fill Restrictions may apply
?Route of Administration: Injection

Diagnosis: Plaque Psoriasis:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oTrial and failure of methotrexate for 90 consecutive days in the previous 120-day period, or contraindication to methotrexate
oPatients has greater than 10% BSA involvement or affected area includes palms, soles, head, neck, or genitalia
oTrial and failure or intolerant to topical agents and one additional systemic therapy (cyclosporine, or acitretin)
oTrial and failure of UVB or UVA therapy or contraindication to therapy
oTrial and failure of a 90-day trial of Otezla
oTrial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
?Trial and failure of Infliximab does not apply to members less than 18 years old
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
?Quantity: 80mg day one, then 40mg every other week starting one week after the initial dose
?Route of Administration: Injection
Diagnosis: Rheumatoid Arthritis/Psoriatic Arthritis (Adults):
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure

Diagnosis: Rheumatoid Arthritis/Psoriatic Arthritis (Adults), continued
oTrial and failure of methotrexate or at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
oTrial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oTrial and failure of a 90-day trial of one of the following: Actemra, Xeljanz, Cimzia, or Orencia
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
?Quantity:
o40mg subcutaneously every other week
oFor RA, may be increased to 40mg every week
?Route of Administration: Injection

Diagnosis: Juvenile idiopathic arthritis (JIA):
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oTrial and failure of methotrexate for at least 4 to 6 weeks or contraindication/intolerance to methotrexate AND
oTrial and failure of a 90-day trial of SQ Actemra or SQ Orencia, unless provider states that there has been rapid disease progression during trial
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
?Quantity: (2 years and older)
o10 kg to less than 15 kg: 10mg every other week
o15 to less than 30 kg: 20mg every other week
o? than 30 kg: 40mg every other week
?Age: 2 years and older
?Route of Administration: Injection

Diagnosis: Crohn’s Disease (CD)/Ulcerative Colitis (UC):
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oTrial and failure of oral or intravenous corticosteroids for at least one month or a contraindication/intolerance to corticosteroids
oTrial and failure of 1 or more of the following for 90 consecutive days in the previous 120-day period, or a

contraindication or intolerance to
?Azathioprine

Diagnosis: Crohn’s Disease (CD)/Ulcerative Colitis (UC), continued
?Budesonide
?Oral aminosalicylates (e.g., mesalamine, sulfasalazine, balsazide disodium)
?Rectal aminosalicylates
?Cyclosporine
?Mercaptopurine (CD, UC)
oTrial and failure of 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
?Trial and failure of Infliximab does not apply to members less than 18 years old
oTrial and failure of 90-day trial of Cimzia (for Crohn’s disease)
?Duration of Approval:
oInitial Authorization:
?For diagnosis of UC the initial coverage is for 2 months. *Must have evidence of clinical remission by week 8 for continuation.
?For diagnosis of CD the initial coverage is for 6 months
oContinuation of Approval: 6 months for both UC and CD
?Quantity: Adult Crohn’s Disease (CD) and Ulcerative Colitis (UC)
oDay 1: 160 mg or 80 mg for two consecutive days
oDay 15: 80 mg
oDay 29/Maintenance: 40 mg every other week
oUC initial coverage for 2 months, followed by 6 months continuation
?Route of Administration: Injection

Diagnosis: Severe Ulcerative Colitis/Crohn’s Disease: For moderate to severe disease dosed more frequently than every other week requires:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oPatient must have previously responded to Humira doses every other week
oPatient must be experiencing a flare
oThe flare must be likely to result in hospitalization
oApproved for 2 months, for treatment of the flare and then must be resumed at every other week dosing
oTrial and failure of a 90-day trial with infliximab (medical benefit) unless there are transportation or other access issues documented

?Trial and failure of Infliximab does not apply to members less than 18 years old
oTrial and failure of a 90-day trial with Cimzia (for Crohn's disease)
?Duration of Approval:
oInitial Authorization:
?For diagnosis of severe UC the initial coverage is for 2 months. *Must have evidence of clinical remission by week 8 for continuation. Reauthorization for additional 6 months.
?For diagnosis of severe CD the initial coverage is for 6 months
oContinuation of Approval: 6 months for both UC and CD

Diagnosis: Severe Ulcerative Colitis/Crohn's Disease, continued
?Quantity: Adult Crohn's Disease (CD) and Ulcerative Colitis (UC)
oDay 1: 160 mg or 80 mg for two consecutive days
oDay 15: 80 mg
oDay 29/Maintenance: 40 mg every other week
oSevere UC initial coverage for 2 months, followed by 6 months continuation
?Route of Administration: Injection

Diagnosis: Pediatric Crohn's Disease:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
oDocumentation of a negative TB test within last 12 months
oMust not have heart failure
oPatient has had an inadequate response to two of the following:
?Corticosteroids
?Azathioprine
?Methotrexate
oTrial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
?Trial and failure of Infliximab does not apply to members less than 18 years old
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 6 months
?Quantity: (6 years and older)
o17 to less than 40 kg
?Day 1: 80mg
?Day 15: 40mg
?Day 29/Maintenance: 20mg every other week
o40 kg and above:
?Day 1: 160mg or 80mg for two consecutive days
?Day 15: 80mg

?Day 29/Maintenance: 40mg every other week
?Age: 6 years of age or older
?Route of Administration: Injection
Diagnosis: Non-infectious Uveitis:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)
o Documentation of a negative TB test within last 12 months
o Must not have heart failure
oTrial and failure of periocular, intraocular, or systemic corticosteroids
oTrial and failure of immunosuppressive drugs (e.g., azathioprine, cyclosporine, mycophenolate or methotrexate) at maximally tolerated doses
oTrial and failure or intolerance to infliximab (medical benefit) unless there are transportation or other access issues documented
?Trial and failure of Infliximab does not apply to members less than 18 years old
?Duration of Approval:
o Initial Authorization: 6 months
oContinuation of Approval: 6 months
Diagnosis: Non-infectious Uveitis, continued
?Quantity: 80mg day one, then 40mg every other week starting one week after initial dose
?Route of Administration: Injection

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPlans must continue to cover Humira, adalimumab, or available biosimilar for established patients when continuation criteria is met.
oDocumentation by respective specialty that the patient continues to have a beneficial response to therapy.
oMember continues to have yearly negative Tb test
Contraindications/Exclusions/Discontinuation:
•Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
•Patient receiving additional biologic DMARD therapy.

Other special considerations:
•Additional information may be required on a case-by-case basis to allow for adequate review. Aminosalicylates, corticosteroids, methotrexate, nonsteroidal anti-inflammatory drugs, analgesics, immunomodulatory agents (e.g., 6-mercaptopurine, azathioprine), and/or other non-biologic DMARDs may be continued during treatment with adalimumab.
•Black Box Warning: Increased risk of serious infections and malignancy.

Updated 4/1/20

MEDICATION(S)
HUMULIN R U-500

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
Clinical Criteria

1. Documentation of an FDA Approved Indication or medically accepted indication as noted by compendia (AHFS-DI, Micromedex Drug Dex, Clinical
   Pharmacology.
2. Documentation that patient requires more than 200 units of insulin per day.

Duration of Approval: 1 year

Effective 6/1/16

MEDICATION(S)
EUCRISA, PIMECROLIMUS, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

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
IMMUNOMODULATORS: ATOPIC DERMATITIS

Drug Class: Immunomodulators: Atopic Dermatitis

Preferred Agents: Clinical Prior Authorization below

Elidel® cream

Non-Preferred Agents: Prior Authorization Criteria below

Dupixent® syringe
Eucrisa® ointment
Pimecrolimus cream (generic for Elidel)
Protopic® ointment

Tacrolimus ointment

PA Criteria:
•Therapeutic failure on two topical steroids.
•Atopic dermatitis
oElidel®: mild to moderate for ages greater than 2 years
oEucrisa®: mild to moderate for ages greater than or equal to 2 years
oProtopic® 0.03%: moderate to severe for ages greater than 2 years
OProtopic® 0.1%: moderate to severe for ages greater than 16 years
•See additional medication-specific criteria below:

DUPIXENT® (DUPILUMAB)
•Diagnosis of moderate to severe chronic atopic dermatitis, AND
•Patient ? 6 years old, AND
•Trial and failure or contraindication to both of the following therapies:
oOne preferred topical corticosteroid of medium potency to very high potency (i.e., mometasone, fluticasone, betamethasone valerate, triamcinolone, clobetasol), AND
oOne preferred calcineurin inhibitor (i.e., Elidel)
•For renewal requests, documentation (i.e., progress note) of positive clinical response will be required.
•Length of authorization: Initial approval = 6 months, renewal = 1 year

OR

•Patient must have moderate to severe asthma diagnosed as ONE of the following types:
oAsthma with eosinophilic phenotype with eosinophil count ? 150 cells/mcL, OR
oOral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months, AND
DUPIXENT® (DUPILUMAB), continued
•Patient must be 12 years of age or older, AND
•Patient must have had inadequate control of asthma symptoms after a minimum of 3 months of compliant use of an inhaled corticosteroid and ONE of the following controller medications within the past 6 months:
oinhaled long acting beta2 agonist
oinhaled long acting anticholinergic
•Length of authorization: 1 year

OR

•Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), AND

•Patient ? 18 years old
•Length of authorization: 1 year

QUANTITY LIMITS
Elidel® (pimecrolimus)30gm per 30 days
Eucrisa® (crisaborole)100 gm per 30 days
Protopic® (tacrolimus)30gm per 30 days

?Duration of Approval: 6 months for FDA approved diagnosis noted above, unless otherwise noted in Medication/Diagnosis-Specific Criteria

Updated 7/1/20

MEDICATION(S)
INCRELEX

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
Clinical Criteria

1. Must be prescribed by a endocrinologist or pediatric endocrinologist.
2. Patient must be greater than 2 years of age and less than 18 years of age.
3. Documented diagnosis of:
   a. Severe primary IGF-1 deficiency
      i. mutation in the GH-receptor
      ii. mutation of post GHR signaling pathway
      iii. IGF-1 gene defects
   b. Growth hormone gene deletion and have developed neutralizing antibodies to growth hormone.
3. Documentation of all of the following
   a. Current height measurement at less that the 3rd percentile for age and gender
   b. IGF-1 level greater than or equal to 3 SD below normal (based on lab reference for age and gender).
   c. For Primary IGFD:
      i. Normal or elevated growth hormone levels (Stimulation testing is not required when levels are

normal or high)

d. Epiphyses must be confirmed as open for members age 10 and older (submit radiograph report).

e. Parental height (height of each parent, if available, or explanation of why not available – such as child adopted, or one parent no longer involved and is unavailable for measurement)

f. Abnormal growth velocity as defined by the following:

4. Abnormal growth velocity as defined by the following:

a.History of lower than normal growth velocity, as shown by growth charts spanning at least 6 months of time AND

b. Baseline height must be less than 3rd percentile or greater than 2 SD below the mean for age and gender, a measure of the degree of short stature.

5. Prescriber must submit patient's height and weight measurements:

a. These measurements must be logged in a table and plotted on a standard CDC growth chart.

b. Height and weight measures must cover at least a on year time span.

i. Exception: if a patient is in puberty, bone age may be advancing secondary to sex hormone production. If previous growth data cannot be found to prove the one-year or longer time span of data, then sexual maturity rating (Tanner Staging) and measurements of sex hormones may be submitted with only 6 months of growth data.

