MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

Administered by

ABATACEPT - IV (NSA) (MANAGED MEDICAID)

Generic	Brand			
ABATACEPT/MALTOSE	ORENCIA - IV			

NOTE: For requests for the SQ dosage form of Orencia, please see the Orencia SQ PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ABATACEPT - IV (Orencia - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 6 years of age or older

For patients with psoriatic arthritis, approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

RENEWAL CRITERIA

The guideline named **ABATACEPT - IV (ORENCIA - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criterion must be met:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

ABATACEPT - SQ (MANAGED MEDICAID)

Generic	Brand			
ABATACEPT - SQ	ORENCIA - SQ ORENCIA CLICKJECT - SQ			

NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 2 years of age or older

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

RENEWAL CRITERIA

The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criteria must be met:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

ABIRATERONE SUBMICRONIZED (MANAGED MEDICAID)

Generic	Brand			
ABIRATERONE ACET, SUBMICRONIZED	YONSA			

GUIDELINES FOR USE

Our guideline named **ABIRATERONE (Yonsa)** requires the following rule(s) be met for approval:

A. You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
B. The requested medication will be used in combination with methylprednisolone
C. You meet ONE of the following:
    1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
    2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
    3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, or degarelix)

Medicaid Effective: 04/01/21

ADALIMUMAB (MANAGED MEDICAID)

Generic	Brand			
ADALIMUMAB	HUMIRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. Documentation of your current weight

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INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication) such as: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

G. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 5 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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ADALIMUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)
   4. If you are 2 to 17 years of age, we require documentation of your current weight

RENEWAL CRITERIA

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal approval:

A. You have a diagnosis ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, we require you have tried at least a 3-month trial of Humira 40mg every other week

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

G. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have developed a new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. You have a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

ALEMTUZUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
ALEMTUZUMAB	LEMTRADA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried **TWO** agents that have been FDA (Food and Drug Administration) approved for the treatment of relapsing forms of multiple sclerosis (MS). (**Please note:** The following agents are preferred and may also require prior authorization: Aubagio, Gilenya, Glatiramer/Glatopa, Rebif, dimethyl fumarate)

RENEWAL CRITERIA

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. At least 12 months have passed since you received the most recent course of Lemtrada

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Medicaid Effective: 01/01/21

ALIROCUMAB (MANAGED MEDICAID)

Generic	Brand			
ALIROCUMAB	PRALUENT PEN, PRALUENT SYRINGE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALIROCUMAB (Praluent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque build up causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])
   3. Homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
E. **If you have primary hyperlipidemia (such as heterozygous familial hypercholesterolemia [HeFH]), approval also requires the diagnosis is determined by meeting ONE of the following:**
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 6
F. **If you have homozygous familial hypercholesterolemia (HoFH), approval also requires diagnosis is determined by ONE of the following:**
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of 8 or greater
   3. A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either: (a) xanthoma (condition where fatty growth develops underneath the skin) before 10 years of age or (b) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

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ALIROCUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Praluent
   2. You meet ONE of the following:
      a. You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
      b. You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) but are currently taking a maximally tolerated dose of any statin AND have been taking it for a duration of at least 8 weeks

H. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **ALIROCUMAB (Praluent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH]: type of inherited high cholesterol)
   3. Homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)

B. You also meet ONE of the following:
   1. You have continued to take a high intensity statin atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
   2. You have continued therapy with a maximally tolerated dose of any statin along with the requested medication
   3. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   4. You have complete statin intolerance

ANAKINRA (MANAGED MEDICAID)

Generic	Brand			
ANAKINRA	KINERET			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a rare life-threatening autoinflammatory disease caused by genetic mutations)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

Note: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

NOTE: For the diagnoses of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) or Deficiency of Interleukin-1 Receptor Antagonist (DIRA), please refer to the Initial Criteria section.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Medicaid Effective: 02/01/21

APREMILAST (MANAGED MEDICAID)

Generic	Brand			
APREMILAST	OTEZLA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

A. You have a diagnosis of psoriatic arthritis (joint pain and swelling with red scaly skin patches), moderate to severe chronic plaque psoriasis (dry, itchy skin patches with scales) or oral uclers with Behçet's Disease (disorder causing blood vessel inflammation throughout your body) or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, approval requires:**
   1. The requested drug is prescribed or recommended by a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor).
   2. You previously tried at least ONE of the following medications, unless there is a medical reason why you cannot (contraindication): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You are 18 years of age or older

C. **If you have moderate to severe plaque psoriasis, approval requires:**
   1. The requested drug is prescribed or recommended by a dermatologist (skin doctor).
   2. You have plaque psoriasis involving at least 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
   3. You previously tried at least ONE of the following standard treatments, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone, triamcinolone), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You are 18 years of age or older

D. **If you have oral ulcers with Behçet's Disease or history of recurrent oral ulcers based on clinical symptoms, approval requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (joint pain and inflammation doctor)
   3. You had a trial of one or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, etc., unless there is a medical reason why you cannot (contraindication)

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal approval:

A. You have a diagnosis of psoriatic arthritis (joint pain and swelling with red scaly skin patches), moderate to severe chronic plaque psoriasis (dry, itchy skin patches with scales) or oral uclers with Behçet's Disease (disorder causing blood vessel inflammation throughout your body) or history of recurrent oral ulcers based on clinical symptoms

B. **For the diagnosis of psoriatic arthritis, approval requires:**
   You have experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy.

C. **For the diagnosis of moderate to severe plaque psoriasis, approval requires:**
   You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

D. **For the diagnosis of Behçet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval requires:**
   - You have achieved or maintained clinical benefit compared to baseline such as improvement in pain scores, number of ulcers, etc.

Medicaid Effective: 01/01/20

ATOGEPANT (MANAGED MEDICAID)

Generic	Brand			
ATOGEPANT	QULIPTA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
A. The request is for the preventative treatment of episodic migraine
B. You are 18 years of age or older
C. You had a trial of or contraindication (harmful for) to TWO of the following preventative migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

RENEWAL CRITERIA

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
A. The request is for the preventative treatment of episodic
B. You meet ONE of the following criteria:
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
   2. You have experienced a reduction in migraine severity
   3. You have experienced a reduction in migraine duration

Medicaid Effective: 10/25/21

BARICITINIB (MANAGED MEDICAID)

Generic	Brand			
BARICITINIB	OLUMIANT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness of joints)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in the joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 04/01/20

BEMPEDOIC ACID (MANAGED MEDICAID)

Generic	Brand			
BEMPEDOIC ACID	NEXLETOL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEMPEDOIC ACID (Nexletol)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque build up causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You previously had a trial of or contraindication (a medical reason why you cannot use) to ezetimibe
E. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
F. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Nexletol
   2. You meet ONE of the following:
      a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
      b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

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BEMPEDOIC ACID (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID (Nexletol)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
C. You meet ONE of the following:
   1. You have continued therapy with a maximally tolerated dose of any statin
   2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   3. You have complete statin intolerance

Medicaid Effective: 10/01/20

BEMPEDOIC ACID AND EZETIMIBE (MANAGED MEDICAID)

Generic	Brand			
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol]
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You previously had a trial of ezetimibe
E. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
F. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Nexlizet
   2. You meet ONE of the following:
      a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
      b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

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BEMPEDOIC ACID AND EZETIMIBE (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
C. You meet ONE of the following:
   1. You have continued therapy with a maximally tolerated dose of any statin
   2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   3. You have complete statin intolerance

Medicaid Effective: 10/01/20

BEVACIZUMAB (MANAGED MEDICAID)

Generic	Brand			
BEVACIZUMAB	AVASTIN			

GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Platinum-resistant recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-sensitive recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Stage III or IV epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Avastin is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
      b. Avastin is being used in combination with fluoropyrimidine- irinotecan-(for example, FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Avastin is being used in combination with carboplatin and paclitaxel for first-line treatment
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

(Criteria continued on next page)

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BEVACIZUMAB (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Avastin is being used in combination with interferon-alfa
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

F. **If you have any ophthalmic (eye) indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb, approval also requires:**
   1. Therapy is prescribed by an ophthalmologist (eye doctor) and/or retina specialist (a special type of eye doctor)

G. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. Avastin is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Avastin is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than 2 prior chemotherapy regimens
   3. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Avastin is being used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
      b. Avastin is being used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
   2. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

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BEVACIZUMAB (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

J. **If you have Stage III or IV epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal cancer, approval also requires:**
   1. Avastin is being used following initial surgical resection
   2. Avastin is being used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel
   3. You have tried ONE of the following preferred medications, unless you have a contraindication (harmful for) to: Mvasi or Zirabev

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Avastin will be used in combination with atezolizumab
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

Medicaid Effective: 01/01/22

BRODALUMAB (MANAGED MEDICAID)

Generic	Brand			
BRODALUMAB	SILIQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: scaly, itchy dry skin patches)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
G. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication) such as Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO; scaly, itchy dry skin patches)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
C. You have not developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq

Medicaid Effective: 05/01/20

CANAKINUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
CANAKINUMAB/PF	ILARIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) bet met for approval:

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic *disorders* that have recurrent fever episodes and inflammation)
   4. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   5. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)

C. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You had a previous trial of the preferred immunomodulator: Actemra, unless there is a medical reason why you cannot (contraindication)

(Initial criteria continued on next page)

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CANAKINUMAB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have Adult-Onset Still's Disease (AOSD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) dermatologist (skin doctor), or immunologist (immune system doctor)
   2. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

NOTE: For the diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF), please refer to the Initial Criteria section.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
   3. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

Medicaid Effective: 04/01/21

CENOBAMATE (MANAGED MEDICAID)

Generic	Brand			
CENOBAMATE	XCOPRI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CENOBAMATE (Xcopri)** requires the following rule(s) be met for approval:

A. You have partial-onset seizures
B. You are 18 years of age or older
C. You have previously tried TWO generic anticonvulsant agents (drugs used to treat seizures) indicated for partial-onset seizures

RENEWAL CRITERIA

Our guideline named **CENOBAMATE (Xcopri)** requires the following rule(s) be met for renewal:

A. You have partial-onset seizures
B. You have experienced an improvement in seizure rate compared to baseline at treatment initiation

Medicaid Effective: 10/01/20

CERTOLIZUMAB PEGOL (MANAGED MEDICAID)

Generic	Brand			
CERTOLIZUMAB PEGOL	CIMZIA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

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CERTOLIZUMAB PEGOL (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in the digestive system)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (for example budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (patches) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

G. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You meet ONE of the following objective signs (shown by lab data) of inflammation:
      a. C-reactive protein (CRP: measures how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

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CERTOLIZUMAB PEGOL (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy

E. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy

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Medicaid Effective: 12/12/20

CLADRIBINE (MANAGED MEDICAID)

Generic	Brand			
CLADRIBINE	MAVENCLAD			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves). This includes relapsing-remitting MS (symptoms come and go away) and active secondary progressive MS (advanced disease)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. You have previously tried ONE agent indicated for the treatment of multiple sclerosis (MS). (**Please note:** The following agents are preferred and may also require prior authorization: Aubagio, Gilenya, Glatiramer/Glatopa, Rebif, dimethyl fumarate)
   2. You show signs of severe disease requiring high-efficacy disease modifying therap. Signs include high lesion volume (high affected areas) and/or count, walking disability, or rapid decline

RENEWAL CRITERIA

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves). This includes relapsing-remitting MS (symptoms come and go away) and active secondary progressive MS (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
D. You have not received a total of two years of treatment with Mavenclad

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Medicaid Effective: 01/01/21

CONTINUOUS GLUCOSE MONITORS - STAND-ALONE (MANAGED MEDICAID)

Generic	Brand			
CONTINUOUS BLOOD-GLUCOSE METER	DEXCOM G4, DEXCOM G5, DEXCOM G6			
FLASH GLUCOSE SCANNING READER	FREESTYLE LIBRE 14/10, FREESTYLE LIBRE 2			
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER			
BLOOD-GLUCOSE SENSOR	DEXCOM G6, DEXCOM G5-G4 SENSOR, GUARDIAN SENSOR 3			
FLASH GLUCOSE SENSOR	FREESTYLE LIBRE SENSOR, FREESTYLE LIBRE 2 SENSOR			

GUIDELINES FOR USE

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:

A. You have type 1, type 2, or gestational (during pregnancy) diabetes (too much sugar in your blood)
B. You meet ONE of the following:
    1. You are being treated with insulin and meet ONE of the following:
        a. You are using a continuous subcutaneous (injection under the skin) insulin infusion pump
        b. You use 3 or more administrations of insulin daily
        c. You are on an insulin treatment plan that requires frequent adjustment of insulin dosing

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

2. You meet ALL of the following:
   a. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)
   b. You have either tried (without adequate results or continuous need is identified by your doctor) or do not have access to a professional continuous glucose monitor from your doctor's office

C. **If you are requesting Dexcom G4, G5, or G6 system (meter, sensor, transmitter), approval also requires:**
   1. You are 2 years of age or older
D. **If you are requesting FreeStyle Libre System (reader, sensor), approval also requires:**
   1. You are 18 years of age or older
E. **If you are requesting FreeStyle Libre 2.0 System (reader, sensor), approval also requires:**
   1. You are 4 years of age or older
F. **If you are requesting Medtronic Guardian Connect (sensor, transmitter), approval also requires:**
   1. You are between 14 to 75 years of age
G. **If you are requesting Eversense Smart Transmitter, approval also requires:**
   1. You are 18 years of age or older

Medicaid Effective: 01/01/22

DACLATASVIR (MANAGED MEDICAID)

Generic	Brand			
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA			

GUIDELINES FOR USE

Our guideline named **DACLATASVIR (Daklinza)** requires the following rule(s) be met for approval:

A. You have a diagnosis of hepatitis C, with genotype 1 or genotype 3 infection.
B. You are least 18 years old
C. Medication is prescribed by or recommended by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
E. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi
F. **For Genotype 1 infection approval also requires:**
    1. *Patients without cirrhosis (liver scarring):*
        a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
        b. You have previously tried Epclusa, Harvoni or Mavyret and experienced things such as adverse effect, intolerance early in therapy, or you have a contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
        a. You have previously tried Epclusa or Harvoni and experienced things such as adverse effect, intolerance early in therapy, or you have a contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    3. *Patients status post liver transplant:*
        a. You have previously Harvoni or Mavyret and experienced things such as adverse effect, intolerance early in therapy, or you have a contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
        b. Concurrent (used at the same time with) ribavirin use required

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

G. **For Genotype 3 infection, approval also requires:**
   1. *Patients without cirrhosis:*
      a. You are treatment naive (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret required and experienced things such as adverse effect, intolerance early in therapy, or you have a contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and experienced things such as adverse effect, intolerance early in therapy, or you have a contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   3. *Patients status post-liver transplant, with compensated cirrhosis (you do not have symptoms related to liver scarring) OR without cirrhosis:*
      a. You had a previous short trial of Mavyret and experienced things such as adverse effect, intolerance early in therapy OR you have a contraindication (medical reason why you cannot use) to Mavyret; (an individual who has completed a full course of therapy that did not achieve SVR will not be approved)
      b. Concurrent (used at the same time with) ribavirin use required

Daklinza will not be approved for ANY of the following patients:
- Patient using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
- Patients using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
- Patients with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Patients with compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) that are not status post liver transplant (you have not had a liver transplant)

Medicaid Effective: 06/01/21

DIMETHYL FUMARATE (MANAGED MEDICAID)

Generic	Brand			
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE			

GUIDELINES FOR USE

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Medicaid Effective: 10/19/20

DIROXIMEL FUMARATE (MANAGED MEDICAID)

Generic	Brand			
DIROXIMEL FUMARATE	VUMERITY			

GUIDELINES FOR USE

Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried dimethyl fumarate and ONE of the following medications, unless there is a medical reason why you cannot (contraindication): Aubagio, Glatiramer/Glatopa, Rebif

(**Please note:** The preferred MS agents may also a require prior authorization)

Medicaid Effective: 01/01/21

ELAGOLIX/ESTRADIOL/NORETHINDRONE (MANAGED MEDICAID)

Generic	Brand			
ELAGOLIX/ESTRADIOL /NORETHINDRONE	ORIAHNN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You previously had a trial of any TWO agents from the following, unless there is a medical reason you cannot (contraindication): oral tranexamic acid, contraceptive preparations (such as oral contraceptive, levonorgestrel intra-uterine device [Mirena, Kyleena, Skyla, Liletta], or other forms of contraceptives)
F. You have not received a total of 24 months cumulative treatment with Oriahnn

RENEWAL CRITERIA

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You had improvement of heavy menstrual bleeding on therapy
C. You have not received a total of 24 months cumulative treatment with Oriahnn

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Medicaid Effective: 01/01/21

ELBASVIR/GRAZOPREVIR (MANAGED MEDICAID)

Generic	Brand			
ELBASVIR/GRAZOPREVIR	ZEPATIER			

GUIDELINES FOR USE

Our guideline named **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have a diagnosis of hepatitis C (type of liver inflammation caused by a virus)
B. You have genotype 1 or genotype 4 hepatitis C
C. You are at least 18 years old
D. You are currently supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have documentation of HCV (hepatitis C virus) infection such as at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. If you have Genotype 1a infection, we require testing for baseline NS5A (Nonstructural protein 5A) polymorphisms (many variations of a type of protein)
G. If you are treatment-experienced OR if you are treatment naïve (never previously treated) with genotype 1a infection and baseline NS5A (Nonstructural protein 5A) polymorphisms (many variations of a type of protein), we require that you use Ribavirin
H. You had a previous short trial of (such as inability to tolerate, adverse effect early in therapy) Mavyret **OR** contraindication to (medical reason why you cannot use) Mavyret therapy [**NOTE:** An individual who has completed a full course of therapy with Mavyret that did not achieve SVR will not be approved.]

The medication will not be approved for the following patients:

1. If you are using any of the following interacting medications at the same time while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
2. If you are taking Sovaldi (sofosbuvir) with Zepatier
3. If you have moderate or severe hepatic impairment (Child-Pugh B or C)
4. If you have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Medicaid Effective: 09/17/18

EPTINEZUMAB-JJMR (MANAGED MEDICAID)

Generic	Brand			
EPTINEZUMAB-JJMR	VYEPTI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You had a previous trial of any TWO of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You had a previous trial of any TWO of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

RENEWAL CRITERIA

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

A. Vyepti is being prescribed for preventive treatment of migraines
B. You also meet ONE of the following:
   1. You have experienced a reduction in migraine or headache frequency by at least 2 days per month with Vyepti therapy
   2. You have experienced a reduction in migraine severity with Vyepti therapy
   3. You have experienced a reduction in migraine duration (length of time) with Vyepti therapy

Medicaid Effective: 07/01/21

ERENUMAB-AOOE (MANAGED MEDICAID)

Generic	Brand			
ERENUMAB-AOOE	AIMOVIG			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried **TWO** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried **TWO** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. Aimovig is being prescribed for preventive treatment of migraines
B. You meet **ONE** of the following criteria:
   1. You have experienced less migraine or headache attacks by at least 2 days per month with Aimovig therapy
   2. You have experienced a lessening in migraine severity with Aimovig therapy
   3. You have experienced a lessening in migraine duration with Aimovig therapy

Medicaid Effective: 07/01/21

ETANERCEPT (MANAGED MEDICAID)

Generic	Brand			
ETANERCEPT	ENBREL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. If **you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If** you **have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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ETANERCEPT (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You had a previous trial of an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have plaque psoriasis (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (patches) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapy, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

E. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

Medicaid Effective: 09/07/20

EVOLOCUMAB (MANAGED MEDICAID)