Effective 6/1/16

MEDICATION(S)
AMNESTEEM, CLARAVIS, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, MYORISAN, ZENATANE

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
CLARAVIS® / ISOTRETINOIN
AMNESTEEM® / ISOTRETINOIN
MYORISAN™ / ISOTRETINOIN
ZENATANE™ / ISOTRETINOIN

Drug Class: Acne Therapy Systemic - Retinoids & Derivatives

FDA-approved uses: Treatment of severe (multiple locations) recalcitrant nodular acne unresponsive to conventional therapy including conventional antibiotics

Available dosage forms: Claravis Capsule 10 mg, 20 mg, 30 mg, and 40 mg, Amnesteem Capsule 10mg, 20mg and 40mg, Myorisan Capsule 10mg, 20mg, 30mg and 40mg, Zenatane Capsule 10mg, 20mg, 30mg and 40mg
Coverage Criteria/Limitations for initial authorization:
?Diagnoses: severe (multiple locations) recalcitrant nodular acne unresponsive to conventional therapy

including conventional antibiotics
?Duration of Approval
oInitial Authorization: 5 months, with monthly office visits
oContinuation of Therapy: Reviewed for coverage after a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne
?Prescriber Specialty: Dermatologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oProper diagnosis of an FDA approved indication OR
oIf request is for a non-FDA Approved indication, the request must be for a “medically accepted indication” as noted in the following Compendia:
?American Hospital Formulary Drug Service (AHFS-DI)
?Micromedex DrugDex
?Clinical Pharmacology
oMust be prescribed by a dermatologist
oCurrent chart notes detailing the diagnosis, including laboratory tests as appropriate for diagnosis
oDocumentation of dose, dates of therapy, and clinical outcomes as appropriate
oFailed/intolerant to at least 2 oral antibiotics (must have used consistently for 6 months)
oFailed/intolerant to topical retinoid product (must have used consistently for 6 months)
oFailed/intolerant to Benzoyl Peroxide wash (must have used consistently for 6 months)
oFailed/intolerant to Clindamycin and/or Erythromycin topical therapy (must have used consistently for 6 months)
oNegative pregnancy test
oMust select 2 forms of effective contraception simultaneously
oMust meet requirements of the iPledge Program

?Not approved If:
oPatient has any contraindications to the use of isotretinoin
oPatient is not compliant with current therapy?
?Dosing:
oAdult Acne, severe recalcitrant nodular:
?Oral: 0.5-1 mg/kg/day in 2 divided doses for 15-20 weeks
?May discontinue earlier if the total cyst count decreases by 70%
?Adults with very severe disease/scarring or primarily involves the trunk may require dosage adjustment up to 2 mg/kg/day
?A second course of therapy may be initiated after a period of ? 2 months off therapy
?A dose of ?0.5 mg/kg/day may be used to minimize initial flaring
oPediatric Acne, severe recalcitrant nodular:
?Children 12-17 years:
•Oral: 0.5-1 mg/kg/day in 2 divided doses for 15-20 weeks
•May discontinue earlier if the total cyst count decreases by 70%

•A second course of therapy may be initiated after a period of ? 2 months off therapy
•A dose of ?0.5 mg/kg/day may be used to minimize initial flaring
?Age: 12 years and older
?Route of Administration: Oral

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oOffice visit every month with verified compliance and improvement or stability on drug

Contraindications/Exclusions/Discontinuation:
•Patient is noncompliant with medical or pharmacologic therapy
•No demonstrable of improvement in clinical condition has occurred after initiation of drug therapy

References:
a.American Academy of Pediatrics Committee on Drugs, “Retinoid Therapy for Severe Dermatological Disorders,” Pediatrics, 1992, 90(1 Pt 1):119-20.
b.Claravis [package insert]. Sellersville PA: Teva Pharmaceuticals USA, January 2015.
c.Facts & Comparisons. (2012). Claravis. Retrieved from http://0-online.factsandcomparisons.com.libcat.ferris.edu/MonoDisp.aspx?monoID=fandc-hcp1943&quick=159351%7c5&search=159351%7c5&isstemmed=True.
d.Mitchell AA, Van Bennekom CM, Louik C, et al, “A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin,” N Engl J Med, 1995, 333(2):101-6.
e.iPledge. (2015). Claravis iPledge Program. www.ipledgeprogram.com
f.Graber E, et al “Treatment of Acne Vulgaris,” UptoDate, November, 10, 2015.

Effective 6/1/16
Update 4/1/20

MEDICATION(S)
KRINTAFEL

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
KRINTAFEL®/ TAFENOQUINE

Drug Class: Antimalarials

FDA-approved uses:
?Indicated for the radical cure (prevention of relapse) of Plasmodium vivax malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection. It is not indicated for the treatment of acute P. vivax malaria

Available dosage forms: 150 mg tablet

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Prevention of Plasmodium vivax
?Duration of approval:
oInitial authorization:
?Plasmodium vivax – one-time single dose

oContinuation of Therapy:
?A repeat dose should be given if vomiting occurs within 1 hour after dosing. Re-dosing should not be attempted more than once.
?Prescriber Specialty: infectious disease
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMedical record
oMust be tested negative for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to prescribing
oNegative pregnancy test result in all women of reproductive potential
oBreastfeeding an infant found to be G6PD deficient or unknown status is contraindicated
?Quantity: Two (2), 150 mg tablets per 365 days
?Age: 16 years of age and older
?Gender: males and non-pregnant and non-lactating females
?Route of Administration: Oral
?Place of Service: Outpatient

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oUpdated medical record

Contraindications/Exclusions/Discontinuation:
•Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status
•May cause hemolytic anemia for patients when administered to pregnant woman with a G6PD-deficient fetus. A G6PD-deficient infant may be at risk for hemolytic anemia from exposure through breast milk. Check infant’s G6PD status before breastfeeding begins
•Patients with known hypersensitivity to tafenoquine, other 8-aminoquinolines, or any component of Krintafel

Other special considerations:
• Refer to the CDC website for recommendations for treatment and prevention of Plasmodium vivax malaria.

MEDICATION(S)
AMBRISENTAN

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
Clinical Criteria

PULMONARY ARTERIAL HYPERTENSION
- ADCIRCA® / TADALAFIL/ ALYQ
- ADEMPAS® / RIOCIGUAT
- LETAIRIS® / AMBRISENTAN
- REVATIO® / SILDENAFIL
- TRACLEER® / BOSENTAN

Drug Class: Pulmonary Antihypertensive Agents

FDA-approved uses:
- Adcirca: Pulmonary Arterial Hypertension (PAH), WHO Group 1
- Letairis - Pulmonary Hypertension, with WHO Group 1
- Tracleer - Pulmonary Hypertension, with WHO Group 1

Adempas:
o Chronic Thromboembolic Pulmonary Hypertension
o Pulmonary Arterial Hypertension
Sildenafil: Pulmonary Hypertension

Available dosage forms:
*Adcirca: 20 mg tablet
*Adempas: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg,
*Letairis: 5 mg, 10 mg tablet
Revatio: 10 mg/ml Oral Suspension, 10 mg/12.5ml IV solution
*Sildenafil: 20 mg tablet
*Tracleer: 32mg tablet for oral suspension, 62.5 mg, 125 mg tablet
Viagra: 25 mg, 50 mg, 100 mg Tablet
*Covered on the Managed Care Common Formulary

Letairis is covered for members who meet the following criteria: Drug Class: Pulmonary Antihypertensive Agents - Endothelin Receptor Antagonists Coverage Criteria/Limitations for initial authorization:
Diagnoses: Diagnosed with primary pulmonary hypertension OR secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease by a Pulmonologist or Cardiologist
Duration of approval:
o Initial Authorization: 4 months
o Continuation of therapy: 1 year
Prescriber Specialty: Pulmonologist or cardiologist
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o WHO Group I with NYHA functional class II or III
o Patient has received adequate treatment trial with anticoagulants +/- diuretics +/- digoxin
o Acute vasoreactivity testing result:
For patients with positive testing result, documentation of a trial and failure with calcium channel blocker therapy, unless it is contraindicated, such as those with right heart failure or hemodynamic instability
OR
For patients with negative testing result, calcium channel blocker is not indicated
Age: greater than 18 years of age
Route of Administration: Oral

Criteria for continuation of therapy:

Documentation of the following is required:

o Stabilization or improvement in functional status (NYHA functional class), or

o Improvement in PAP or other measures of pulmonary hypertension

Duration of Therapy:

Initial - 4 months

Continuation - 12 months

Effective 7/1/19

MDCH COMMON - LINEZOLID (ZYVOX)

MEDICATION(S)
LINEZOLID

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
Clinical Criteria

Initial

1. Must be prescribed by or in consultation with a Infection Disease physician.
2. FDA approved indication.
3. Cultures and sensitivity labs that identify susceptibility to linezoid.

Quantity:
- 14 days (dosed Q12 hours)
- 28 days for VRE
- ID recommendation for longer course of therapy is required.

Effective 6/1/16

MEDICATION(S)
LUCEMYRA

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
LUCEMYRA / LOFEXIDINE

Drug Class Agents for Opioid Withdrawal, Central Alpha-2 Adrenergic Agonist-Type

FDA-approved uses: Indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

Available dosage forms: Tablets 0.18 mg

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Opioid dependence or opioid use disorder (OUD)
?Duration of approval:
oInitial authorization: If the criteria are met, the request will be approved for no more than 14 days
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMember is undergoing abrupt opioid discontinuation and requires agent to mitigate opioid withdrawal symptoms

oDocumentation of trial and failure of or contraindication/intolerance to clonidine tablets OR clonidine patch
oDocumentation provided that the member is undergoing a comprehensive treatment program for opioid dependence/OUD treatment (not required if the prescriber is Board Certified specialist in Addiction Medicine)
?Quantity: Maximum of 16 tablets per day for no more than 14 days
?Age: 18 years or older

MDCH COMMON - MEFLOQUINE (LARIAM)

MEDICATION(S)
MEFLOQUINE HCL

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
Clinical Criteria

1. Diagnosis of treatment or prevention of malaria.
2. Acute Treatment
   a. cultures and sensitivities to support diagnosis.
3. Prophylaxis
   a. Country or region where the patient will be traveling
   b. Date and duration of travel
   c. Use of doxycycline

Quantity: 5 tabs per 30 days

Effective 6/1/16

MEDICATION(S)
MOTEGRITY

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
MOTEGRITY / PRUCALOPRIDE

Drug class: Serotonin 5-HT4 receptor agonist, Prokinetic agent

FDA-approved uses: Chronic idiopathic constipation

Available dosage forms: 1mg tablet, 2mg tablet

Coverage criteria/Limitations for initial authorization:
?Diagnoses: FDA-approved indication of chronic idiopathic constipation
?Duration of approval:
oInitial authorization: 3 months
oContinuation of Therapy: 12 months
?Prescriber specialty: Prescribed by or in consultation with a gastroenterologist
?Documentation requirements (e.g. Labs, Medical Record, Special Studies):
oDocumented age of greater than 18 years.

oDocumented diagnosis of chronic idiopathic constipation according to the current Rome Diagnostic Criteria for constipation.
oDocumentation of lifestyle modifications including the following:
?Increased fluid intake
?Increased dietary fiber intake
?Increased mobility/exercise (if able)
oDocumentation of trial and failure or intolerance to the combined use of at least 2 of the following agents with different mechanisms of action:
?Stimulant laxatives
?Bulk-forming laxatives
?Osmotic laxatives
?Stool softeners
?Lubricants
oDocumentation of trial and failure or intolerance to both polyethylene glycol and lactulose for a minimum period of 14 days.
oDocumentation of trial and failure or intolerance to lubiprostone (Amitiza) for a minimum period of 3 months:
oDocumentation of renal function with creatinine clearance (CrCl) and serum creatinine (SCr).
oDocumentation of appropriate monitoring for worsening depression or emergence of suicidal ideation/behavior.
oDocumentation that Motegrity will not be used in combination with other functional gastro-intestinal disorder drugs (Amitiza, Linzess, Relistor, Symproid, Movantik, Trulance, or Zelnorm).
o
?Quantity: 1 tablet per day
oCrCl greater than 30 mL/min: 2 mg daily
oCrCl less than 30 mL/min: 1 mg daily
?Age: greater than 18 years of age
?Gender: Male and female
?Route of administration: Oral
?Place of service: Retail pharmacy

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of a positive response to therapy using the following measures:
?Greater than 3 complete spontaneous bowel movements per week
?Increase of greater than 1 complete spontaneous bowel movement per week for at least 9 out 12 weeks, including 3 of the last 4 weeks
?Decrease in both straining during defecation and incidences of incomplete evacuation
oContinued monitoring and documentation of renal function and emergence of suicidal ideation/behavior.

Contraindications/Exclusions/Discontinuation:
?Contraindications include hypersensitivity to Motegrity, known or suspected intestinal perforation or obstruction, obstructive ileus, and severe inflammatory conditions of the gastrointestinal tract including Crohn's disease and ulcerative colitis.
?Use of Motegrity for indications other than chronic idiopathic constipation are considered off-label and are excluded.
?Motegrity should not be used in patients with end stage renal disease requiring dialysis. A reduced dose is recommended in patients with severe renal impairment. The recommended dose in patients with severe renal impairment (CrCl less than 30 mL/min) is 1 mg once daily.
?Motegrity has not been studied in combination with other functional gastrointestinal disorder agents including laxatives and secretory agents and therefore should not be combined with these agents.
?Motegrity should be discontinued if a patient demonstrates unusual changes in mood or behavior consistent with worsening depression or emergence of suicidal ideation/behavior.