Generic	Brand			
EVOLOCUMAB	REPATHA SYRINGE, REPATHA SURECLICK, REPATHA PUSHTRONEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health issues related to heart and blood vessels) such as: history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of the aorta), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol)
   3. Primary hyperlipidemia (high level of fat in the blood due to genetic causes)
   4. Homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)
B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
C. You have a low-density lipoprotein (LDL: bad cholesterol)-cholesterol level greater than or equal to 70 mg/dL
D. **If you have established cardiovascular disease, approval also requires:**
   1. You are 18 years of age or older
E. **If you have heterozygous familial hypercholesterolemia [HeFH], approval also requires:**
   1. You are 10 years of age or older
   2. Your diagnosis is determined by (a) Simon Broome diagnostic criteria (definite) or (b) Dutch Lipid Network criteria with a score of 6 or greater
F. **If you have primary hyperlipidemia, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis is determined by (a) Simon Broome diagnostic criteria (definite) or (b) Dutch Lipid Network criteria with a score of 6 or greater

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EVOLOCUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you have homozygous familial hypercholesterolemia (HoFH), approval also requires:**
   1. You are 10 years of age or older
   2. Your diagnosis is determined by ONE of the following:
      a. Simon Broome diagnostic criteria (definite)
      b. Dutch Lipid Network criteria with a score of 8 or greater
      c. A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either: (a) xanthoma (a type of skin condition) before 10 years of age or (b) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

H. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Repatha
   2. You meet ONE of the following:
      a. You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for at least 8 weeks
      b. You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) but are currently taking a maximally tolerated dose of any statin AND have been taking it for at least 8 weeks

I. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (medical reason why you cannot use) to statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, hypersensitivity (allergic) reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

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EVOLOCUMAB (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health issues related to heart and blood vessels)
   2. Primary hyperlipidemia (high level of fat in the blood due to genetic causes)
   3. Heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol)
   4. Homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)

B. You meet ONE of the following:
   1. You have continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
   2. You have continued therapy with a maximally tolerated dose of any statin along with the requested medication
   3. You have an absolute contraindication (medical reason why you cannot use) to statin therapy
   4. You have complete statin intolerance

Medicaid Effective: 10/25/21

FENTANYL NASAL SPRAY (MANAGED MEDICAID)

Generic	Brand			
FENTANYL NASAL SPRAY	LAZANDA			

GUIDELINES FOR USE

Our guideline for **FENTANYL NASAL SPRAY** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

Medicaid Effective: 01/01/15

FENTANYL SUBLINGUAL SPRAY (MANAGED MEDICAID)

Generic	Brand			
FENTANYL SUBLINGUAL SPRAY	SUBSYS			

GUIDELINES FOR USE

Our guideline for **FENTANYL SUBLINGUAL SPRAY** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge.

Medicaid Effective: 01/01/15

FINGOLIMOD (MANAGED MEDICAID)

Generic	Brand			
FINGOLIMOD HCL	GILENYA			

GUIDELINES FOR USE

The guideline named **FINGOLIMOD (Gilenya)** requires the diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in patients 10 years of age and older. In addition, approval requires the absence of medical history or cardiac events that are contraindicated with the use of Gilenya (those that may increase risk of cardiac events associated with Gilenya), which includes any of the following criteria:

- A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker
- A baseline QTC interval 500 msec or above
- Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Medicaid Effective: 10/07/19

FREMANEZUMAB-VFRM (MANAGED MEDICAID)

Generic	Brand			
FREMANEZUMAB-VFRM	AJOVY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried TWO of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried TWO of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

RENEWAL CRITERIA

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:

A. Ajovy is prescribed for the preventive treatment of migraines
B. You meet **ONE** of the following:
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   2. You have experienced a reduction in migraine severity with Ajovy therapy
   3. You have experienced a reduction in migraine duration with Ajovy therapy

Medicaid Effective: 07/01/21

GALCANEZUMAB-GNLM (MANAGED MEDICAID)

Generic	Brand			
GALCANEZUMAB-GNLM	EMGALITY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
B. **If you have episodic migraines (0-14 headache days per month)**, **approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried TWO of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headaches per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried TWO of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]**
D. **If you have episodic cluster headaches, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried verapamil for prophylactic (preventative) treatment, unless there is a medical reason why you cannot (contraindication)
   3. You have previously tried abortive therapies such as sumatriptan, zolmitriptan, oxygen, unless there is a medical reason why you cannot (contraindication)

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GALCANEZUMAB-GNLM (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. Emgality is being prescribed for preventive treatment of migraines OR treatment of episodic cluster headache (very painful headaches that occur in patterns)
B. **If you have migraines, renewal also requires ONE of the following:**
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
   2. You have experienced a reduction in migraine severity with Emgality therapy
   3. You have experienced a reduction in migraine duration with Emgality therapy
C. **If you have episodic cluster headache, renewal also requires:**
   1. You had improvement in episodic cluster headache frequency as compared to baseline

Medicaid Effective: 07/01/21

GLATIRAMER ACETATE (MANAGED MEDICAID)

Generic	Brand			
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE			

GUIDELINES FOR USE

Our guideline named **GLATIRAMER ACETATE (Copaxone/Glatopa)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Medicaid Effective: 01/01/21

GLECAPREVIR/PIBRENTASVIR (MANAGED MEDICAID)

Generic	Brand			
GLECAPREVIR/ PIBRENTASVIR	MAVYRET			

GUIDELINES FOR USE

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

1. You have a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
2. You are 3 years of age or older
3. Therapy is prescribed by or recommended by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist (doctor who specializes in treatment of infections), physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
4. You have documentation of HCV (hepatitis c virus) infection. We require at least ONE detectable HCV RNA level (amount of virus in your blood) within the last 6 months)
5. You have compensated cirrhosis (no symptoms related to liver damage) or no cirrhosis (no liver damage) and meet ONE of the following:
   a. You are treatment naïve (never been treated) (genotype 1-6)
   b. You are treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6)
   c. You are treatment experienced with NS5A (Nonstructural protein 5A) inhibitor or NS3/4A protease inhibitor (genotype 1)
   d. You had a kidney transplant or liver transplant and are treatment naïve or treatment experienced (genotype 1-6)

The medication will not be approved if you meet any of the following:

- You are concurrently taking any of the following medications (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
- You have moderate or severe liver impairment (Child-Pugh B or C)
- You had a previous failure of a full course of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor and NS3/4A protease inhibitor (for example, Technivie, Viekira, Vosevi, Zepatier), or you had prior concurrent treatments containing a NS5A inhibitor AND a NS3/4A protease inhibitor
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Medicaid Effective: 07/26/21

GLYCOPYRRONIUM TOPICAL (MANAGED MEDICAID)

Generic	Brand			
GLYCOPYRRONIUM TOSYLATE	QBREXZA			

GUIDELINES FOR USE

Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You had a trial of a prescription strength aluminum chloride product such as Drysol
D. You have primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least six months duration with all secondary causes ruled out
E. You have at least two of the following:
    1. Symptoms occur bilaterally (on both sides of body)
    2. Symptoms impair daily activities
    3. You have at least one episode per week
    4. Onset occurred before you turn(ed) 25 years old
    5. You have a family history of primary axillary hyperhidrosis
    6. Symptoms do not occur during sleep

Medicaid Effective: 10/01/20

GOLIMUMAB - IV (NSA) (MANAGED MEDICAID)

Generic	Brand			
GOLIMUMAB - IV	SIMPONI ARIA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate at the same time with the requested medication, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   2. You meet ONE of the following criteria:
      a. You are 2 to 17 years old
      b. You are 18 years of age or older and have previously tried any TWO of the following preferred agents unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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GOLIMUMAB - IV (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (nonsteroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred agents, unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Orencia, Actemra

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate at the same time as the requested drug, unless there is a medical reason why you cannot (contraindication)

(Renewal criteria continued on the next page)

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GOLIMUMAB - IV (NSA) (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 01/01/21

GOLIMUMAB - SQ (MANAGED MEDICAID)

Generic	Brand			
GOLIMUMAB - SQ	SIMPONI - SQ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB-SQ (Simponi - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory bowel disease that causes inflammation in the digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq
   5. You are currently using methotrexate at the same time as the requested medication, unless there is a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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GOLIMUMAB - SQ (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (nonsteroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB-SQ (Simponi - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate at the same time as the requested medication, unless there is a medical reason why you cannot (contraindication)

(Renewal criteria continued on next page)

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GOLIMUMAB - SQ (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have moderate to severe ankylosing spondylitis (AS), renewal also requires:**
   5. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

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Medicaid Effective: 04/01/20

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (MANAGED MEDICAID)

Generic	Brand			
LEUPROLIDE ACETATE	ELIGARD			
NAFARELIN	SYNAREL			
TRIPTORELIN PAMOATE	TRIPTODUR			
TRIPTORELIN PAMOATE	TRELSTAR			
HISTRELIN ACETATE	SUPPRELIN LA, VANTAS			
LEUPROLIDE ACETATE	LUPRON DEPOT–PED, LUPRON DEPOT			
LEUPROLIDE ACETATE	LUPRON DEPOT (LUPANETA)			
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE			
LEUPROLIDE ACETATE	FENSOLVI			
GOSERELIN	ZOLADEX			

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (MANAGED MEDICAID)

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST** requires the following rule(s) be met for approval:

A. You have or are using the requested medication for ONE of the following:
   1. Advanced prostate cancer
   2. Moderate to severe pain from endometriosis (condition affecting the uterus)
   3. Central precocious puberty (CPP: early sexual development in girls and boys)
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you have gender dysphoria as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (a type of hormone doctor) or other provider experienced in assessing individuals for hormonal treatment
   2. If you are younger than 16 years of age, your prescriber has provided documentation of pubertal Tanner stage (scale of physical measurements of development based on external sex characteristics) of at least G2/B2 or above

C. **If you have moderate to severe pain from endometriosis, approval also requires:**
   1. The request is for Synarel, Lupron Depot, Lupaneta, or Zoladex
   2. You are 18 years of age or older if the request is for Synarel, Lupaneta, or Zoladex
   3. Therapy is prescribed by or given in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   4. You had a previous trial of a nonsteroidal anti-inflammatory drug (NSAID) and/or a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   5. You had a previous trial of preferred gonadotropin-releasing hormone-modulating agent