Other special considerations:
?Motegrity should not be used in patients with known history of suicidal ideation/behavior.
?Due to limited data regarding use in pregnancy, Motegrity should not be used in pregnancy or in patients planning to become pregnant.
?Motegrity is present in breast milk, due to limited data regarding use in lactation, Motegrity should be used with caution only when the benefits to the mother outweigh the risks of infant exposure.

Effective 1/1/20

MEDICATION(S)

NAPROXEN 125 MG/5 ML SUSPEN

COVERED USES

Diagnosis of:

a. Relief of the signs and symptoms of Rheumatoid Arthritis

b. Relief of the signs and symptoms of Osteoarthritis

c. Relief of the signs and symptoms of Ankylosing Spondylitis

d. Relief of the signs and symptoms of Juvenile Rheumatoid Arthritis

EXCLUSION CRITERIA

Contraindications/Exclusions/Discontinuation:

a. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

a. Trial and failure of Ibuprofen Suspension OR

b. Clinical reason that Ibuprofen Suspension cannot be used

AGE RESTRICTION

Age: 12 years of age and under

PRESCRIBER RESTRICTION

Prescriber Specialty: Rheumatologist

COVERAGE DURATION

N/A

OTHER CRITERIA

Effective 4/1/2018

MEDICATION(S)
FULPHILA, GRANIX, NEUPOGEN, ZARXIO

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
GRANULOCYTE COLONY-STIMULATING FACTOR (G-CSF)
GRANIX® (TBO-FILGRASTIM)
NEUPOGEN® (FILGRASTIM) ZARXIO™ (FILGRASTIM-SDZ)
FULPHILA™ (PEGFILGRASTIM-JMDB)

Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).

Drug Class: Granulocyte Colony-Stimulating Factor (G-CSF)
FDA-approved uses:

?Granix:
oreduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

?Neupogen & Zarxio:
oTo decrease the duration of neutropenia in patients undergoing myeloablative chemotherapy followed by marrow transplantation for non-myeloid malignancies
oTo decrease the incidence of infections from febrile neutropenia in patients with non-myeloid malignancies who are receiving myelosuppressive chemotherapy
oTo reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia
oTo reduce the incidence and duration of neutropenia sequelae, including fever, infections, or oropharyngeal ulcers, in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
oMobilization of hematopoietic progenitor cells before autologous stem cell transplant
oMobilization of hematopoietic progenitor cells in the donor before allogenic stem cell transplant
oTreatment of acute radiation exposure, to increase survival, in patients who receive myelosuppressive doses of radiation at a dose of 2 gray (Gy)

?Fulphila:
oto decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Available dosage forms:

Granix:
?Injection: 300 mcg/mL solution in single-dose vials
?Injection: 480 mcg/1.6 mL solution in single-dose vials
?Injection: 300 mcg/0.5 mL solution in single-use prefilled syringe
?Injection: 480 mcg/0.8 mL solution in single-use prefilled syringe

Neupogen
?Injection: 300 mcg/mL in a single-use vial
?Injection: 480 mcg/1.6 mL in a single-use vial
?Injection: 300 mcg/0.5 mL in a single-use prefilled syringe
?Injection: 480 mcg/0.8 mL in a single-use prefilled syringe

Zarxio:
?Injection: 300 mcg/0.5 mL in a single-use prefilled syringe
?Injection: 480 mcg/0.8 mL in a single-use prefilled syringe

Fulphila:
?Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only.

Coverage Criteria/Limitations for initial authorization:
?Diagnoses:
FDA approved indications detailed above

oChemotherapy-induced neutropenia
?Chemotherapy regimen is identified as having a high overall risk (greater than 20%) of febrile neutropenia#
OR
?Chemotherapy regimen is identified as having an intermediate overall risk (10% - 20%) of febrile neutropenia# AND
?Member is at high-risk for neutropenic complications (e.g., age greater than 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities)
OR
?Patient experienced a neutropenic complication from a prior cycle of the same chemotherapeutic regimen
?Administered 24 – 72 hours after completion of chemotherapy
?Patient is not receiving concurrent chemotherapy and radiation therapy

#National Comprehensive Cancer Network. Myeloid Growth Factors (Version 2.2018 – August 3, 2018) Pages MGF-A.1 (Regimens with High Risk) and MGF-A.2 (Regimens with Intermediate Risk) https://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf

Agent Coverage for Diagnosis 1

Tbo-filgrastim (Granix®) is considered medically necessary as first line therapy

Second line therapy of Filgrastim-sndz (Zarxio™) may be covered when:

?First Tbo-filgrastim (Granix®) has been tried and failed, OR
?There is a contraindication to the use of Tbo-filgrastim (Granix®) OR
?Patient is less than 18 years old OR
?Patient issues related to geographic challenges and an inability to self-administer GCSF may be considered for coverage of the longer acting second line agents on a case by case basis.

Third line therapy of Filgrastim (Neupogen®) may be covered when:

•Second line therapy of Filgrastim-sndz (Zarxio™) has been tried and failed, OR
•There is a contraindication to the use of Filgrastim-sndz (Zarxio™)
Pegylated Filgrastim Requests:

Fulphila™ (Pegfilgrastim-jmdb) – Formulary (preferred)
Neulasta® (Pegfilgrastim) – Non-formulary
Udenyca™ (Pegfilgrastim-cbqv) – Non-formulary

•Trial and failure of, or contraindication to, one preferred filgrastim product
oTbo-filgrastim (Granix®)
oFilgrastim-sndz (Zarxio™)

•If Fulphila™ is approved, the following dosing and administration recommendations apply:
oThe recommended dosage of Fulphila is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
oFor dosing in pediatric patients weighing less than 45kg, the following weight based dosing is recommended:
?Less than 10 kg = 0.1 mg/kg
?10-20 kg = 1.5 mg (0.15 mL)
?21-30 kg = 2.5 mg (0.25 mL)
?31-44 kg = 4mgg (0.4 mL)
oNot to be administered within 14 days before and 24 hours after administration of cytotoxic chemotherapy.

oTreatment of neutropenia
?Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
?Drug-induced neutropenia in immunosuppressed patients
•Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR
•Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR
•Patient has a documented bacterial infection
?Myeloid reconstitution after autologous or allogenic or autologous bone marrow transplant
•Patient has a non-myeloid malignancy
?Following reinfusion of peripheral blood stem cells (PBSCs)

oPeripheral blood stem cell (PBSC) mobilization
?Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation

oAcute radiation exposure
?Following exposure to myelosuppressive doses of radiation at a dose of 2gray (GY)
Agent Coverage for Diagnoses 2-4

Filgrastim-sndz (Zarxio™) is considered medically necessary as first line therapy for patients at risk of

severe febrile neutropenia

Second line therapy of Filgrastim (Neupogen®) may be covered when:

o First Filgrastim-sndz (Zarxio™) has been tried and failed, OR
o Member requires a does less than 0.3 ml (180mcg) OR
    o There is a contraindication to the use of Filgrastim-sndz (Zarxio™)

?CSFs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMedical Record which documents the FDA approved indication and Absolute neutrophil count (ANC)
?Prescriber Specialty: Prescribed by hematologist and/or oncologist, or other specialist per associated diagnosis/indication
?Quantity:
oChemotherapy-induced neutropenia (primary or secondary prophylaxis):
?Approve per cycle of chemotherapy up to a 14 day supply
?Include refills if number of cycles is provided
oTreatment of neutropenia (e.g., congenital, cyclic, or idiopathic, or after chemo + BMT):
?Approve for 3 months
?Gender: Male or Female
?Route of Administration: Subcutaneous
?Place of Service: Outpatient

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oChemotherapy-induced neutropenia (primary or secondary prophylaxis):
?Recent ANC showing a response to therapy
?Approve per cycle of chemotherapy up to a 14 day supply
?Include refills if number of cycles is provided
oAll other indications:
?Recent ANC
?Approve every 30 days.

Contraindications/Exclusions/Discontinuation:

•Contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim
•In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Updated 4/1/19

MEDICATION(S)

OCTREOTIDE 1,000 MCG/5 ML VIAL, OCTREOTIDE 1,000 MCG/ML VIAL, OCTREOTIDE 5,000 MCG/5 ML VIAL, OCTREOTIDE ACET 0.05 MG/ML VL, OCTREOTIDE ACET 100 MCG/ML AMP, OCTREOTIDE ACET 100 MCG/ML VL, OCTREOTIDE ACET 200 MCG/ML VL, OCTREOTIDE ACET 50 MCG/ML AMP, OCTREOTIDE ACET 50 MCG/ML VIAL

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

Clinical criteria

Initial

1. Patient must be 18 years of age or older.
2. Must be prescribed by or in consultation with an endocrinologist.
3. Documented diagnosis of:
   a. Acromegaly
   b. Metastatic VIP
   c. Chemotherapy or radiations
   d. HIV AIDS induced diarrhea
   e. Metastatic carcinoid tumors
   f. Carcinoid Tumors

Continuation

1. All of the above criteria initial criteria must be applicable.
2. Documentation of decreased or normalized IGF 1 levels.
3. Claims documentation of compliance with prescribed therapy.

Effective 6/1/16

MEDICATION(S)
OLUMIANT

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
OLUMIANT (BARICITINIB)

Drug Class: Janus kinase (JAK) inhibitor

FDA-approved uses: Moderate to severe RA in adults who have not responded well enough to or could not tolerate at least one tumor necrosis factor (TNF) antagonist.

Available dosage forms: 1mg oral tablet, 2mg oral tablet

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Moderate to severe RA in adults who have not responded well enough to or could not tolerate at least one tumor necrosis factor (TNF) antagonist
?Duration of approval:
oInitial authorization: 3-months
oContinuation of Therapy: 12-months
?Prescriber Specialty: Prescribed by or in consultation with a Rheumatologist

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
1.Documentation of a negative TB test in the past 12 months.
2.The patient has had a documented trial (minimum 3 months) with at least one of the following DMARDs of (methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) or documented contraindication or clinically significant adverse effects are experienced.
3.Documented failure of two of the following (Cimzia, Humira, Enbrel or infliximab), each used for 3 months or greater or documented contraindication or clinically significant adverse effects are experienced.
?Quantity: 1 per day (1mg only to be used for patients with renal impairment)
?Age: 18 years of age or older
?Route of Administration: oral
Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
1.Patient is compliant on therapy.
2.? 20% improvement or maintenance in tender joint count or swollen joint count while on therapy.

Contraindications/Exclusions/Discontinuation:
Limitation(s) of use: Use of Olumiant in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Updated 4/1/20

MEDICATION(S)
OMEGA-3 ACID ETHYL ESTERS

COVERED USES
Documented diagnosis of hypertriglyceridemia, adjunct to diet in adults with triglyceride levels 500mg/dL or higher

EXCLUSION CRITERIA
Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
Initial

1. Trial, failure, intolerance or contraindication to at least two formulary fibric acid derivatives (fenofibrate, gemfibrozil)

Continuation

1. Documentation that patient is responsive to treatment.

Effective 6/1/16

MEDICATION(S)

ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALKERAN 2 MG TABLET, BEXAROTENE, CAPECITABINE, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, EMCYT, ERIVEDGE, ERLEADA, ETOPOSIDE 50 MG CAPSULE, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FARESTON, FARYDAK, FLUTAMIDE, GLEOSTINE, HEXALEN, HYCAMTIN 1 MG CAPSULE, IDHIFA, INTRON A 10 MILLION UNITS VIAL, INTRON A 18 MILLION UNIT/3 ML, INTRON A 25 MILLION UNIT/2.5ML, INTRON A 50 MILLION UNITS VIAL, JAKAFI, LEUKERAN, LEUPROLIDE 2WK 1 MG/0.2 ML KIT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LONSURF, LYSODREN, MATULANE, MESNEX 400 MG TABLET, MYLERAN, NILUTAMIDE, ODOMZO, POMALYST, REVLIMID, TABLOID, TEMOZOLOMIDE, THALOMID, TIBSOVO, TRETINOIN 10 MG CAPSULE, XATMEP, XTANDI, ZOLINZA

COVERED USES

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oProper diagnosis of an FDA Approved Indication OR
oIf request is for a non-FDA Approved indication, the request must be for a “medically accepted indication” as noted in the following Compendia:
?American Hospital Formulary Drug Service (AHFS-DI)
?NCCN Drugs and Biologic Compendium/ NCCN Guidelines
•Categories 1, 2a, and 2b will be accepted. (See Table 1 for explanation of Categories)
?Micromedex DrugDex
?Clinical Pharmacology
oMember must be under the care of an Oncologist
oDocumentation of dose and dates of all previous therapy and the resulting outcomes
oDocumentation that the proper succession of the therapies has been tried and failed (i.e. intolerance, contraindication, or progression)
oChart notes detailing the member’s current clinical status
oRelated lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment

EXCLUSION CRITERIA

oPatient has any contraindications to the use of any requested ingredients
oRequest is for experimental/investigational use
oMember is enrolled in a clinical trial
•Hypersensitivity to the requested agent or any component of the formulation
•Member at risk through drug-drug interactions of contraindications noted in the package insert
•Patient is noncompliant with medical or pharmacologic therapy
•No demonstrable clinically significant improvement in condition has occulted after initiation of

drug therapy

REQUIRED MEDICAL INFORMATION

oDocumentation of dose and dates of all previous therapy and the resulting outcomes
oDocumentation that the proper succession of the therapies has been tried and failed (i.e. intolerance, contraindication, or progression)
oChart notes detailing the member's current clinical status
oRelated lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment

?Dosing:
oAs noted in Package Insert
oAs noted in Above described Compendium

Criteria for continuation of therapy
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oCurrent chart notes detailing response and compliance to therapy
oDocumented clinically significant improvements in the disease state, and stability on the medication

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be written by an oncologist.

COVERAGE DURATION

Duration of Approval:
oInitial Authorization: 3 months
oContinuation of Therapy: 3 month increments

OTHER CRITERIA

Effective 6/1/16
Updated: 7/1/20

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
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
ORENCIA-SQ/ ABATACEPT-SQ

Drug Class: Selective T cell costimulation modulator

FDA-approved uses:
?Rheumatoid Arthritis (RA)
?Juvenile Idiopathic Arthritis (JIA)
?Psoriatic Arthritis (PsA)

Available dosage forms: Subcutaneous injection: 50mg/0.4ml, 87.5mg/0.7ml, 125mg/ml solution in single-dose prefilled syringes, 125mg/ml in a single-dose prefilled ClickJectTM autoinjector

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approved indications detailed above
?Duration of approval:

oInitial authorization: 6 months
oContinuation of Therapy: 1 year
?Prescriber Specialty: Therapy is prescribed by or in consultation with a rheumatologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of a negative TB test in the past 12 months
oDocumentation that member has been screened for viral hepatitis (Hep B) prior to starting therapy
oRheumatoid Arthritis (RA): (age 18 years or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate OR
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. Orencia 125mg in prefilled syringes or in Orencia ClickJectTM autoinjector should be administered by subcutaneous injection once weekly and may be initiated with or without an intravenous loading dose. For patients initiated with an intravenous loading dose, Orencia should be initiated with a single intravenous infusion, followed by the first 125mg subcutaneous injection administered within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. Max 4 syringes/28 days
oJuvenile Idiopathic Arthritis (JIA): (age 2 years or older)
?Trial and failure of methotrexate for at least 4 to 6 weeks or contraindication/intolerance to methotrexate OR
?Patient has tried and failed at least one other non-biologic DMARD for 3 months
OR
?Provider states that there has been rapid disease progression
oOrencia may be used as monotherapy or concomitantly with methotrexate. The safety and efficacy of Orencia ClickJect auto-injector for subcutaneous injection has not been studied in patients under 18 years of age.
oQuantity: Based on FDA dosing. Orencia for subcutaneous injection should be initiated without an intravenous loading dose and be administered utilizing the weight range-based dosing as specified below:

Body Weight of Patient	Dose (ONCE WEEKLY)
10 to less than 25kg	50mg
25 to less than 50kg	87.5mg
50kg or more	125mg

The safety and efficacy of Orencia ClickJectTM autoinjector has not been studied in patients under 18 years of age

oPsoriatic Arthritis (PsA): (age 18 or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate OR
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. 125mg once weekly without the need for an intravenous loading dose. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. Max 4 syringes/28 days
?Route of Administration: Subcutaneous injection
?Place of Service: Self-administered

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oThe patient has experienced symptomatic improvement or maintained stable clinical status.
oMember continues to have yearly negative TB test

Contraindications/Exclusions/Discontinuation:
oShould not be given concomitantly with TNF antagonists
oTherapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Updated 4/1/20

MEDICATION(S)
OTEZLA

COVERED USES
Documented diagnosis of psoriatic arthritis or plaque psoriasis.

EXCLUSION CRITERIA
oTherapy may he discontinued if the patient is noncompliant with medical or pharmacological therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
oPatient receiving additional biologic DMARD therapy.

REQUIRED MEDICAL INFORMATION
Plaque Psoriasis
•Clinically diagnosed with moderate to severe chronic plaque psoriasis
•Involvement of greater than 10% of body surface area (unless hands, feet, head, neck, or genitalia are involved)
•Trial and failure of at least one topical agent
•Trial and failure of UVB or PUVA therapy or contraindication to therapy
•Trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate
•Trial and failure of at least one additional systemic treatments (azathioprine, cyclosporine, or acitretin) or contraindication/intolerance to systemic treatment

Psoriatic arthritis
•Trial and failure of methotrexate for at least 90 consecutive days in the previous 120 day period, or contraindication/intolerance to methotrexate
•Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance

AGE RESTRICTION
Must be 18 years of age or older.

PRESCRIBER RESTRICTION
Must be prescribed by a dermatologist or rheumatologist per diagnosis

COVERAGE DURATION
Initial 3 months

Renewal 12 months

Otezla Starter Pack: 1/365 days

OTHER CRITERIA

Effective 7/1/17

Updated 7/1/2018

MEDICATION(S)
OXBRYTA

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
OXBRYTA® / VOXELOTOR

Drug Class: Sickle Hemoglobin (HbS) Polymerization Inhibitor

FDA-approved uses: sickle-cell disease

Available dosage forms: 500mg Tablet

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: sickle-cell disease
?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: 1 year
?Prescriber Specialty: Prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

oPatient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months AND
oBaseline hemoglobin level between 5.5 g/dL and 10.5g/dL AND
oPatient is not receiving concomitant chronic, prophylactic blood transfusion therapy
oWill not be approved for use in combination with Adakveo (crizanlizumab-tmca)

?Age: ? 12 years of age
?Quantity: 90 tablets/30 days
?Route of Administration: oral
?Place of Service: outpatient

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient must show an increase in hemoglobin by ?1 g/dL from initial baseline OR
oPatient has experienced a reduction in sickle cell-related vaso-occlusive crises AND
oPatient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca) AND
oPatient is not receiving concomitant chronic, prophylactic blood transfusion therapy

Contraindications/Exclusions/Discontinuation:
?Patient has not shown an increase in hemoglobin by ?1 g/dL from baseline OR
?Patient has experienced an increase in sickle cell-related vaso-occlusive crises OR
?Patient is receiving Adakveo (crizanlizumab-tmca) therapy OR
?Patient is undergoing active concomitant chronic, prophylactic blood transfusion therapy

Updated 7/1/20

MEDICATION(S)
OXERVATE

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
OXERVATETM (CENEGERMIN-BKBJ)

Drug Class: Recombinant human nerve growth factor (rhNGF)

FDA-approved uses: Indicated for the treatment of neurotrophic keratitis

Available dosage forms: Ophthalmic solution, 0.002% (per mL)

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approved indications as listed above
?Duration of approval:
oInitial authorization: 56 days
?Prescriber Specialty: Prescribed by, or in consultation with, an ophthalmologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oAttestation that the patient or caregiver has been counseled on proper administration technique
oDocumentation that the member has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage

3 (corneal ulcer) neurotrophic keratitis in affected eye(s)
oDocumentation that the member has tried and failed at least two conventional non-surgical treatments (e.g. preservative-free artificial tears, lubricant eye ointment, topical antibiotic eye drops, therapeutic contact lenses)
?Quantity: 28 vials every 28 days for the treatment of one eye (additional quantities may be approved for the treatment of the second eye when appropriate). Total of 8 kits (1 kit = 7 multi-dose vials) per affected eye per lifetime.
?Age: 2 years of age or older
?Route of Administration: Topical eye drop

Updated 7/1/20

MEDICATION(S)
PULMOZYME

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
Drug Class: Mucolytics
FDA-approved uses:
? In conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.
? To reduce the risk of respiratory tract infections requiring parenteral antibiotics in CF patients with an FVC ? 40% of predicted.
Available dosage forms: 2.5 mg/2.5 mL in single-use ampules
Coverage Criteria/Limitations for initial authorization:
? Diagnoses: cystic fibrosis
? Duration of Approval:
o Initial Authorization: 1 year
o Continuation of Therapy: 1 year
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Medical records to support a diagnosis of CF
? Prescriber Specialty:
o Pulmonologist

o Infectious disease
? Quantity: 30 ampules per 30 days
? Age: at least 5 years of age
? Gender: male or female
? Route of Administration: inhalation
? Place of Service: outpatient
Criteria for continuation of therapy:
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o FVC
o Medical records showing stable disease
o Medical records supporting decreased incidence of respiratory infections
Contraindications/Exclusions/Discontinuation:
• Pulmozyme®
(dornase alpha) is not authorized for non-FDA-approved indication
• Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
OR no demonstrable clinically significant improvement in condition has occurred after initiation
of drug therapy.
Other special considerations:
• Per FDA-approved label: Pulmozyme®
(dornase alpha) was studied in patients 3 months to 5
years of age, while clinical trial data are limited in patients less than 5 years, the use of Pulmozyme®
(dornase alpha) should be considered for pediatric patients with CF who may experience
potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

MEDICATION(S)
RANOLAZINE ER

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
Clinical Criteria

1. Documented diagnosis of chronic angina.
2. Claims documentation or chart notes supporting medication usage of at least 1 formulary anti-anginal agent and ALL 3 drug classes

Beta Blocker: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
Calcium Channel Blocker: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
Long Acting Nitrate: isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch

3. Documentation detailing that Ranexa will be used in addition (add-on) to another anti-anginal medication (i.e., beta-blocker, calcium channel blocker, long-acting nitrate) or patient has contraindications to beta-blockers, calcium channel blockers AND long-acting nitrates.

4. Documentation that patient does not have any contraindications such as
- Hepatic impairment (Child-Pugh Classes A and B)

- Combined administration with other drugs that are strong inhibitors of CYP3A including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir
- Combined administration with other drugs that are inducers of CYP3A including rifampin, rifabutin, phenobarbitol, phenytoin, carbamazepine, and St. John's wort
- Moderate to severe renal impairment CrCl LT 60mL per min

Quantity Limit: 60 tabs per 30 day supply

Authorization:

Initial 6 months

Renewal 12 months

Effective 4/1/17

MEDICATION(S)
RENAGEL, SEVELAMER CARBONATE 800 MG TAB

COVERED USES
Indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis

EXCLUSION CRITERIA
Bowel obstruction.

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
Serum Phosphorus

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a nephrologist

COVERAGE DURATION
N/A

OTHER CRITERIA
Initial

1. Documentation of hyperphospatemia.
2. Documented trial and failure of calcium acetate.

Continuation
1. Current labs for serum phosphorus
2. Claims documentation of compliance with therapy.

Effective 6/1/16

MEDICATION(S)

INVOKAMET, INVOKAMET XR, INVOKANA, JARDIANCE, SEGLUROMET, STEGLATRO, SYNJARDY, SYNJARDY XR

COVERED USES

Single Ingredient SGLT-2 Inhibitor

Type 2 diabetes mellitus: Treatment of type 2 diabetes mellitus (noninsulin dependent) as an adjunct to diet and exercise to improve glycemic control

Invokana Only: Added indication for the reduction of cardiovascular mortality and major cardiovascular events (MACE) in type 2 diabetes mellitus patients with established cardiovascular disease.

Combination SGLT-2 Inhibitor

Type 2 diabetes mellitus: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (non-insulin dependent NIDDM) who are not adequately controlled on a regimen containing metformin or individual SGLT-2 agents, or in patients who are already treated with both an individual SGLT-2 and metformin.