D. **If you are a female patient diagnosed with central precocious puberty, approval also requires:**
   1. The request is for Synarel, Leuprolide (generic), Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
   2. You are 2 years of age or older if the request is for Synarel, Leuprolide (generic), Triptodur, Supprelin LA, or Fensolvi
   3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (a type of hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are younger than 8 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you are a male patient with central precocious puberty, approval also requires:**
   1. The request is for Synarel, Leuprolide (generic), Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
   2. You are 2 years of age or older if the request is for Synarel, Leuprolide (generic), Triptodur, Supprelin LA, or Fensolvi
   3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (a type of hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are younger than 9 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

F. **Requests for Zoladex will also be approved for any ONE of the following:**
   1. When used in combination with flutamide for the management of locally confined carcinoma (cancer) of the prostate
   2. When used as an endometrial-thinning agent prior to endometrial ablation for a patient with dysfunctional uterine bleeding
   3. You are premenopausal or perimenopausal with a diagnosis of hormone receptor positive breast cancer

RENEWAL CRITERIA

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST** requires the following rule(s) be met for renewal:

A. You have or are using the requested medication for ONE of the following:
   1. Moderate to severe pain from endometriosis (condition affecting the uterus)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)
   3. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you have moderate to severe pain from endometriosis, renewal also requires:**
   1. You experienced improvement in endometriosis-related pain while on therapy
   2. You are receiving add-back therapy at the same time (such combination estrogen-progestin contraceptive preparation)

C. **If you have central precocious puberty (CPP), renewal also requires:**
   1. Tanner scale staging scale (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   2. You have not reached actual age, which corresponds to current pubertal age

GUSELKUMAB (MANAGED MEDICAID)

Generic	Brand			
GUSELKUMAB	TREMFYA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Orencia, Otezla, Taltz

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GUSELKUMAB (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 01/01/21

INFLIXIMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
INFLIXIMAB	REMICADE, INFLIXIMAB			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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INFLIXIMAB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried at least ONE or more form of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried the preferred immunomodulator (class of drugs): Humira
      b. You are 18 years of age or older AND have tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia and Humira

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INFLIXIMAB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have tried the preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate or have a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

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INFLIXIMAB (NSA) (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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Medicaid Effective: 01/01/22

INFLIXIMAB-ABDA (NSA) (MANAGED MEDICAID)

Generic	Brand			
INFLIXIMAB-ABDA	RENFLEXIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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INFLIXIMAB-ABDA (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried the following preferred immunomodulatory (class of drugs): Humira
      b. You are 18 years of age or older AND have tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia and Humira

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

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INFLIXIMAB-ABDA (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

4. You have tried the preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira

Note: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate or have a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

INFLIXIMAB-AXXQ (NSA) (MANAGED MEDICAID)

Generic	Brand			
INFLIXIMAB-AXXQ	AVSOLA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried at least ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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INFLIXIMAB-AXXQ (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried at least ONE or more forms of the following standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have tried at least ONE standard therapy, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless there is a medical reason why you cannot (contraindication)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried the preferred immunomodulator (class of drug): Humira
      b. You are 18 years of age or older AND have tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia and Humira

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INFLIXIMAB-AXXQ (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried at least ONE standard therapy such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless there is a medical reason why you cannot (contraindication)
   4. You have tried the preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate or have a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Renewal criteria continued on next page)

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INFLIXIMAB-AXXQ (NSA) (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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Medicaid Effective: 01/01/22

INFLIXIMAB-DYYB (NSA) (MANAGED MEDICAID)

Generic	Brand			
INFLIXIMAB-DYYB	INFLECTRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **INFLIXIMAB-DYYB (Inflectra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using or have a contraindication (a medical reason why you cannot use) to methotrexate
   4. You have tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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INFLIXIMAB-DYYB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Enbrel, Humira, Taltz

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried the preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira
      b. You are 18 years of age or older AND have tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia and Humira

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INFLIXIMAB-DYYB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have tried the preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-DYYB (Inflectra**) requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Renewal criteria continued on next page)

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INFLIXIMAB-DYYB (NSA) (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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Medicaid Effective: 01/01/22

INHALED INSULIN (MANAGED MEDICAID)

Generic	Brand			
INSULIN REGULAR, HUMAN	AFREZZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, patient is 18 years of age or older, and a baseline spirometry to measure FEV1 is performed. In addition, the following criteria must be met:

For type 1 diabetes, approval requires:

- The patient is concurrently using a long-acting insulin
- The patient had a trial of a preferred formulary rapid acting insulin: Admelog

For type 2 diabetes, approval requires:

- The patient had a trial of a preferred formulary rapid acting insulin: Admelog
- The prescriber indicated that the patient is physically unable or unwilling to administer injectable insulin

Afrezza will NOT be approved for patients with any of the following conditions:

- Chronic lung disease
- Active lung cancer
- Currently in diabetic ketoacidosis
- The patient is currently smoking or has quit smoking within the past 6 months

RENEWAL CRITERIA

The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, and a follow up spirometry to measure FEV1 after 6 months of treatment and annually thereafter. In addition, the following criteria must be met for renewal:

- **For type 1 diabetes:** approval requires concurrent use of a long acting insulin.
- **Afrezza will NOT be approved** for patients with a FEV1 that has declined 20% or more from baseline

Medicaid Effective: 02/25/19

INTERFERON ALFA-2B (MANAGED MEDICAID)

Generic	Brand			
INTERFERON ALFA-2B	INTRON A			

GUIDELINES FOR USE

Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) OR interferon use is treatment of one of the following: hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi's sarcoma, chronic hepatitis B, non-Hodgkin's lymphoma, malignant melanoma, chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis), follicular lymphoma, angioblastoma, carcinoid tumor, chronic myeloid leukemia, laryngeal papillomatosis, multiple myeloma, neoplasm of conjunctiva-neoplasm of cornea, ovarian cancer, polycythemia vera, renal cell carcinoma, skin cancer, Thrombocytosis, or vulvar vestibulitis.

Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist), requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) and HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.

Medicaid Effective: 04/01/16

INTERFERONS FOR MULTIPLE SCLEROSIS (MANAGED MEDICAID)

Generic	Brand			
INTERFERON BETA-1A	AVONEX, AVONEX PEN			
INTERFERON BETA-1A/ALBUMIN	AVONEX ADMINISTRATION PACK, REBIF, REBIF REBIDOSE			
INTERFERON BETA-1B	BETASERON, EXTAVIA			
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN			

****Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

REBIF

Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Rebif)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of nerves and you have new or increasing symptoms), which includes clinically isolated syndrome, relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

PLEGRIDY, BETASERON, EXTAVIA, AVONEX

Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Plegridy, Betaseron, Extavia, Avonex)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of nerves and you have new or increasing symptoms), which include clinically isolated syndrome, relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried any TWO of the following formulary preferred drugs, unless there is a medical reason why you cannot (contraindication): dimethyl fumarate, Rebif, Gilenya, Glatiramer/Glatopa, Aubagio

(**Please note:** The preferred MS agents may also a require prior authorization)

Medicaid Effective: 01/01/21

IXEKIZUMAB (MANAGED MEDICAID)

Generic	Brand			
IXEKIZUMAB	TALTZ			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. The requested medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried ONE or more forms of the following standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

(Initial criteria continued on next page)

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IXEKIZUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

RENEWAL CRITERIA

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis OR non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

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Medicaid Effective: 12/01/21

LASMIDITAN (MANAGED MEDICAID)

Generic	Brand			
LASMIDITAN SUCCINATE	REYVOW			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
   1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
   2. You have experienced clinical improvement as defined by ONE of the following:
      a. Ability to function normally within 2 hours of dose
      b. Headache pain disappears within 2 hours of dose
      c. Treatment works consistently in majority of migraine attacks

Medicaid Effective: 12/12/20

LEDIPASVIR/SOFOSBUVIR (MANAGED MEDICAID)

Generic	Brand			
LEDIPASVIR/SOFOSBUVIR	HARVONI			

GUIDELINES FOR USE

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation)
B. You have genotype 1, genotype 4, genotype 5, or genotype 6 hepatitis C
C. You are 3 years of age or older
D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. If you are treatment-experienced (previously treated) with no cirrhosis (liver damage) and genotype 1, previous treatment should include one of the following: 1) peginterferon and ribavirin, or 2) triple therapy with hepatitis C virus protease inhibitor (type of drug to treat hepatitis), peginterferon and ribavirin, or 3) Sovaldi/ribavirin with or without peginterferon
G. If you are treatment-experienced (previously treated) with compensated cirrhosis (no symptoms related to liver damage) and genotype 1, previous treatment should include either 1) peginterferon and ribavirin, or 2) triple therapy with hepatitis C virus protease inhibitor (type of drug to treat hepatitis), peginterferon and ribavirin
H. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
    1. You will be using a ribavirin-containing regimen
I. **If you are a post-liver transplant (without cirrhosis or compensated cirrhosis) patient, approval also requires:**
    1. You will be using a ribavirin-containing regimen
J. **If the request is for Harvoni 45mg/200mg pellets, approval also requires:**
    1. You are unable to swallow tablets

The medication will not be approved for the following patients:

A. Patients using any of the following medications concurrently while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/ tenofovir), or the combination agent tipranavir/ritonavir
B. Patients with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

Medicaid Effective: 07/01/20

LOMUSTINE (MANAGED MEDICAID)

Generic	Brand			
LOMUSTINE	GLEOSTINE			

GUIDELINES FOR USE

The guideline named **LOMUSTINE (Gleostine)** requires a diagnosis of Hodgkin's Lymphoma or that the request is being used for the treatment of primary and metastatic brain tumors in patients who previously received appropriate surgical and/or radiotherapeutic procedures.