EXCLUSION CRITERIA

•Hypersensitivity to any component of the formulations,

•Severe renal impairment (eGFR less than 30 ml/minute/1.73m2)

•End-stage renal disease

•Patient on dialysis

•In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION

Coverage Criteria/Limitations for initial authorization

?Diagnoses: FDA Approved Indication as listed above

?Duration of Approval:

oInitial Authorization: 6 months

oContinuation of Therapy: 6 months

?Age: ? 18 years of age

Single Ingredient SGLT-2 Inhibitor

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

oTrial, failure or intolerance to Metformin + formulary sulfonylurea, TZD or DPP-4 agent in the past 120

days
oA1C must be less than or equal to 9
Combination SGLT-2 Inhibitor
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oClinically document successful treatment with individual components of the product for at least 60 of the most recent 120 days
oA1C must be less than or equal to 9

AGE RESTRICTION
18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
SGLT-2 INHIBITOR
INVOKANA® / CANAGLIFLOZIN
JARDIANCE® / EMPAGLIFLOZIN
STEGLATRO™/ERTUGLIFLOZIN

COMBINATION SGLT-2 INHIBITOR
INVOKAMET® / CANAGLIFLOZIN & METFORMIN
INVOKAMET XR® / CANAGLIFLOZIN & METFORMIN
SYNJARDY® / EMPAGLIFLOZIN & METFORMIN
SYNJARDY XR® / EMPAGLIFLOZIN & METFORMIN
SEGLUROMET™ /ERTUGLIFLOZIN & METFORMIN

Drug Class: Antihyperglycemic – SGLT-2 Inhibitor & Biguanide Combination
FDA-approved uses:
Single Ingredient SGLT-2 Inhibitor
Type 2 diabetes mellitus: Treatment of type 2 diabetes mellitus (noninsulin dependent) as an adjunct to diet and exercise to improve glycemic control

Invokana Only: Added indication for the reduction of cardiovascular mortality and major cardiovascular events (MACE) in type 2 diabetes mellitus patients with established cardiovascular disease.

Combination SGLT-2 Inhibitor
Type 2 diabetes mellitus: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (non-insulin dependent NIDDM) who are not adequately controlled on a regimen containing metformin or individual SGLT-2 agents, or in patients who are already treated with both an individual SGLT-2 and metformin.

Available dosage forms:
Single Ingredient Products
?Invokana Tablet 100 mg, 300 mg
?Jardiance Tablet 10 mg, 25 mg
?Steglatro Tablet 5mg, 15mg
Combination Ingredient Products
?Invokamet Tablet 50 mg/500 mg, 150 mg/500 mg, 50 mg/1000 mg, 150 mg/1000 mg
?Invokamet XR Tablet 50 mg/500 mg, 150 mg/500 mg, 50 mg/1000 mg, 150 mg/1000 mg
?Synjardy Tablet 5/500 mg, 12.5/500 mg, 5/1000 mg, 12.5/1000 mg
?Synjardy XR Tablet 5/1000 mg, 10/1000 mg, 12.5/1000 mg, 25/1000 mg
?Segluromet tablets 2.5mg/500mg, 2.5mg/1,000mg, 7.5mg/500mg, 7.5mg/1,000mg
?
Coverage Criteria/Limitations for initial authorization
?Diagnoses: FDA Approved Indication as listed above
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Therapy: 6 months
?Age: ? 18 years of age
Single Ingredient SGLT-2 Inhibitor
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oTrial, failure or intolerance to Metformin + formulary sulfonylurea, TZD or DPP-4 agent in the past 120 days
oA1C must be less than or equal to 9
Combination SGLT-2 Inhibitor
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oClinically document successful treatment with individual components of the product for at least 60 of the most recent 120 days
oA1C must be less than or equal to 9
Criteria for continuation of therapy:
Single Ingredient SGLT-2 Inhibitor
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient responding to treatment
oPatient tolerating treatment
oeGFR must be greater than 45ml/min/1.73m2

Combination SGLT-2 Inhibitor
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient responding to treatment
oPatient tolerating treatment

Contraindications/Exclusions/Discontinuation:
•Hypersensitivity to any component of the formulations,
•Severe renal impairment (eGFR less than 30 ml/minute/1.73m2)
•End-stage renal disease
•Patient on dialysis
•In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 6/1/16
Updated 1/1/20

MEDICATION(S)
SILDENAFIL 20 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
N/A

OTHER CRITERIA
Clinical Criteria

Sildenafil is covered for members who meet the following criteria: Drug Class: Pulmonary Antihypertensive Agents - Selective c-GMP PDE Type 5 Inhibitor Coverage Criteria/Limitations for initial authorization:
Diagnoses: Pulmonary Arterial Hypertension, WHO Group I with symptoms
Duration of approval:
o Initial Authorization: 1 year
o Continuation of therapy: 1 year
Prescriber Specialty: Pulmonologist or Cardiologist
Documentation Requirements- (e.g. Labs, Medical Record, Special Studies):
o Report with pretreatment results from right heart catheterization:
Member has PAH defined as WHO Group 1 of pulmonary hypertension
PAH was confirmed by one of the below:
•Pretreatment right heart catheterization with all of the following results:
oMPAP greater than 25mmHg
oPCWP less than 15 mmHg

oPVR greater than 3 Wood units
OR
•For infants less than one year of age with any of the following conditions, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed:
o Post cardiac surgery
o Chronic Heart Disease
o Chronic lung disease associated with prematurity
o Congenital diaphragmatic hernia
Member has NYHA functional Class II or III symptoms
Route of Administration: Oral-tablet or suspension

Sildenafil: continued
Place of Service: Outpatient /Home
Dosage: Use of Revatio, especially long term, is not recommended for children. If used in children, must use cautiously. After 2 years of treatment, increased mortality seen in long-term use at higher doses (20-80 mg-weight dependent):
o For members who are less than 18 years of age (tablets or suspension): maximum 30 mg per day
o For members who are greater than 18 years of age (tablets only):
For initial therapy: maximum 60 mg per day
For continuation of therapy: maximum 240 mg per day for members who have been titrated without difficulty and have clinically benefited.

Criteria for continuation of therapy:
Documentation of the following is required:
o All initial authorization criteria must be met.

Contraindications/Exclusions/Discontinuation:
Use of organic nitrates medication (e.g. Nitroglycerin, isosorbide dinitrate) on a regular or intermittent basis is contra-indicated.
Concomitant treatment with guanylate cyclase stimulator (e.g. Adempas) is contraindicated.
Hypersensitivity reaction to this product.

Other special considerations:

- Renal function impairment: No dosage adjustment required for any degree of impairment.
- Hepatic function impairment: No need for dosage adjustment for mild to moderate impairment, has not been studied in patient with severe impairment.
- Cardiovascular disease: Use cautiously in patient with hypotension, uncontrolled hypertension, life-threatening arrhythmias, stoke or MI within the last 6 months and other cardiac conditions.
- Not recommended in patient with pulmonary veno-occlusive disease.
- Risk of hearing loss, color discrimination, vision loss.
- Safety in patients with sickle cell anemia, a bleeding disorder or peptic ulcer disease has not been established.

Duration of Approval: 1 year

Effective 7/1/19

MEDICATION(S)
SILIQ

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
SILIQ/ BRODALUMAB

Drug Class: Interleukin-17 receptor

FDA-approved uses:
?Plaque psoriasis (PsO)

Available dosage forms: Subcutaneous injection: 210mg/1.5 ml solution in a single-dose prefilled syringe

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: plaque psoriasis (PsO)
?Duration of Approval:
oInitial Authorization: 6 months
oContinuation of Approval: 1 year
?Prescriber Specialty: Therapy is prescribed by or in consultation with a dermatologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies)

oDocumentation of a negative TB test within last 12 months
oPatients has greater than 10% BSA involvement or affected area includes palms, soles, head, neck, or genitalia
oTrial and failure of methotrexate for 90 consecutive days in the previous 120-day period, or contraindication to methotrexate
oTrial and failure of a 90-day trial of Otezla
oTrial and failure or intolerant to topical agents and one additional systemic therapy (cyclosporine, or acitretin)
oTrial and failure of UVB or UVA therapy or contraindication to therapy
oTrial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oPrescriber and patient must be enrolled in the Siliq REMS program
?Quantity: Based on FDA dosing. 210 mg by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks
?Route of Administration: Injection
?Place of Service: Self-administered

Criteria for continuation of therapy: Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oThe patient has experienced symptomatic improvement or maintained stable clinical status.
Contraindications/Exclusions/Discontinuation:
oTherapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
oPatient receiving additional biologic DMARD therapy.
oCrohn’s disease

Updated 1/1/20

MEDICATION(S)
SPIRIVA RESPIMAT 1.25 MCG INH

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
SPIRIVA RESPIMAT / TIOTROPIUM

Drug Class: Asthma/COPD – Anticholinergic Agents, Inhaled Long Acting

FDA-approved uses: Maintenance treatment of Asthma

Available dosage forms: Spiriva Respimat 1.25 mcg/actuation inhalation

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Asthma
?Duration of approval:
oInitial authorization: 1 year
oContinuation of Therapy: for up to 1 year
?Prescriber Specialty:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oMember must have used at least a medium-dose inhaled corticosteroid AND long-acting beta2 agonist

(ICS/LABA) product for at least the past 2 months while being compliant on treatment, and
oMember must have a history of exacerbations despite required trials, and
oMember requires rescue inhaler more than two days per week or requires oral systemic steroids despite compliance on required trials, and
oMember must remain on an ICS or ICS/LABA while on tiotropium therapy
?Quantity: 1 inhaler (4 grams) per 30 days
?Age: 6 years and older

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies): improvement and compliance on treatment AND continue on an ICS or ICS/LABA while on tiotropium

Contraindications/Exclusions/Discontinuation:
?Spiriva Respimat will not be approved for COPD indication

MEDICATION(S)

SUMATRIPTAN 20 MG NASAL SPRAY, SUMATRIPTAN 5 MG NASAL SPRAY, SUMATRIPTAN 4 MG/0.5 ML CART, SUMATRIPTAN 4 MG/0.5 ML INJECT, SUMATRIPTAN 6 MG/0.5 ML INJECT, SUMATRIPTAN 6 MG/0.5 ML VIAL

COVERED USES

Diagnosis: Migraine

EXCLUSION CRITERIA

Contraindications/Exclusions/Discontinuation:

a. History, symptoms, or signs of ischemic cardiac disease, peripheral vascular disease, uncontrolled hypertension.

b. Within 24 hours of ergot?type drugs or within 2 weeks of discontinuing MAOIs

c. Basilar headaches or hemiplegic migraine

d. Hypersensitivity to sumatriptan or any of its components.

e. Patients with Hepatic Impairment Dosing

i. Hepatic impairment may cause unpredictable increases in the bioavailability of orally administered sumatriptan. Do not exceed 50 mg/dose PO. Hepatic impairment does not significantly affect intranasal or subcutaneous sumatriptan. All formulations are contraindicated for use in patients with severe hepatic impairment.

f. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

i. Poor response to treatment as evidenced by physical findings and/or clinical symptoms following the initial 12 weeks approval for coverage

ii. Intolerable adverse effects or drug toxicity

REQUIRED MEDICAL INFORMATION

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

a. Documentation of migraine induced vomiting

b. Failed/intolerant to at least one formulary preferred alternative products (triptans) tablet

i. Sumatriptan tablet

ii. Naratriptan tablet

iii. Rizatriptan tablet

AND

c. Failed/intolerant to at least one formulary preferred alternative products (triptans) orally disintegrating tablet

i. Rizatriptan ODT tablet

AGE RESTRICTION

Age: Adults. Safety and efficacy has not been determined for adolescents and children

PRESCRIBER RESTRICTION

Prescriber Specialty: Neurologist or pain management specialist

COVERAGE DURATION

a. Initial: up to 12 wks

b. Cont: Re-auth req every 6 mos based on documented positive clinical resp

OTHER CRITERIA

Criteria for Continuation of Therapy

a. Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

i. Maintenance therapy may be authorized when therapy has demonstrated efficacy as evidenced by an improvement in symptom management after initial therapy.

ii. Documentation of improvement is required for continuation of therapy.