Medicaid Effective: 04/01/18

MEBENDAZOLE (MANAGED MEDICAID)

Generic	Brand			
MEBENDAZOLE	EMVERM			

GUIDELINES FOR USE

The guideline named **MEBENDAZOLE (Emverm)** requires that the medication is used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm). The following criteria must also be met:

For treatment of trichuris trichiura (whipworm), ascaris lumbricoides (common roundworm), ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval requires:

- Documentation confirming a diagnosis of *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm)
- The patient has had a trial of or has a contraindication to albendazole (Albenza)

Medicaid Effective: 01/01/18

METHYLNALTREXONE (MANAGED MEDICAID)

Generic	Brand			
METHYLNALTREXONE BROMIDE	RELISTOR			

GUIDELINES FOR USE

The guideline named **METHYLNALTREXONE (Relistor)** requires that the patient have a diagnosis of opioid-induced constipation with chronic non-cancer pain, OR with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. The patient must also be 18 years of age or older. For patients with advanced (terminal) illness, or pain caused by active cancer who require opioid dosage escalation for palliative care, only Relistor injection may be approved. The following criteria must also be met:

For patients with chronic non-cancer pain, approval requires all of the following:

- The patient has been taking opioids for at least four weeks
- The patient had a previous trial of or contraindication to naloxegol (Movantik) and lubiprostone (Amitiza)

Medicaid Effective: 11/19/18

MILTEFOSINE

Generic	Brand			
MILTEFOSINE	IMPAVIDO			

GUIDELINES FOR USE

The guideline for **MILTEFOSINE (Impavido)** requires that the patient is 12 years of age or older and has a diagnosis of Leishmaniasis with one of the following types of infection:

- Visceral leishmaniasis due to *Leishmania donovani*
- Cutaneous leishmaniasis due to ALL of the following: *Leishmania braziliensis, Leishmania guyanensis*, and *Leishmania panamensis*
- Mucosal leishmaniasis due to *Leishmania braziliensis*

In addition, species identification must be confirmed via one of the following CDC recommended tests:

- Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
- Culture medium
- Polymerase chain reaction (PCR)
- Serologic testing (e.g. rK39 Rapid Test)

Medicaid Effective: 07/01/16

MONOMETHYL FUMARATE (MANAGED MEDICAID)

Generic	Brand			
MONOMETHYL FUMARATE	BAFIERTAM			

GUIDELINES FOR USE

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication (medical reason why you cannot take) to dimethyl fumarate AND ONE of the following: Aubagio, Glatiramer/Glatopa, Rebif

(**Please note:** Other multiple sclerosis medications may also require prior authorization)

Medicaid Effective: 01/01/21

NATALIZUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
NATALIZUMAB	TYSABRI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract)
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira AND Cimzia [**NOTE:** Pharmaceutical samples from the prescriber or manufacturer assistance programs do not qualify]

C. **If you have a relapsing form of multiple sclerosis (MS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is being used as monotherapy (used by itself)
   3. You have previously tried at least **ONE** drug indicated for the treatment of multiple sclerosis (MS) [**NOTE:** The following agents are preferred and may also require prior authorization: Aubagio, Gilenya, Glatiramer/Glatopa, Rebif, dimethyl fumarate]

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NATALIZUMAB (NSA) (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, renewal also requires ONE of the following:**
   1. **If you have received at least 12 months of Tysabri therapy, renewal also requires** that you have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tysabri
   2. **If you have only received 6 months of Tysabri therapy, renewal also requires** that you are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

Medicaid Effective: 01/01/21

OCRELIZUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
OCRELIZUMAB	OCREVUS			

GUIDELINES FOR USE

Our guideline named **OCRELIZUMAB (Ocrevus)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary progressive multiple sclerosis (PPMS: type of disease where body attacks its own nerves and it slowly gets worse)
   2. Relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)

B. **If you have primary progressive multiple sclerosis (PPMS), approval also requires:**
   1. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet **ONE** of the following:
      a. You had a previous trial of ONE agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Aubagio, Gilenya, Glatiramer/Glatopa, Rebif, dimethyl fumarate
      b. You show signs of severe disease requiring high-efficacy disease modifying therapy (DMT) such as high lesion (affected areas) volume and/or count, walking disability, or rapid decline

Medicaid Effective: 01/01/21

OFATUMUMAB-SQ (MANAGED MEDICAID)

Generic	Brand			
OFATUMUMAB	KESIMPTA			

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. You previously had a trial of or contraindication (medical reason why you cannot) to ONE of the following platform therapies (type of medication for multiple sclerosis): Aubagio, Glatiramer/Glatopa, Rebif, dimethyl fumarate
    2. You show signs of high-severity disease (such as high frequency or intensity of relapses) which merit (justify) immediate progression to high-efficacy disease-modifying therapies (type of medication for multiple sclerosis)
D. You previously had a trial of or contraindication (medical reason why you cannot) to the high-efficacy disease-modifying therapy (type of medication for multiple sclerosis): Gilenya

Please note: Other multiple sclerosis agents may also require prior authorization.

Medicaid Effective: 01/01/21

OLANZAPINE/SAMIDORPHAN (MANAGED MEDICAID)

Generic	Brand			
OLANZAPINE/ SAMIDORPHAN MALATE	LYBALVI			

GUIDELINES FOR USE

Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Schizophrenia (type of mental health disorder)
   2. Bipolar I disorder (type of mood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
D. You are at high risk for weight gain
E. You had a trial and failure of or contraindication (harmful for) to two generic antipsychotics (such as aripiprazole, quetiapine, risperidone)
F. **If you have bipolar I disorder, approval also requires ONE of the following:**
   1. Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
   2. Lybalvi is being used as maintenance monotherapy treatment

Medicaid Effective:10/11/21

OMBITASVIR/PARITAPREVIR/RITONAVIR (MANAGED MEDICAID)

Generic	Brand			
OMBITASVIR/PARITAPREVIR/ RITONAVIR	TECHNIVIE			

GUIDELINES FOR USE

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires the following rule(s) be met for approval:

- You have a diagnosis of chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
- You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
- Requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
- You are at least 18 years old
- You have failed a previous trial of Mavyret. Reasons for failure include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) Mavyret; (**NOTE:** If you completed a full course of therapy with Mavyret and you did not achieve sustained virologic response (no virus can be detected in blood), the request will not be approved)
- You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Evidence of current hepatitis C virus infection and chronic hepatitis C virus infection as documented by at least one detectable HCV RNA levels (amount of virus in your blood) within past 6 months

A total of 12 weeks of therapy will be approved.

The medication will NOT be approved for the following:

- You are using any of the following medications at the same time while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
- You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
- You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)

(Criteria continued on next page)

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OMBITASVIR/PARITAPREVIR/RITONAVIR (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- You have previously used or are currently using Viekira Pak or Viekira XR, or previous failure of any of the following regimens: a nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir), a combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir), and/or a HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

Medicaid Effective: 09/17/18

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR (MANAGED MEDICAID)

Generic	Brand			
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA PAK			
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA XR			

GUIDELINES FOR USE

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak or Viekira XR)** requires the following rule(s) be met for approval:

A. You have a diagnosis of chronic hepatitis C, genotype 1
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. You will use the requested medication with ribavirin, unless you have genotype 1b
D. You are least 18 years old
E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You have failed a short trial with Mavyret. Reasons for failure include that you had adverse effects early in therapy or have a contraindication to (medical reason why you cannot use) Mavyret. If you have completed a full course of therapy with Mavyret and did not achieve sustained virologic response (you have no detectable amount of virus), the request will not be approved.
G. Documentation at least one detectable HCV RNA level (amount of hepatitis virus within the last 6 months

The medication will NOT be approved for the following patients:

- You are using any of the following medications concurrently while on Viekira Pak: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
- You have decompensated cirrhosis (you have symptoms related to liver damage)
- You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
- You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

- You had prior use of or concurrent use of a nucleotide NS5B polymerase inhibitor (type of hepatitis C drug), or failure of a full treatment course of any of the following: including Sovaldi (sofosbuvir), a combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir), or hepatitis C virus protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved. 24 weeks of therapy will be approced for 1) genotype 1a with cirrhosis (liver damage) if you are treatment experienced, with no previous response or 2) you are a liver transplant recipient.

Medicaid Effective: 09/17/18

OMNIPOD/OMNIPOD DASH INSULIN DEVICES (MANAGED MEDICAID)

Generic	Brand			
SUBCUTANEOUS INSULIN PUMP	OMNIPOD			
INSULIN PUMP CONTROLLER	OMNIPOD DASH PDM KIT			

GUIDELINES FOR USE

Our guideline named **OMNIPOD/OMNIPOD DASH INSULIN DEVICES** requires the following rule(s) be met for approval:

A. The requested pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and frequent self-adjustments of insulin dose for the past 6 months
D. You require glucose (blood sugar) self-testing at least 4 times per day on average in the previous 2 months
E. You have not received a device (personal diabetes manager [PDM]) within the last 4 years (Exception: your device is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

Medicaid Effective: 02/08/21

OPIOID DEPENDENCY AGENTS (MANAGED MEDICAID)

Generic	Brand			
BUPRENORPHINE	SUBUTEX			

GUIDELINES FOR USE

The guideline named **OPIOID DEPENDENCY AGENTS** requires that all of the following criteria are met:

- A diagnosis of opioid addiction/dependence
- The prescriber is a buprenorphine-certified prescriber in accordance with the Drug Addiction Treatment Act
- The patient is not currently dependent on/abusing CNS depressants (i.e., benzodiazepines, barbiturates, sedative hypnotics) **OR** is being rapidly tapered off these medications
- The patient is not currently dependent on/abusing alcohol
- The patient is not using opioid analgesics concurrently

In addition, requests for buprenorphine monotherapy (generic for Subutex) may be approved if one of the following conditions is met:

- Patient is pregnant
- Patient has documentation of naloxone-induced anaphylaxis, bronchospasm, or angioneurotic edema
- Patient is being transitioned directly from a long-acting opioid (i.e., methadone) during induction only

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Medicaid Effective: 10/01/17

OZANIMOD (MANAGED MEDICAID)

Generic	Brand			
OZANIMOD	ZEPOSIA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. A relapsing form of multiple sclerosis (MS: type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects the lining of the digestive tract)

B. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You have previously tried ONE agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Aubagio, Gilenya, Glatiramer/Glatopa, Rebif, dimethyl fumarate)

D. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE conventional (standard) therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried the following preferred immunomodulator, unless there is a medical reason why you cannot (contraindication): Humira

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for renewal:

A. You have moderate to severe active ulcerative colitis (UC: type of inflammatory disease that affects the lining of the digestive tract)

Medicaid Effective: 10/01/21

PATIROMER (MANAGED MEDICAID)

Generic	Brand			
PATIROMER CALCIUM SORBITEX	VELTASSA			

GUIDELINES FOR USE

Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:

A. You have a diagnosis of hyperkalemia (high levels of potassium in blood)
B. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor) or cardiologist (heart doctor)
C. The requested drug is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
D. The requested drug will NOT be used if you are currently receiving dialysis
E. You have tried **ONE** of the following to lower the risks for hyperkalemia:
    1. Limit to taking no more than one of the following drugs at any given time: (Angiotensin converting enzyme inhibitor [ACE-I such as lisinopril, benazepril], Angiotensin receptor blocker [ARB such as valsartan, losartan])
    2. You have considered lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone)
F. If estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2): you have tried to treat hyperkalemia with loop diuretics such as bumetanide, ethacrynic acid, furosemide, torsemide
G. If estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above: you have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide, OR thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone

Medicaid Effective: 04/01/19

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON) (MANAGED MEDICAID)

Generic	Brand			
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK			
PEGINTERFERON ALFA-2B	PEGINTRON			

GUIDELINES FOR USE

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires the following rule(s) be met for approval:

A. You have diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 (type of liver inflammation caused by hepatitis C virus). Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B

B. **If you have a diagnosis of chronic hepatitis B (type of liver inflammation caused by hepatitis B virus), approval requires:**
   1. You are at least 3 years old; and
   2. The drug is prescribed by a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specialzing in disorders caused by viruses, bacteria, fungi and parasites), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model; and
   3. You do not have cirrhosis (liver damage); and
   4. You have tested positive for HBeAg (hepatitis B e-antigen); and
   5. You have evidence of viral replication (the virus has multiplied in your body) with high serum ALT (high amount of a type of liver enzymes).

C. **If you have a diagnosis of chronic hepatitis C, approval requires:**
   1. You are between 3 and 11 years old; and
   2. The drug is prescribed by a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specialzing in disorders caused by viruses, bacteria, fungi and parasites) or a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor); and
   3. You have other symptoms of hepatitis C (extrahepatic manifestations) such as cryoglobulinemia (abnormal proteins in the blood), rashes, and glomerulonephritis (inflammation in your kidneys) AND you have advanced fibrosis (scar tissue in the liver) that requires urgent treatment to lower your risks of getting worse or dying; and
   4. Peginterferon is being used with ribavirin, unless there is a medical reason why you cannot use ribavirin (contraindication)
   5. You have a detectable pretreatment HCV RNA level/viral load (amount of virus in your blood). The level varies by lab assay (test) but is a level typically greater than or equal to 25 IU/mL

PONESIMOD (MANAGED MEDICAID)

Generic	Brand			
PONESIMOD	PONVORY			

GUIDELINES FOR USE

Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You had a trial of one agent indicated for the treatment of multiple sclerosis (**Please note:** other multiple sclerosis agents may also require prior authorization)

Medicaid Effective: 04/10/21

RELUGOLIX-ESTRADIOL-NORETHINDRONE (MANAGED MEDICAID)

Generic	Brand			
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You have tried and failed TWO agents from the following unless there is a medical reason why you cannot (contraindication): oral tranexamic acid, contraceptive preparations (such as oral contraceptive, levonorgestrel intra-uterine device [such as Mirena, Kyleena, Skyla, Liletta] or other forms of contraceptive)
F. You have not received a total of 24 months cumulative (total) treatment with Myfembree

RENEWAL CRITERIA

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You had improvement of heavy menstrual bleeding on therapy
C. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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Medicaid Effective: 10/01/21

RESLIZUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
RESLIZUMAB	CINQAIR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
E. You are being treated with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
F. You have ONE of the following:
    1. Experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
    2. Poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma
G. You will NOT use Cinqair concurrently (at the same time) with Xolair, Dupixent, or another anti-IL5 biologic (such as Nucala, Fasenra) when these are used for the treatment of asthma

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RESLIZUMAB (NSA) (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

A. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
B. You have shown a clinical response as evidenced by ONE of the following:
   1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
   2. Decreased use of rescue medications
   3. Increase in percent predicted FEV1 (type of lung test) from pretreatment baseline
   4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

Medicaid Effective: 01/01/22

RIBOCICLIB (MANAGED MEDICAID)

Generic	Brand			
RIBOCICLIB	KISQALI			
RIBOCICLIB LETROZOLE	KISQALI FEMARA CO-PACK			

GUIDELINES FOR USE

Our guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (cancer that has spread throughout the body and has a type of hormone with no gene mutation)

B. **For Kisqali-Femara Co-Pack request, approval requires:**
   1. You are female and pre/perimenopausal **OR** post-menopausal
   2. You have **NOT** received prior endocrine(hormone)-based therapy for advanced or metastatic breast cancer such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane
   3. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)

C. **For Kisqali request, approval requires ONE of the following:**
   1. **Kisqali will be used in combination with an aromatase inhibitor (type of breast cancer drug) and meet all of the following:**
      a. You are female and pre/perimenopausal **OR** post-menopausal
      b. You have **NOT** received prior endocrine(hormone)-based therapy for advanced or metastatic breast cancer such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane
      c. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
   2. **Kisqali will be used in combination with Faslodex (fulvestrant) and meet all of the following:**
      a. You are female and post-menopausal
      b. You have not received prior endocrine (hormone)-based therapy for advanced or metastatic breast cancer (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane) **OR** you have experienced disease progression (has gotten worse) on endocrine therapy
      c. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)

RIMEGEPANT (MANAGED MEDICAID)

Generic	Brand			
RIMEGEPANT SULFATE	NURTEC ODT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of acute (quick onset) migraine
   2. Preventive treatment of episodic migraines
B. You are 18 years of age or older
C. **If the request is for the treatment of acute migraine, approval also requires:**
   1. You had a trial of TWO triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)
D. **If the request is for the preventive treatment of episodic migraines, approval also requires:**
   1. You previously tried TWO of the following preventative migraine treatments, unless there is a medical reason why you cannot (contraindication): divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

RENEWAL CRITERIA

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Treatment of acute (quick onset) migraine
   2. Preventive treatment of episodic migraines
B. **If the request is for treatment of acute migraine, approval also requires ONE of the following:**
   1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
   2. You have experienced clinical improvement as defined by ONE of the following:
      a. Ability to function normally within 2 hours of dose
      b. Headache pain disappears within 2 hours of dose
      c. Treatment works consistently in majority of migraine attacks

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If the request is for the preventive treatment of episodic migraines, approval also requires ONE of the following:**
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
   2. You experienced a reduction in migraine severity
   3. You experienced a reduction in migraine duration

Medicaid Effective: 10/25/21

RIOCIGUAT (MANAGED MEDICAID)

Generic	Brand			
RIOCIGUAT	ADEMPAS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) (World Health Organization [WHO] Group 4)
   2. Pulmonary arterial hypertension (PAH: type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

C. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   3. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   4. You had a previous trial of a phosphodiesterase-5 inhibitor such as Revatio or Adcirca, unless there is a medical reason why you cannot (contraindication)
   5. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

D. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
   3. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
   2. Pulmonary arterial hypertension (PAH: type of heart and lung condition) (WHO Group 1)

B. You show improvement from baseline in the 6-minute walk distance OR have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class

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Medicaid Effective: 01/01/22

RISANKIZUMAB-RZAA (MANAGED MEDICAID)

Generic	Brand			
RISANKIZUMAB-RZAA	SKYRIZI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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Medicaid Effective: 06/01/21

RITUXIMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
RITUXIMAB	RITUXAN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   3. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   4. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)
   6. Moderate to severe Pemphigus Vulgaris (PV: immune disease with blisters that break out on the skin and on the lining of the mouth)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)

D. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
   3. You are currently using chemotherapy at the same time with the requested medication

(Initial criteria continued on next page)

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RITUXIMAB (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 2 years of age or older
   2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) with the requested medication

F. **If you have moderate to severe Pemphigus Vulgaris (PV), approval also requires:**
   1. You are 18 years of age or older

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

NOTE: For the diagnoses of Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Wegener's Granulomatosis (WG), Microscopic Polyangiitis (MPA), and moderate to severe Pemphigus Vulgaris (PV), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal.

Medicaid Effective: 07/01/21

RITUXIMAB-ABBS (NSA) (MANAGED MEDICAID)

Generic	Brand			
RITUXIMAB-ABBS	TRUXIMA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   3. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   4. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

B. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

C. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

D. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

(*Initial criteria continued on the next page)*

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RITUXIMAB-ABBS (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq [NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.]

E. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 18 years of age or older
   2. You are on currently on glucocorticoids (steroids such as methylprednisolone or prednisone) with the requested medication

RENEWAL CRITERIA

NOTE: For the diagnoses of Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Wegener's Granulomatosis (WG), and Microscopic Polyangiitis (MPA), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 07/01/21

RITUXIMAB-PVVR (NSA) (MANAGED MEDICAID)

Generic	Brand			
RITUXIMAB-PVVR	RUXIENCE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   3. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   4. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)
   5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)

B. You are 18 years of age or older

C. **If you have Non-Hodgkin's Lymphoma, approval also requires:**
   1. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)

D. **If you have Chronic Lymphocytic Leukemia, approval also requires:**
   1. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   2. The requested medication will be used in combination with chemotherapy

E. **If you have Wegener's Granulomatosis or Microscopic Polyangiitis, approval also requires:**
   1. You are using glucocorticoids (steroids such as methylprednisolone or prednisone) at the same time with the requested medication

F. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You are currently using methotrexate, unless you have a contraindication (harmful for)
   3. You had a trial of or contraindication to (harmful for) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had a trial of or contraindication to (harmful for) any TWO of the following preferred medications: Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-PVVR (NSA) (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), Wegener's Granulomatosis (WG), and Microscopic Polyangiitis (MPA), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 01/01/22

SARILUMAB (MANAGED MEDICAID)

Generic	Brand			
SARILUMAB	KEVZARA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:
A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:
A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 04/01/20

SECUKINUMAB (MANAGED MEDICAID)

Generic	Brand			
SECUKINUMAB	COSENTYX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine pain that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. Request for 300mg dosage in psoriatic arthritis without coexisting plaque psoriasis requires you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. Request for 300mg dosage requires you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis

(Initial criteria continued on next page)

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SECUKINUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following objective signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

RENEWAL CRITERIA

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy.