Quantity:

a. Injection

i. Maximum 4mL per month

ii. 6mg SC per headache, may repeat 1 hour after first dose, maximum 12mg/day

b. Nasal Spray

i. 6 Unit per 30 days

Effective 6/1/16

Updated 7/1/2018

MEDICATION(S)
SYNAGIS

COVERED USES
Prevention of RSV for children less than 2 years old at high risk of RSV disease
Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis®) may be considered medically necessary in the following infants and children to a maximum of five monthly doses:

? Prematurity:
  o Infants who are younger than 12 months of age at the start of RSV season and are born before 29 weeks 0 days gestation.
? Chronic Lung Disease (CLD):
  o Preterm infants younger than 12 months of age who develop CLD of prematurity (defined as gestational age less than 32 weeks, 0 days) and required greater than 21% oxygen for at least the first 28 days after birth.
  o Infants between 12 and 24 months of age who developed CLD of prematurity as defined above and who continue to require medical support (chronic corticosteroid therapy, diuretic therapy, supplemental oxygen or bronchodilator therapy) within 6 months of the start of RSV season.
? Heart Disease:
  o Infants who are 12 months of age or younger with hemodynamically significant Congenital Heart Disease (CHD). Those children with CHD who are most likely to benefit from immunoprophylaxis include those with:
    - acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures, or
    - moderate to severe pulmonary hypertension, or
    - cyanotic heart disease (if recommended by a pediatric cardiologist).
  o Additionally, children younger than 24 months who undergo cardiac transplantation during the RSV season may be considered for prophylaxis.
? Immune prophylaxis for RSV is considered not medically necessary for
  o Infants and children with hemodynamically insignificant heart disease including but not limited to:
    - secundum atrial septal defect,
    - small ventricular septal defect,
    - pulmonic stenosis,
    - uncomplicated aortic stenosis,
    - mild coarctation of the aorta,
    - patent ductus arteriosus
    - Lesions adequately corrected by surgery unless they continue to require medication for congestive

heart failure.
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

Note: Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-coporeal membrane oxygenation for infants and children younger than 24 months.
?
? Neuromuscular disease, congenital airway anomaly or pulmonary abnormality
o Infants under 12 months of age with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway because of ineffective cough.
? Immunocompromised
o Infants and children, who are 24 months of age or younger, who are profoundly immunocompromised because of chemotherapy or other conditions during the RSV season.

EXCLUSION CRITERIA
Contraindications/Exclusions/Discontinuation:
• History of severe prior reaction to palivizumab or any component of the formulation.
• In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
Coverage Criteria/Limitations for initial authorization:
? Diagnoses: Medically necessary FDA-approved uses as listed above
? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Infants who are younger than 12 months of age at the start of the Synagis season and who are born before 29 weeks, 0 days' gestation.
o Infants in the first 12 months of life, who are diagnosed with CLD (chronic lung disease) of prematurity defined as birth at less than 32 weeks, 0 days' gestation and a requirement for greater than 21% oxygen for at least 28 days after birth.
o Infants in the second year of life who are diagnosed with CLD (as per above criteria) AND who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) within the 6-month period before the start of the second RSV season.
o Children who are 12 months or younger with hemodynamically significant CHD as evidenced by:
- acyanotic heart disease and are receiving medication to control congestive heart failure, and will require cardiac surgical procedures
o Infants with moderate to severe pulmonary hypertension. Children with pulmonary abnormality or

neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.

- o Child younger than 24 months who will be profoundly immunocompromised during the RSV season.

Criteria for continuation of therapy:

? Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

- o Requests for coverage outside of RSV season will require authorization.

AGE RESTRICTION

? Age: 24 months and younger, See criteria for authorization for age specific indications.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

? Duration of Approval

- o Initial Approval: Maximum of 5 doses or thru the end of the RSV season, whichever comes first. Typically RSV season is October 1 - May 1. This must be confirmed on an annual basis.

- o Continuation of Therapy: Considered in a case by case basis by each plan. If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (less than 0.5%).

OTHER CRITERIA

? Quantity:

- o The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (greater than 24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses.

Other special considerations:

- Routine use in cystic fibrosis and Down Syndrome is not recommended.
- The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients

undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer.

Last Updated 10/1/2018

MDCH COMMON - TACROLIMUS (PROTOPIC) 0.03% OINT

MEDICATION(S)
TACROLIMUS 0.03% OINTMENT

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
Clinical Criteria

1. The patient must be 2 years of age or older.
2. Documented diagnosis of atopic dermatitis.
3. Documentation of a trial, failure or contraindication to two topical corticosteriods. OR
4. Clinical documentation to support topical corticosteroids are inappropriate for the patient. (i.e., previous response, skin atrophy, body
   location is at high risk of skin atrophy (face, skin folds).

Quantity: 30 grams per 30 days

Duration of Authorization: 12 months

Effective 6/1/16

MDCH COMMON - TACROLIMUS (PROTOPIC) 0.1% OINT

MEDICATION(S)
TACROLIMUS 0.1% OINTMENT

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
Clinical Criteria

1. The patient must be 16 years of age or older.
2. Documented diagnosis of atopic dermatitis.
3. Documentation of a trial, failure or contraindication to two topical corticosteriods. OR
4. Clinical documentation to support topical corticosteroids are inappropriate for the patient. (i.e., previous response, skin atrophy, body
   location is at high risk of skin atrophy (face, skin folds).

Quantity: 30 grams per 30 days

Duration of Authorization: 12 months

Effective 6/1/16

MEDICATION(S)
TECFIDERA

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
TECFIDERA® / DIMETHYL FUMARATE

Drug Class: Multiple Sclerosis Agent - Others

FDA-approved uses: treatment of patients with relapsing forms of multiple sclerosis

Available dosage forms: Capsules 120 mg and 240 mg

Coverage Criteria/Limitations for initial authorization:
Diagnoses: Indicated for the treatment of patients with relapsing forms of multiple sclerosis including:
o Relapsing-remitting multiple sclerosis [RRMS]
o Secondary-progressive multiple sclerosis [SPMS] with relapses
o Progressive-relapsing multiple sclerosis [PRMS]
Duration of Approval:

o Initial Approval: 1 year
o Continuation of Therapy: 1 year
Prescriber Specialty:
o Board-certified Neurologist
o Board-certified Multiple Sclerosis physician specialist
oConsult with a Board-certified neurologist or physician specialist with experience in prescribing multiple sclerosis therapy (submit consultation notes)
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o A definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria.
oExpanded Disability Status Scale (EDSS) score between 0 and 5 (disability severe enough to impair full daily activities) OR documentation supporting the disability within this range
oDocumented inadequate response (at least 6 months of therapy) to a non-interferon, glatiramer acetate (Copaxone®)
NOTE: “Needle phobia” or “needle fatigue” is not considered an intolerance or contraindication to the first-line disease-modifying therapies (DMT's)
Inadequate response is defined as meeting TWO of the following three criteria during treatment with one of these agents: [TWO]
•Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses
•Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
•Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, or ability to perform activities of daily living

Documentation Requirements: continued
o Confirmation of ONE of the following from the Prescriber AND by verifying in member’s prescription profile
Member is not currently being treated with another disease-modifying agent for MS
Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent
o Documentation of the following BASELINE lab reports/exams [ALL]
Baseline MRI [utilized to identify lesion progression (response to treatment) while on Tecfidera therapy]
Member does not have a low lymphocyte count as documented by a recent (within 6 months) Complete Blood Count (CBC) prior to initiating therapy.
•NOTE: Further CBC monitoring is recommended at least annually during therapy or as clinically necessary (based on signs and symptoms of infection).

Quantity:
o Tecfidera Starter Kit: ONE-time authorization of a 30-day supply only
o Tecfidera 120mg delayed release capsules: 14 capsules (starting dose, one-time fill)
o Tecfidera 240mg delayed release capsules: 60 capsules per 30 days (maintenance dose)
Age: Must be greater than 18 years of age
Gender: Male or Female
Route of Administration: Oral
Place of Service: Outpatient

Criteria for continuation of therapy:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o Confirmation of ONE of the following from the Prescriber AND by verifying in member's prescription profile
Member is not currently being treated with another disease-modifying agent for MS
Member is currently being treated with another disease-modifying agent for MS AND the disease-modifying agent will be discontinued before starting the requested agent
o Adherence to Therapy
Member compliance with therapy as verified by Prescriber and member's medication fill history (review prescription history for compliance)
•NOTE: Therapy may be discontinued due to compliance issues or poor adherence upon agreement among treating physician, member, and Medical Director.
o Labs/Reports/Documentation required [ALL]
Treatment with dimethyl fumarate may decrease lymphocyte counts, therefore a complete blood count should be obtained within six months of starting the medication and at least annually or as clinically indicated during the course of treatment. Dimethyl fumarate has not been studied in patient with pre-existing low lymphocyte counts.

Documentation Requirements: continued
o Stabilization or positive response to Tecfidera® (dimethyl fumarate) treatment.
Demonstrated efficacy as evidenced by (including but not limited to the following): [ALL APPLICABLE]
Relapses: A decrease in frequency, severity, sequelae relapses from baseline
Radiologic evidence of disease activity: Beneficial effect on MRI measures of disease severity (decrease in number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
oDisability progression: EDSS score remains less than or equal to 5.5 or stabilization/improvement routine

neurological observation, mobility, or ability to perform activities of daily living
o Validated patient reported outcome measure [i.e. Fatigue Impact Scale (FIS), Medical Outcome Study SF-36, etc]
Fatigue Impact Scale (FIS) is a validated patient reported outcome measure that evaluates the effect of fatigue on the lives of people with MS. The Medical Outcome Study SF-36 is a self-administered health-reported quality of life outcome measure that is validated for several indications and patient populations

Contraindications/Exclusions/Discontinuation:

- Steady progression of disability
- Drug toxicity or serious adverse reaction
- Non-FDA approved indications
- Authorization will not be granted if ANY of the following Contraindications/Exclusions to Tecfidera® (dimethyl fumarate) therapy apply:

oHypersensitivity to Tecfidera® (dimethyl fumarate) or any ingredient in the formulation
oHistory of significant gastrointestinal (GI) disease, chronic use of GI symptomatic therapy
o Active malignancies
o NOTE: “Needle phobia” or “needle fatigue” is not considered a contraindication.

- Concomitant therapy of any two disease modifying agents in MS
- Patient is noncompliant with medical or pharmacologic therapy

•No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:

- For use as monotherapy therapy only:

oPrescriber intends to use Tecfidera® (dimethyl fumarate) as a single agent, no other disease-modifying multiple sclerosis medications are being administered concomitantly, including but not limited to: interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), glatiramer acetate (Copaxone®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), fingolimod (Gilenya™), teriflunomide (Aubagio®)

Updated 4/1/19

MEDICATION(S)
ALISKIREN

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
TEKTURNA® / ALISKIREN

Drug Class: Renin Inhibitor, Direct

FDA-approved uses: For the treatment of hypertension either as monotherapy or in combination with other antihypertensive agents

Available dosage forms:
Tekturna Tablets 150 mg and 300 mg

Coverage Criteria/Limitations for initial authorization:
Diagnoses: Mild to moderate hypertension
Duration of Approval:
o Initial Approval: 3 months

o Continuation of Therapy: 1 year

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

oDocumentation of trial and failure of previous therapies (Technician review of relevant patient fill history)

o Must have tried and failed two drug combinations

Failed/intolerant to thiazide diuretics

Failed/intolerant to ACE inhibitors

Failed/intolerant to ARBs

Failed/intolerant to beta blockers

Failed/intolerant to calcium channel blockers

Quantity: #30 per month

Age: Adults. Safety and efficacy has not been determined for adolescents and children

Route of Administration: Oral

Criteria for continuation of therapy:

Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

o Member currently meets ALL initial coverage criteria

o Compliance:

Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance), including:

- Compliance in taking the medication as prescribed
- No intolerable adverse effects or drug toxicity

NOTE: Therapy may be discontinued due to poor adherence upon recommendation of the Medical Director when adherence less than 85% has been demonstrated in at least two months during the course of therapy

Documentation Requirements: continued

o Labs/Reports/Documentation required:

•Maintenance therapy may be authorized when therapy has demonstrated efficacy as evidenced by an improvement in disease activity after initial therapy.

•Documentation of disease stabilization or improvement is required for continuation of therapy

Contraindications/Exclusions/Discontinuation:

- Discontinuation of Treatment [ANY]

oPoor response to treatment as evidenced by physical findings and/or clinical symptoms following the initial

12 weeks approval for coverage
o Intolerable adverse effects or drug toxicity
o Persistent and uncorrectable problems with adherence to treatment
o Drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:

- Adverse Effects:

oA concern is hypotension that is not reversed when the drug is stopped due to the strong binding of renin and the long half-life of aliskiren (24?30 hrs).
o Aliskiren still is detectable in the kidneys up to 3 weeks after discontinuation.
o Doses greater than 300mg did not give an increased blood pressure response but increased the rate of diarrhea.
o Rate of cough was 1.1%, which was about one?half to one?third the rate of cough seen with ACE inhibitors.
oTwo cases of angioedema with respiratory symptoms and two cases of periorbital edema without respiratory symptoms were noted. Therefore angioedema occurred in 0.06% of patients.
o Increases in potassium were uncommon (0.9% compared with 0.6% with placebo). However the rate of hyperkalemia is expected to be greater if aliskiren is combined with an ACE inhibitor.

- Cautions:

oExperience with the use of aliskiren in patients with severe renal impairment is limited and therefore, caution is warranted. It does not appear to have an effect on serum creatinine, but data is lacking to confirm this.

- Indications:

o The majority of trials included patients with mild to moderate hypertension.
o Limited data suggest that aliskiren also could be safe in severe hypertension as part of a combination therapy strategy.

Other special considerations: continued

- Efficacy:

oOverall data from studies show aliskiren to be superior to placebo and similar or better efficacy compared with other commonly used agents.
o Aliskiren directly inhibits rennin while other antihypertensives target the rennin? angiotensin system.
o Has not been studied with maximal dose of ACE inhibitors.

o Modestly lowers blood pressure when used as monotherapy and has shown to have additive effects when combined with a thiazide diuretic or an ARB.
oAliskiren has not been shown to improve clinical outcomes as seen with ACE inhibitors and ARB's in heart failure, coronary artery disease and renal disease therefore should only be used for hypertension at this time

Duration of Approval: Initial 3-months, renewal up to 1 year

Effective 6/1/16

MEDICATION(S)
BETHKIS, KITABIS PAK, TOBI, TOBI PODHALER

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
Clinical Criteria

Initial

1. Patient must be 6 years of age or older.
2. Documented diagnosis of Cystic Fibrosis.
3. Prescribed by a Pediatrician, Pulmonologist or Infectious Disease specialist
4. Suspected or confirmed diagnosis of Pseudomonas auruginosa lung infection.
5. FEV1 between 25 - 80 percent predicted

For Tobi Podhaler Only: must have tried and failed tobramycin inhalation (Generic Tobi)

Continuation of Therapy

1. Confirmation that the patient continues to have a beneficial response to therapy as accessed and documented by the prescriber.

Quantity: 28 day supply per 56 days (28 days on, 28 days off)

Duration of Therapy: Initial 6-months, Renewal 1 year

Effective 6/1/16
Update 10/1/7, 1/1/18

MEDICATION(S)
TRACLEER

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
Clinical Criteria

Tracleer is covered for members who meet the following criteria: Drug Class: Pulmonary Antihypertensive Agents - Endothelin Receptor Antagonists Coverage Criteria/Limitations for initial authorization:
Diagnoses: Diagnosed with primary pulmonary hypertension OR secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease by a Pulmonologist or Cardiologist
Duration of approval:
o Initial Authorization: 4 months
o Continuation of therapy: 1 year
Prescriber Specialty: Pulmonologist or cardiologist
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
o WHO Group I
o NYHA functional class II, III or IV
o Has received adequate treatment trial with anticoagulants +/- diuretics +/- digoxin
o Acute vasoreactivity testing result:

For patients with a positive testing result, documentation of a trial and failure with calcium channel blocker therapy is required, unless it is contraindicated, such as those with right heart failure or hemodynamic instability.

OR

For patients with a negative testing result, calcium channel blocker therapy is not indicated

Age:

o 32mg tablet for oral suspension: 3 to 12 years of age

o 62.5mg, 125mg tablets: greater than 12 years of age

Route of Administration: Oral

Criteria for continuation of therapy:

Documentation of the following is required:

o Stabilization or improvement in functional status (NYHA functional class), or

o Improvement in PAP or other measures of pulmonary hypertension

Contraindications/Exclusions/Discontinuation:

•Boxed Warning: Pregnancy- Do not administer ambrisentan to a pregnant woman because it may cause fetal harm. Ambrisentan is very likely to produce serious birth defects if used by pregnant women because this effect has been seen consistently when it is administered to animals. Therefore, pregnancy must be excluded before the initiation of treatment. Females of reproductive potential must use acceptable methods of contraception during treatment and for 1 month after treatment. Obtain monthly pregnancy tests during treatment and 1 month after discontinuation.

- Hypersensitivity to any product
- Drug interaction specific to Bosentan: concomitant use with cyclosporine A or glyburide

Tracleer: continued

Contraindications/Exclusions/Discontinuation: continued

•In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 6/1/16
Updated 7/1/2019

MEDICATION(S)
TYMLOS

COVERED USES
Diagnoses: For the treatment of Osteoporosis in postmenopausal women

EXCLUSION CRITERIA
Contraindications/Exclusions/Discontinuation:
a. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REQUIRED MEDICAL INFORMATION
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
a. T-score less than or equal to -3 with a previous low-impact fracture, AND
b. Documented failure of an oral bisphosphonate (or documented intolerance or contraindication to the medication) despite compliance for at least 2 years, AND
c. Documented failure or intolerance to a compliant (at least 12 months) regimen of zoledronic acid (generic Reclast)
NOTE: Failure is defined by new fracture while on treatment or reduction in BMD per recent DEXA scan. If member has a new fracture while on a bisphosphonate, we will only require a clinical trial of one bisphosphonate (oral or IV)

AGE RESTRICTION
Age: Greater than 18 years old, Safety and efficacy have not been established in pediatrics.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial Authorization: Osteoporosis-1 year, need baseline DEXA T-Score

OTHER CRITERIA
DURATION Continuation of Therapy: Osteoporosis-1 year, Use of abaloparatide or other parathyroid hormone analogs for more than 2 years is not recommended.

Criteria for continuation of therapy:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
a. Osteoporosis:

i. Continue to meet qualifying criteria.

ii. Responding to treatment with evidence of maintenance or improved T-Score on DEXA scan.

MEDICATION(S)
VEMLIDY

COVERED USES
Chronic Hepatitis B

EXCLUSION CRITERIA
1.HIV and HBV coinfection: Should not be used as a single agent for the treatment of HIV due to resistance development risk
2.If HIV positive - provide further justification
3.For females: There have been no data reported to the antiretrovial registry related to the use of this drug in pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines note data are insufficient to recommend tenofovir alafenamide for initial therapy in antiretrovial-naive pregnant women. Tenofovir disoproxil fumarate (Viread) preferred in pregnant women.
4.Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REQUIRED MEDICAL INFORMATION
Initial Critiera

a.Diagnosis of Chronic Hepatitis B infection with compensated liver disease
b.HIV testing – mandatory lab report
c.Failure of Entecavir (geq), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
d.Use is not recommended in those with CrCl LT 15mL oer minute or if Child-Pugh class B or C
e.HIV testing: HIV antibody testing should be offered to all HBV infected patients prior to treatment initiation
f.HBV DNA every three months until undetectable for at least two consecutive visits. We then decrease the frequency to every six months.
g.Aminotransferases every three months. The frequency can be decreased to every six months in patients with an undetectable HBV DNA or normalized ALT.
h.HBeAg and antibody to HBeAg (anti-HBe) every six months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, we repeat the HBeAg to confirm the result.
i.HBsAg should be tested yearly.
j.Creatinine and phosphate every 6 months.

Renewal Criteria

a.HBV DNA every three months until undetectable for at least two consecutive visits. We then decrease the frequency to every six months.
b.Aminotransferases every three months. The frequency can be decreased to every six months in patients with an undetectable HBV DNA or normalized ALT.
c.HBeAg and antibody to HBeAg (anti-HBe) every six months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, we repeat the HBeAg to confirm the result.
d.HBsAg should be tested yearly.
e.Creatinine and phosphate every 6 months.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
Must be prescribed by hepatologist, infectious disease specialist or gastroenterologist.

COVERAGE DURATION
Six (6) months

OTHER CRITERIA
Quantity Limit: 30 per 30 days

Effective 10/1/17

MEDICATION(S)
VYNDAMAX, VYNDAQEL

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
VYNDAMAX AND VYNDAQEL / TAFAMIDIS AND TAFAMIDIS MEGLUMINE

Drug Class (ETC_Name): Transthyretin stabilizer

FDA-approved uses: Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization.

Available dosage forms: Vyndaqel (tafamidis meglumine) 20 mg capsules, Vyndamax (tafamidis) 61 mg capsules

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: Wild-type or hereditary ATTR-CM
?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: for up to 1 year
?Prescriber Specialty: Cardiologist or a physician in consult with a Cardiologist

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of confirmed ATTR-CM diagnosis
oAttestation – negative history of New York Heart Association (NYHA) Class III heart failure
oGenetic testing to confirm wild type OR hereditary transthyretin-mediated amyloidosis (ATTR-CM)
oMedical history of heart failure that includes one of the following: at least 1 prior hospitalization of heart failure OR clinical evidence of heart failure
oEvidence of cardiac involvement on an echo with increased wall thickness
?Quantity:
Vyndaqel 20mg capsules: 4/day
Vyndamax 61mg capsule: 1/day
?Age: 18 and older
?Route of Administration: Oral

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of clinical benefit through improvement of symptoms

Contraindications/Exclusions/Discontinuation:
•Requests will not be approved for members with NYHA Class III heart failure
•Contraindicated in members with previous hypersensitivity to tafamidis or tafamidis meglumine
•Should not be taken concurrently with Onpattro OR Tegsedi

Other special considerations:
•Based on animal studies, tafamidis may cause fetal harm when administered during pregnancy, resulting in postnatal mortality, growth retardation, impaired learning.
•Tafamidis meglumine and tafamidis are not substitutable on a milligram-per-milligram basis.
•Pharmacokinetics show no clinically significant differences with mild hepatic impairment (Child-Pugh score of 5-6) when compared to healthy subjects. No dose adjustment is required with moderate impairment (Child-Pugh score of 7-9) since although systemic exposure is decreased in this population, TRR levels are also lower.

Updated 1/1/20

MEDICATION(S)

XARELTO 10 MG TABLET, XARELTO 15 MG TABLET, XARELTO 20 MG TABLET, XARELTO DVT-PE TREAT START 30D

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

Clinical Criteria

Initial

1. Patient must be 18 years of age or older.
2. Patient was stated on Xarelto therapy in the hospital and was discharged while on therapy. OR
3. Patient has A-fib and Xarelto therapy is being used for stroke prevention. AND
   a. Documented diagnosis of non-valcular atrial fibrillation.
   b. Documented trial, failure or intolerance to warfarin therapy.
   c. Must have moderate to high risk of stroke as determined by the following:
      i. Either history or stroke, TIA or systemic embolism OR
      ii. Two of the following:
         1. Heart failure or LVEF less than or equal to 35 percent
         2. Hypertension
         3. Patient is 75 years of age or older

4. Diabetes mellitus

OR

4. Treatment of DVT or PE
   a. Documented DVT or PE
   b. Trial, failure or intolerance to warfarin therapy.

OR

5. DVT prophylaxis
   a. Documentation that the patient has undergone elective total hip or knee arthoplasty.

Quantity-Duration

Non-valvular Afib, DVT or PE - as determined by prescriber
DVT Prophylaxis
- hip replacement surgery - 35 days recommended
- knee replacement surgery - 12 days recommended

Treatment of DVT and PE to be determined by prescriber

Quantity for Starter Pack: 1 Starter Pack per 90 days

Continuation Criteria (documentation requirements)

- Member is tolerating and responding to medication and there continues to be a medical need for the medication
- CrCL is being monitored

Contraindications/Exclusions/Discontinuation:

•Box Warning :

oDiscontinuing Xarelto can lead to higher risk of stroke. If discontinuation is warranted for reasons other than pathological bleeding, consider use of another anticoagulation agent.

oAdministration of Xarelto while also receiving neuraxial anesthesia or undergoing spinal puncture can lead to epidural or spinal hematomas, which can result in long term or permanent paralysis.

oIf discontinuation is warranted due to risk of bleeding with surgery or other procedures, temporarily stop Xarelto at least 24 hours before procedure. Restart after the procedure once adequate hemostasis has been established.

oAvoid in CrCl less than 15 ml/min

oPer the Beers Criteria, for patients older than 65, avoid Xarelto if CrCl less than 30 ml/min

oAvoid use with P-gp and strong CYP3A4 inhibitors/inducers.