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy.

Medicaid Effective: 01/01/22

SIMEPREVIR (MANAGED MEDICAID)

Generic	Brand			
SIMEPREVIR	OLYSIO			

GUIDELINES FOR USE

Our guideline named **SIMEPREVIR (Olysio)** requires the following rule(s) be met for approval:

A. You have a diagnosis of chronic hepatitis C, genotype 1 (type of liver inflammation)
B. You will be using Olysio with Sovaldi taken at the same time
C. You are at least 18 years old
D. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin
E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
G. You must have had a short trial of Mavyret and stopped due to things such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication). An individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved

Olysio will not be approved for the following patients:

- Patients who have failed a full course of treatment with 1) any hepatitis C protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) **OR** 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
- Patients with compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
- Patients with a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Patients who are using Olysio with ribavirin and peginterferon alfa
- Patients who are taking any of the following medications that are not recommended for concurrent use with Olysio:
    - Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
    - Any cobicistat-containing medication (e.g., Genvoya or Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
    - Delavirdine, etravirine, nevirapine, or efavirenz
    - Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

SIPONIMOD (MANAGED MEDICAID)

Generic	Brand			
SIPONIMOD	MAYZENT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried ONE of the following: Gilenya, Aubagio, Glatiramer/Glatopa, Rebif, dimethyl fumarate
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

RENEWAL CRITERIA

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline
C. You do not have lymphopenia (condition where you have a low amount of a type of white blood cell)
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

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Medicaid Effective: 01/01/21

SODIUM ZIRCONIUM CYCLOSILICATE (MANAGED MEDICAID)

Generic	Brand			
SODIUM ZIRCONIUM CYCLOSILICATE	LOKELMA			

GUIDELINES FOR USE

The guideline named **SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma)** requires a diagnosis of hyperkalemia. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist or cardiologist
- The requested drug is NOT being used as an emergency treatment for life-threatening hyperkalemia
- The requested drug will NOT be used in a patient currently receiving dialysis
- The patient has attempted **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia:
  - Limit to taking no more than one of the following drugs at any given time (Angiotensin converting enzyme inhibitor [ACE-I], Angiotensin receptor blocker [ARB])
  - Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)
- If estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2): the patient has tried to treat hyperkalemia with loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)
- If estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above: the patient has tried to treat hyperkalemia with a loop diuretic (e.g., bumetanide, ethacrynic acid, furosemide, torsemide), OR thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

Medicaid Effective: 04/01/19

SOFOSBUVIR (MANAGED MEDICAID)

Generic	Brand			
SOFOSBUVIR	SOVALDI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3 **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You will be using Sovaldi together with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    2. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
F. **If you are a pediatric patient (under age 18), approval also requires:**
    1. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)
G. You had a previous short trial of ONE preferred agent and stopped due to reasons such as intolerance, adverse effect early in therapy, or you have a contraindication to (medical reason why you cannot use) ALL preferred agent(s). An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved:
    1. If you are an adult with genotype 1 infection without cirrhosis (liver scarring), trial of preferred Mavyret is required
    2. If you are an adult with genotype 1 infection and post-liver transplant, the preferred agent is Mavyret
    3. If you are an adult with genotype 3 infection without cirrhosis, the preferred agent is Mavyret
    4. If you are an adult with genotype 3 infection and post-liver transplant, the preferred agent is Mavyret
    5. If you are an adult with decompensated cirrhosis (you have symptoms related to liver damage) with genotype 1 or 3 infection, no trial is required
    6. If you are a pediatric patient: no trial is required

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SOFOSBUVIR (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following:

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)
D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with peginterferon alfa and ribavirin

Requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:

A. You are 18 years of age or older and without cirrhosis (liver scarring)
B. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug) OR 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
C. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use a drug) or not recommended by the manufacturer:
    1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
    2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
    3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/ emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
    4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

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SOFOSBUVIR (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

For patients using Sovaldi with Daklinza, the following criteria must be met:

A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (there is a medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

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Medicaid Effective: 06/01/21

SOFOSBUVIR/VELPATASVIR (MANAGED MEDICAID)

Generic	Brand			
SOFOSBUVIR/VELPATASVIR	EPCLUSA			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6.
B. You are 3 years of age or older
C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
    1. The requested medication will be used with ribavirin
F. **If you do not have cirrhosis (liver damage) or you have compensated cirrhosis (a condition where liver is extensively scarred, but you do not have symptoms of liver damage), approval also requires ONE of the following:**
    1. You are treatment naive (never previously treated)
    2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin)
    3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include NS5A inhibitor such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio

Epclusa will not be approved in the following conditions:

A. You are using any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Medicaid Effective: 07/26/21

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (MANAGED MEDICAID)

Generic	Brand			
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
B. You are at least 18 years old
C. You have documentation of hepatitis C virus infection with at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have failed a full course of therapy with a direct-acting antiviral (DAA) regimen that includes NS5A inhibitor (type of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) **OR** You have genotype 1a or genotype 3 and you previously failed a full course of therapy with a DAA regimen that includes sofosbuvir without NS5A inhibitor (such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis C virus protease inhibitor in combination with Sovaldi))

The medication will not be approved for the following:

H. You are concurrently taking: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, human immunodeficiency virus (HIV) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topetecan
I. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
J. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

Medicaid Effective: 04/01/20

SOLIFENACIN SUSPENSION (MANAGED MEDICAID)

Generic	Brand			
SOLIFENACIN SUCCINATE	VESICARE LS			

GUIDELINES FOR USE

Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:

A. You have neurogenic detrusor overactivity (type of bladder dysfunction)
B. You are 2 years of age or older
C. You had a trial of or contraindication (harmful for) to an anticholinergic (such as oxybutynin)
D. You are unable to swallow oral solifenacin tablets

Medicaid Effective: 01/01/22

SOMATROPIN (MANAGED MEDICAID)

Generic	Brand			
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON, ZORBTIVE			

GUIDELINES FOR USE

**** Please use the criteria for the specific drug requested. ****

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:

A. You have a diagnosis of HIV (human mmunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
B. The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
C. Therapy is prescribed by or in consultation with one of the following specialists: gastroenterologist (digestive system doctor), nutritional support specialist OR infectious disease specialist
D. You are on HIV (human mmunodeficiency virus) anti-retroviral therapy
E. You have an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
F. You have an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
G. Alternative causes of wasting have been ruled out. Alternative causes include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies (tumors)
    5. Opportunistic infections

(Initial SEROSTIM criteria continued on next page)

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INITIAL CRITERIA - GENOTROPIN (CONTINUED)

H. You meet **ONE** of the following criteria for weight loss:
   1. 10% unintentional weight loss over 12 months
   2. 7.5% unintentional weight loss over 6 months
   3. 5% body cell mass (BCM) loss within 6 months
   4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
   5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
   6. BMI (body mass index) less than 18.5 kg per meter squared

I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
   1. You meet one of the following criteria for low testosterone:
      a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
      b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
      c. A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
   2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

ZORBTIVE

Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for approval:

A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly)
B. The requested agent requested is NOT prescribed for athletic enhancement or anti-aging purposes
C. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences
D. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor)

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

GENOTROPIN

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

D. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)

E. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. You have no catch-up growth by age 2 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

HUMATROPE

Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

(Initial HUMATROPE criteria continued on next page)

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INITIAL CRITERIA - GENOTROPIN (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature or growth failure in short stature homeobox-containing gene deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   5. You have no catch-up growth by age 2 to 4 years

(Initial HUMATROPE criteria continued on next page)

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - HUMATROPE (CONTINUED)

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

NORDITROPIN FLEXPRO

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least **ONE** of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

(Initial NORDITROPIN FLEXPRO criteria continued on next page)

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You have no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

NUTROPIN AQ NUSPIN

Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Adult growth hormone deficiency

(Initial NUTROPIN AQ NUSPIN criteria continued on next page)

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INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
4. You meet at least ONE of the following criteria for short stature:
   a. Your height greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   b. Your height velocity is less than the 25th percentile for age
   c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have growth failure secondary to chronic kidney disease, approval also requires:**

1. You have NOT undergone a renal (kidney) transplantation
2. Therapy is prescribed by or in consultation with a nephrologist (kidney specialist)
3. Your height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Turner syndrome, approval also requires:**

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have adult growth hormone deficiency, approval also requires:**

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - (CONTINUED)

OMNITROPE

Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity lis ess than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi Syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)

(Initial OMNITROPE criteria continued on next page)

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INITIAL CRITERIA - OMNITROPE (CONTINUED)

D. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. You have no catch-up growth by age 2 years
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are **NOT** closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

SAIZEN

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

ZOMACTON

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - ZOMACTON (CONTINUED)

D. **If you have short stature and are a child born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You have no catch-up growth by age 2 to 4 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have short stature or growth failure and are a child with SHOX deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

RENEWAL CRITERIA

SEROSTIM

Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal approval:

A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
B. You have NOT received more than 24 weeks of therapy within the plan year
C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
D. You have shown clinical benefit in muscle mass and weight as indicated by a 10% increase or greater in weight or BCM (body cell mass) from baseline (**Note**: current and baseline weight must be documented including dates of measurement)
E. You are on HIV anti-retroviral therapy

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

ZORBTIVE

Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:

A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly
B. You have not been on the requested medication for 4 weeks

GENOTROPIN

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) for renewal approval:

A. You have ONE of the following diagnoses:
    1. Pediatric growth hormone deficiency (GHD)
    2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
    3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
    4. Growth failure in children born small for gestational age (SGA)
    5. Adult growth hormone deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
    1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
    2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
    3. You meet ONE of the following:
        a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
        b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
C. **If you have short stature associated with Turner syndrome, renewal also requires:**
    1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
    2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
    3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height
D. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
    1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
    2. You had improvement in body composition

(Renewal GENOTROPIN criteria continued on next page)

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RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

HUMATROPE

Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency.

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have no completed prepubertal growth)
   3. You meet ONE of the following
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

D. **If you have short stature or growth failure and are a child with SHOX deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

NORDITROPIN FLEXPRO

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

(Renewal NORDITROPIN FLEXPRO criteria continued on next page)

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RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) stage of puberty

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

NUTROPIN AQ NUSPIN

Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)**, requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth failure secondary to chronic kidney disease, renewal also requires:**
   1. The patient has not undergone a renal (kidney) transplantation
   2. Your growth velocity is 2 cm or more compared with what was observed from the previous year or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

OMNITROPE

Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

D. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

(Renewal OMNITROPE criteria continued on next page)

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

E. **If you have growth failure associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

SAIZEN

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic Short Stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have no completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN (MANAGED MEDICAID)

RENEWAL CRITERIA (CONTINUED)

ZOMACTON

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency.

   This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature or growth failure and are a child with SHOX deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

(Renewal ZOMACTON criteria continued on next page)

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RENEWAL CRITERIA - ZOMACTON (CONTINUED)

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Medicaid Effective: 12/01/21

TERIFLUNOMIDE (MANAGED MEDICAID)

Generic	Brand			
TERIFLUNOMIDE	AUBAGIO			

GUIDELINES FOR USE

Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:

A. You have a diagnosis of a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. You are 18 years of age and older.

Medicaid Effective: 01/01/20

TESTOSTERONE (MANAGED MEDICAID)

Generic	Brand			
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO			
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE			
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED			
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST			
TESTOSTERONE UNDECANOATE	JATENZO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological disorder (not due to disease)
   3. Gender dysphoria (you identify yourself as a member of the opposite sex)
   4. Female, metastatic breast cancer (cancer spreading to other areas of body)

B. **If you are a female with metastatic breast cancer or you are a male with delayed puberty not secondary to a pathological (extreme) disorder**, only intramuscular (injected into muscle) testosterone enanthate or methyltestosterone (Testred, Android, or Methitest) may be approved

C. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

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TESTOSTERONE (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You had a previously approved prior authorization for testosterone or have been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history OR You have ONE of the following laboratory values confirming you have low testosterone levels:
      i. At least two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state (you have not eaten)
      ii. Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
   2. You have previously tried or have a medical reason why you cannot use (contraindication) generic injectable testosterone (such as testosterone cypionate or intramuscular testosterone enanthate)

E. **For requests of Xyosted, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for testosterone replacement therapy

F. **For requests of Jatenzo, approval also requires:**
   1. You are 18 years of age or older

G. **If you are a male patient requesting methyltestosterone (Testred, Android or Methitest) for delayed puberty not secondary to a pathological disorder**, **approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that intramuscular testosterone enanthate requires a prior authorization.

H. **If you are a female patient requesting methyltestosterone (Testred, Android or Methitest) for metastatic breast cancer, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that intramuscular testosterone enanthate requires a prior authorization.

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TESTOSTERONE (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological (extreme) disorder (not due to disease)
   3. Female, metastatic breast cancer (cancer spreading to other areas of body)
   4. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

C. **If you are a male patient with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Documentation of normalized serum testosterone levels and hematocrit concentrations (type of blood test) compared to baseline

D. **If you are a male patient with delayed puberty not secondary to a pathological disorder, only the following will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest

E. **If you are a female patient with metastatic breast cancer, only the following will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest

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Medicaid Effective: 06/01/20

TILDRAKIZUMAB-ASMN (NSA) (MANAGED MEDICAID)

Generic	Brand			
TILDRAKIZUMAB-ASMN	ILUMYA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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Medicaid Effective: 04/01/20

TOCILIZUMAB - IV (NSA) (MANAGED MEDICAID)

Generic	Brand			
TOCILIZUMAB - IV	ACTEMRA - IV			

For requests for the SQ dosage form of Actemra, please see the Actemra SQ PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   4. Schimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (inflammatory response that can be triggered by a variety of factors such as infections and certain drugs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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TOCILIZUMAB - IV (NSA) (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

E. **For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval also requires:**
   1. You are 2 years of age or older

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

Medicaid Effective: 10/01/20

TOCILIZUMAB - SQ (MANAGED MEDICAID)

Generic	Brand			
TOCILIZUMAB - SQ	ACTEMRA - SQ			

For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have giant cell arteritis (GCA), approval also requires:**
   1. You are 18 years of age or older

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TOCILIZUMAB - SQ (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of Systemic Sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

E. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

F. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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TOCILIZUMAB - SQ (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

D. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

Medicaid Effective: 07/01/21

TOFACITINIB (MANAGED MEDICAID)

Generic	Brand			
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO preferred immunomodulators (class of drug), unless there is a medical reason why you cannot (contraindication): Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant, Orencia, Rinvoq

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drug), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

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INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following preferred immunomodulator (class of drug), unless there is a medical reason why you cannot (contraindication): Humira

E. **If you have polyarticular course juvenile idiopathic arthritis (pcJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drug), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Orencia, Actemra

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

B. **If you have moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (MANAGED MEDICAID)

Generic	Brand			
TRASTUZUMAB	HERCEPTIN			
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Breast cancer
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously tried chemotherapy for metastatic disease (disease has spread to other areas of body)
   3. If you are requesting Herceptin Hylecta, you must be 18 years of age or older

C. **If you have breast cancer, approval also requires:**
   1. The request is for adjuvant therapy (add-on therapy to main treatment)
   2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) tumor as detected by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
   4. If you are requesting Herceptin Hylecta, you must be 18 years of age or older

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (MANAGED MEDICAID)

GUIDELINES FOR USE (CONTINUED)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma (stomach-throat cancer that has spread), approval also requires:**
   1. The request is for Herceptin (not Herceptin Hylecta)
   2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) metastatic breast cancer as detected by a Food and Drug Administration (FDA)-approved test
   3. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   4. You have not received prior treatment for metastatic disease (disease has spread to

TRASTUZUMAB-DTTB (MANAGED MEDICAID)

Generic	Brand			
TRASTUZUMAB-DTTB	ONTRUZANT			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB- DTTB (Ontruzant)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. The request is for adjuvant (add-on) therapy
   2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

TRASTUZUMAB-PKRB (MANAGED MEDICAID)

Generic	Brand			
TRASTUZUMAB-PKRB	HERZUMA			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-PKRB (Herzuma)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The request is for adjuvant (add-on) treatment
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimensfor metastatic disease (disease has spread to other parts of the body)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in stomach cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

UBROGEPANT (MANAGED MEDICAID)

Generic	Brand			
UBROGEPANT	UBRELVY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:

A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:

A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        a. Ability to function normally within 2 hours of dose
        b. Headache pain disappears within 2 hours of dose
        c. Treatment works consistently in majority of migraine attacks

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Medicaid Effective: 01/01/21

UPADACITINIB (MANAGED MEDICAID)

Generic	Brand			
UPADACITINIB	RINVOQ ER			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Medicaid Effective: 04/01/20

USTEKINUMAB (MANAGED MEDICAID)

Generic	Brand			
USTEKINUMAB	STELARA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have psoriatic arthritis without co-existent plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) OR dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried TWO of the following preferred immunomodulators (class of drug), unless there is a medical reason why you cannot (contraindication): Cimzia, Orencia, Cosentyx, Enbrel, Otezla, Taltz, Humira

C. **If you have moderate to severe plaque psoriasis or moderate to severe plaque psoriasis with co-existent psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more form of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have previously tried TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia, Cosentyx, Humira, Taltz, Skyrizi, Enbrel, Otezla

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USTEKINUMAB (MANAGED MEDICAID)

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age of older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia AND Humira

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract

B. **If you have psoriatic arthritis without co-existent plaque psoriasis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis, renewal also requires:**
   1. You have achieved clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

V-GO INSULIN DEVICES (MANAGED MEDICAID)

Generic	Brand			
SUB-Q INSULIN DEVICE, 20 UNIT	V-GO 20			
SUB-Q INSULIN DEVICE, 30 UNIT	V-GO 30			
SUB-Q INSULIN DEVICE, 40 UNIT	V-GO 40			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. You follow a maintenance program of at least 3 injections of insulin per day
D. You have worked with your doctor to adjust your insulin dose for the past 6 months and still have not met your glucose (blood sugar) goals
E. You do not require regular adjustments to your basal rate during a 24-hour time period
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You do not require a total daily insulin dose of more than 76 units
H. You are on a multiple daily insulin injection regimen and meet ONE of the following criteria:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

RENEWAL CRITERIA

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for renewal:

A. You have shown a positive response to therapy AND are adherent to your doctor follow-up visits

VARENICLINE (MANAGED MEDICAID)

Generic	Brand			
VARENICLINE TARTRATE	TYRVAYA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:

A. You have dry eye disease
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctor)
D. You meet at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test, etc.)
E. You had a trial of or contraindication to (harmful for) to one ocular lubricant (such as carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal], polyvinyl alcohol [Liquitears, Refresh Classic], or wetting agents [Systane, Lacrilube])
F. You had a trial of or contraindication to (harmful for) the preferred agent Xiidra

RENEWAL CRITERIA

Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:

A. You have dry eye disease
B. You have demonstrated improvement of dry eye disease

Medicaid Effective:11/08/21

VEDOLIZUMAB (NSA) (MANAGED MEDICAID)

Generic	Brand			
VEDOLIZUMAB	ENTYVIO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract) OR moderate to severe Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)
B. **If you have moderate to severe Crohn's Disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cimzia AND Humira
C. **If you have moderate to severe Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract) OR moderate to severe Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

VERICIGUAT (MANAGED MEDICAID)

Generic	Brand			
VERICIGUAT	VERQUVO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You are 18 years of age or older
D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Invokamet, Invokana, Segluromet, Steglatro
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

RENEWAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

Medicaid Effective: 02/15/21

MedImpact

MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

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