•Active pathological bleeding

•Hypersensitivity reaction to Xarelto

•Patient is noncompliant with medical or pharmacologic therapy

•No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Effective 6/1/16, Update 01/01/2019

MEDICATION(S)
XATMEP

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
XATMEP®/ METHOTREXATE

Drug Class: Folate Analog Metabolic Inhibitor

FDA-approved uses:
?Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen
?Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy

Available dosage forms: 2.5 mg/ml Oral Solution

Diagnosis: Treatment of pediatric patients with acute lymphoblastic leukemia (ALL)
Coverage Criteria/Limitations for initial authorization
?Diagnoses: Cancer
?Duration of Approval:

oInitial Authorization: 3 months
oContinuation of Therapy: 3-month increments
?Prescriber Specialty: Oncologist
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oProper diagnosis of an FDA Approved Indication OR
oIf request is for a non-FDA Approved indication, the request must be for a “medically accepted indication” as noted in the following Compendia:
?American Hospital Formulary Drug Service (AHFS-DI)
?NCCN Drugs and Biologic Compendium/ NCCN Guidelines
•Categories 1, 2a, and 2b will be accepted. (See Table 1 for explanation of Categories)
?Micromedex DrugDex
?Clinical Pharmacology
oMember must be under the care of an Oncologist
oDocumentation of dose and dates of all previous therapy and the resulting outcomes
oDocumentation that the proper succession of the therapies has been tried and failed (i.e. intolerance, contraindication, or progression)
oChart notes detailing the member’s current clinical status
oRelated lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment
?Not Approved If:
oPatient has any contraindications to the use of any requested ingredients
oRequest is for experimental/investigational use
oMember is enrolled in a clinical trial
?Dosing:
oAs noted in Package Insert
oAs noted in Above described Compendium

Diagnosis: Treatment of pediatric patients with acute lymphoblastic leukemia (ALL), continued
Criteria for continuation of therapy
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oCurrent chart notes detailing response and compliance to therapy
oDocumented clinically significant improvements in the disease state, and stability on the medication

Contraindications/Exclusions/Discontinuation:
•Hypersensitivity to the requested agent or any component of the formulation
•Member at risk through drug-drug interactions of contraindications noted in the package insert
•Patient is noncompliant with medical or pharmacologic therapy
•No demonstrable clinically significant improvement in condition has occulted after initiation of drug therapy

References:
•National Comprehensive Cancer Network® (NCCN), “Clinical Practice Guidelines in Oncology™: Available at http://www.nccn.org

Table 1: NCCN Categories of Evidence and Consensus.

Diagnosis: Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA)
Coverage Criteria/Limitations for initial authorization:
?Duration of approval:
oInitial authorization: 3 months
oContinuation of Therapy: 6 months
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient must try or have a documented reason that they cannot tolerate oral tablets
Criteria for continuation of therapy:
?Requires a positive response to therapy

MEDICATION(S)
XELJANZ, XELJANZ XR 11 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
N/A

OTHER CRITERIA
XELJANZ/ TOFACITINIB

Drug Class: Janus kinase (JAK) inhibitor

FDA-approved uses:
?Rheumatoid Arthritis (RA)
?Psoriatic Arthritis (PsA)
?Ulcerative Colitis (UC)

Available dosage forms:
?Xeljanz tablets: 5 mg, 10 mg
?Xeljanz XR tablets: 11 mg

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA approved indications detailed above

?Duration of approval:
oInitial authorization: 6 months
oContinuation of Therapy: 1 year

?Prescriber Specialty: Therapy is prescribed by or in consultation with a gastroenterologist, rheumatologist or dermatologist

?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oDocumentation of a negative TB test in the past 12 months
oDocumentation that member has been screened for viral hepatitis prior to starting therapy

oRheumatoid Arthritis (RA): (age 18 years or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate AND
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
•Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. Xeljanz 5 mg twice daily (QL 60/30) or Xeljanz XR 11 mg once daily (QL 30/30).

oPsoriatic Arthritis (PsA): (age 18 or older)
?Trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate AND
?Patient has tried and failed at least 1 other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months or contraindication/intolerance
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. Xeljanz 5 mg twice daily (QL 60/30) or Xeljanz XR 11 mg once daily (QL 30/30).

oUlcerative Colitis (UC) (age 18 or older)
?Trial and failure of oral or intravenous corticosteroids for at least one month or a contraindication/intolerance to corticosteroids
?Trial and failure of 1 or more of the following for 90 consecutive days in the previous 120 day period, or a

contraindication or intolerance to
•Azathioprine
•Budesonide
•Oral aminosalicylates (e.g., mesalamine, sulfasalazine, balsazide disodium)
•Rectal aminosalicylates
•Cyclosporine
•Mercaptopurine
?Trial and failure of a 90-day trial of infliximab (medical benefit) unless there are transportation or other access issues documented
oQuantity: Based on FDA dosing. Xeljanz 10 mg twice daily for at least 8 weeks, then 5 or 10 mg twice daily (QL 60/30). Discontinue after 16 weeks of 10 mg twice daily, if adequate therapeutic benefit is not achieved. Use the lowest effective dose to maintain response.

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oThe patient has experienced symptomatic improvement or maintained stable clinical status.
oMember continues to have yearly negative Tb test

Contraindications/Exclusions/Discontinuation:
oTherapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
oPatient receiving additional biologic DMARD therapy.

Warning:
oNot recommended to use in conjunction with Azathioprine or Cyclosporine or other potent immunosuppressants.
oBe aware of potential risk for significant infections and malignancies.

Updated 1/1/20

MEDICATION(S)
XYREM

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
XYREM/ SODIUM OXYBATE

Drug Class: Narcolepsy Agent
FDA-approved uses: Excessive daytime sleepiness/cataplexy: Treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.
Available dosage forms: Oral solution, 500 mg per mL
Coverage Criteria/Limitations for initial authorization:
?Diagnoses:
oType 1 Narcolepsy (cataplexy in narcolepsy)
oType 2 Narcolepsy [narcolepsy without cataplexy, excessive daytime sleepiness (EDS) in narcolepsy]
?Duration of approval:
oInitial authorization: 3 months
oContinuation of Therapy: for up to 6 months
?Prescriber Specialty: Board-certified Sleep Medicine Specialist, neurologist, pulmonologist, or psychiatrist. Submit consultation notes if applicable.
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):

oDaily excessive daytime sleepiness for at least 3 months (AASM ICSD-3 Criteria)
oNocturnal polysomnography (PSG) confirmation
•Overnight polysomnography to rule out other conditions and confirm adequate sleep before first Multiple Sleep Latency Test (MSLT)
oPositive MSLT* including:
•Mean Sleep Latency ? 8 minutes
•2 or more sleep onset rapid eye movement (REM) periods less than 15 minutes
EXCEPTION to positive MSLT test for Type 1 Narcolepsy (cataplexy in narcolepsy): Hypocretin-1 ? 110 pg/mL (or less than 1/3 of mean normal control values) may be alternative to MSLT sleep study
oType 1 Narcolepsy (cataplexy in narcolepsy)
•Member has cataplexy defined as more than one episode of generally brief (less than 2 minutes) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness
•Member did not achieve treatment goals or experienced inadequate clinical response after an adherent trial at maximum therapeutic dose, persistent intolerable adverse effects or contraindication to at least ONE (1) medication from BOTH of the following: [BOTH: 1 AND 2]
1.Non-amphetamine stimulant OR Amphetamine-based stimulant or a methylphenidate-based stimulant:
?Non-amphetamine stimulant: modafanil (Provigil) or armodafanil (Nuvigil)
?Amphetamine-based products: amphetamine/dextroamphetamine mixed salts, amphetamine/dextroamphetamine mixed salts extended-release, dextroamphetamine extended-release
? Methylphenidate-based products: methylphenidate, methylphenidate extended-release, dexmethylphenidate

2.Tricyclic Antidepressants (TCA) OR Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin-norepinephrine Reuptake Inhibitor (SNRI):
?TCA: imipramine, nortriptyline, protriptyline, clomipramine, etc.
?SSRI/SNRI: fluoxetine, venlafaxine, atomoxetine, etc.

?Type 2 Narcolepsy [narcolepsy without cataplexy]
•Other conditions that cause EDS have been ruled out or treated, including (but not limited to): shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, effects of sedating medications, idiopathic hypersomnolence, insufficient sleep at night (sleep deprivation), obstructive sleep apnea, central sleep apnea, periodic limb movement disorder (including restless legs syndrome), depression, Circadian rhythm disorders (including delayed sleep phase syndrome), and sedating medications.
•Member did not achieve treatment goals or experienced inadequate clinical response after a documented adherent trial at maximum therapeutic dose, persistent intolerable adverse effects or contraindication to at least ONE (1) medication from ALL of the following: [1,2, AND 3]
1.Non-amphetamine stimulant:
?Modafanil (Provigil)
?Armodafanil (Nuvigil)

2.:
Amphetamine-Based Products: amphetamine/dextroamphetamine mixed salts, amphetamine/dextroamphetamine mixed salts extended-release, dextroamphetamine extended-release
3. Methylphenidate based products: methylphenidate, methylphenidate extended-release, dexmethylphenidate
?Quantity: Maximum Dose: 9 grams per day, 18 mL per day OR 540 mL per 30 days
?Age: greater than 7 years old and greater than 20 kg
?Gender: Male and Female
?Route of Administration: Oral

Criteria for continuation of therapy:
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oConsultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually
oAdherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance), including:
•Adherent to the prescribed medication regimen
•Tolerance to therapy
•No severe adverse reactions or drug toxicity
oDocumentation of efficacy and positive response to Xyrem (sodium oxybate) therapy as evidenced by response of decreasing cataplexy events and improvement in score for appropriate test (e.g. Epworth Sleepiness Scale, Clinical Global Impression of Change, etc.) for EDS [ALL APPLICABLE]
•Decrease or reduction in the frequency of cataplexy events/attacks associated with Xyrem therapy
•Decrease or reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy
•For excessive daytime sleepiness (EDS): Improvement in the Epworth Sleepiness Scale (ESS), Clinical Global Impression of Change or Maintenance of Wakefulness Test (MWT)
oA documented attempt to decrease dose or step down to alternative drugs

Contraindications/Exclusions/Discontinuation:
?Non-FDA approved indications
?Hypersensitivity to Xyrem (sodium oxybate) or any ingredient in the formulation
?Co-administration with CNS depressant anxiolytics, sedatives, and hypnotics or other sedative CNS depressant drugs
oAdministration with alcohol or other psychoactive drugs can potentiate the effects of sodium oxybate.
?Co-administration with alcohol (ethanol)
oEthanol is contraindicated in patients using sodium oxybate. The combined use of alcohol (ethanol) with

sodium oxybate may result in potentiation of the CNS-depressant effects of sodium oxybate and alcohol.
?Succinic Semialdehyde Dehydrogenase Deficiency
oThis rare disorder is an in?born error of metabolism and variably characterized by mental retardation, hypotonia, and ataxia.
?History of drug abuse
oSodium oxybate is a CNS depressant with potential for misdirection and abuse and patients should be evaluated for a history of drug abuse.
?Uncontrolled hypertension (due to sodium content)

Other special considerations:
?Patients with Hepatic Impairment Dosing
oReduce the initial dosage by 50%
References
?Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Decemeber 2018.

?Micromedex Healthcare Series. DrugDex. [Micromedex Web site]. Available at: http://www.thomsonhc.com/micromedex2/librarian [via subscription only].
?Drug Facts and Comparisons. Drug Facts and Comparisons 4.0 [online]. 2018. Available from Wolters Kluwer Health, Inc. [via subscription only]
?Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc., 2018. URL: http://www.clinicalpharmacology.com. [via subscription only]

MEDICATION(S)
STEGLUJAN

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
COMBINATION SGLT-2 INHIBITOR / DPP-4 INHIBITORS
STEGLUJAN® / SITAGLIPTIN & ERTUGLIFLOZIN

Drug Class Antihyperglycemic – SGLT-2 Inhibitor & DPP-4 Inhibitor

FDA-approved uses: Type 2 diabetes mellitus: As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (non-insulin dependent NIDDM) who are not adequately controlled on a regimen containing individual SGLT-2 agents or individual DPP-4 agents, or in patients who are already treated with both an individual SGLT-2 and DPP-4 agent.

Available dosage forms: Steglujan Tablet 5 mg / 100 mg, 15 mg / 100 mg

Coverage Criteria/Limitations for initial authorization:
?Diagnoses: FDA Approved Indication as listed above
?Duration of approval:
oInitial authorization: 6 months

oContinuation of Therapy: 6 months
?Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oTrial and failure of single SGLT-2 with formulary DPP-4 (alogliptin)
oA1C must be less than or equal to 9%
oeGFR must be greater than 60 mL/min/1.73m(2)
?Age: ? 18 years of age

Criteria for continuation of therapy and patients receiving Januvia and Stegaltro Separately:
Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
oPatient responding to treatment
oPatient tolerating treatment
oeGFR must be greater than 60ml/min/1.73m2
oFor patients already receiving both Januvia and Stegaltro separately: provider must cancel remaining refills of Januvia and Stegaltro at the pharmacy where they are currently being filled

Contraindications/Exclusions/Discontinuation:
• Hypersensitivity to any component of the formulations;
• Severe renal impairment (eGFR < 30 ml/minute/1.73m2)
• End-stage renal disease
• Patient on dialysis
• In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Updated 1/1/20