

# Pharmacy Management Drug Policy

**SUBJECT: Clinical Review Prior Authorization (CRPA) Medical**  
**POLICY NUMBER: PHARMACY-63**  
**ANNUAL REVIEW DATE: 12/11/2020**  
**EFFECTIVE DATE: 12/04**  
**LAST REVIEW DATE: 3/23/2020**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.*

## **POLICY:**

The drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the drugs found in this policy. A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

### **Drug Name – generic name (Medical benefit)**

#### **Authorization Criteria**

### **Actimmune – Interferon Gamma-1B (Medical)**

1. For the treatment of Chronic Granulomatous Disease
  - a) The prescribing physician is an infectious disease specialist or a hematologist/oncologist
  - b) Diagnosis has been confirmed through neutrophil function tests
  - c) Combination therapy with antibiotics (i.e, trimethoprim/sulfamethoxazole) and/or antifungals (i.e., itraconazole) has been shown to reduce the risk of severe infections.
2. In the treatment of severe, malignant osteopetrosis
  - a) The prescribing physician is an orthopedic surgeon, hematologist or an endocrinologist
  - b) The diagnosis is confirmed through radiological evidence.
3. Approved dosing for those with a body surface area greater than 0.5 m<sup>2</sup> is 50 mcg/m<sup>2</sup> (1 million units/m<sup>2</sup>) subcutaneously 3 times a week.
4. Doses above 50 mcg/m<sup>2</sup> will not be authorized.

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**Cablivi – caplacizumab-yhdp (Medical)**

1. The prescription must be written by a hematologist
2. The member must be at least 18 years of age or older
3. Must have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)
4. Must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab)
5. If the above criteria are met, Cablivi will be approved under the medical benefit for administration while the patient is receiving plasma exchange. Cablivi will be approved under the pharmacy benefit for 30 days of treatment following the last plasma exchange the patient received.
6. Requests for additional therapy up to a maximum 28 additional days will be considered for recertification if the provider submits documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels)

**Ceprotin - Protein C Concentrate, Human (Medical)**

1. Must be followed by a hematologist
2. Have a diagnosis of severe congenital protein C deficiency confirmed by antigenic and functional plasma coagulation assays

**HCPCS:** J2724

**Hydroxyprogesterone Caproate Injection (Medical)**

1. Must have a diagnosis of advanced adenocarcinoma of the uterine corpus (Stage III or IV) OR
2. Must have a diagnosis of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer **OR**
3. Be used as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.
4. Hydroxyprogesterone Caproate Injection USP (J1729) is only indicated for use in non-pregnant women.
5. Please note: brand and generic Makena (Hydroxyprogesterone Injection – J1726) are indicated for use in pregnant women and do not require prior authorization

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**Ilaris - canakinumab (Medical)**

1. Must be at least 4 years of age and have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with one of the following conditions
  - a. Familial Cold Autoinflammatory Syndrome (FCAS) also known as Familial Cold Urticaria **or**
  - b. Muckle-Wells Syndrome (MWS)
  - c. Dose is not to exceed 150mg every 8 weeks **OR**
2. Must be at least 2 years of age with a diagnosis of active systemic juvenile idiopathic arthritis (SJIA)
  - a. Must have failed to respond to and/or is intolerant to glucocorticoids or methotrexate **AND**
  - b. Must have failed to respond to and/or is intolerant to Enbrel or Humira.
  - c. Dose is not to exceed 300mg every 4 weeks **OR**
3. Must be at least 2 years of age with a diagnosis of one of the following Periodic Fever Syndromes (Hereditary Periodic Fevers)
  - a. Tumor Necrosis Factor-Receptor Associated Periodic Syndrome (TRAPS)
  - b. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
  - c. Familial Mediterranean Fever (FMF)
  - d. Dose is not to exceed 300mg every 4 weeks.
4. Patient does not have an infection and is not at high risk for infection
5. Patient is not on concurrent therapy with any of the following – Arcalyst, Kineret, Enbrel, Humira, infliximab or Simponi  
**Note** – it is not known whether Ilaris is effective in patients with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), also referred to as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA).

**HCPCS:** J0638

**Krystexxa - pegloticase (Medical)**

1. Diagnosis of chronic gout refractory to conventional therapy
  - a. Please note: Krystexxa is NOT recommended for the treatment of asymptomatic hyperurecemia
2. Patient has been evaluated by a rheumatologist
3. Failure of the highest therapeutic dose of either allopurinol or febuxostat in combination with either Probenacid or losartan for a minimum 3-month trial unless contraindicated or serious side effects were experienced
4. Serum uric acid level must be > 6mg/dL at the time of request
5. Member must have symptomatic gout defined by one of the following:
  - a. 3 or more flares in the past 18 months
  - b. 1 or more tophus
  - c. chronic gouty arthritis
6. Individuals with the following comorbidities will be excluded from coverage
  - a. Cardiovascular disease (uncompensated CHF, poorly controlled arrhythmia, or uncontrolled hypertension (>150/90 mmHg)
  - b. On dialysis
  - c. History of solid organ transplant
  - d. Known G6PD deficiency

**HCPCS:** J2507

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**Lemtrada - alemtuzumab (Medical)**

1. Must be 18 years of age or older
2. Must be prescribed by or in consultation with a neurologist
3. Must have a diagnosis of a relapsing form of multiple sclerosis, including: relapsing-remitting disease or active secondary progressive disease
4. Member must have had an inadequate response to two or more drugs indicated for the treatment of MS (minimum 12-week trials) **AND**
5. Member must not have concurrent infection with Human Immunodeficiency Virus or any other uncontrolled active infection
6. The recommended dosage of Lemtrada is for intravenous infusion over 4 hours for 2 or more treatment courses: 12mg/day on 5 consecutive days for the first course and 12mg/day on 3 consecutive days for a second course 12 months after the first treatment course
7. Following the second treatment course, subsequent treatment courses of 12 mg/day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses
8. Lemtrada must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Patients should be monitored for 2 hours after each infusion
9. Coverage will be limited to 5 injections for the first year. Recertification for future courses with 3 injections will require documentation supporting disease response to Lemtrada without adverse effect. If recertification request is approved, the additional course of therapy will be approved to start 366 days after the date that the first dose of the most recent course of Lemtrada was administered.

**HCPCS:** J0202

**Luxturna – voretigene neparvovec-rzyl (Medical)**

1. Must be prescribed by an ophthalmic surgeon for administration at a certified treatment center **AND**
2. Must be  $\geq$  12 months of age based upon ongoing cell proliferation in those under 1 year of age **AND**
3. Must have a diagnosis of Biallelic RPE65 mutation-associated retinal dystrophy
  - a. Diagnosis must be confirmed by genetic testing **AND**
4. Patient must have viable retinal cells
  - b. Viable retinal cells must have been determined by retinal thickness on spectral domain optical coherence tomography (OCT  $>100$  microns within the posterior pole) **AND**
5. Baseline full-field light sensitivity threshold (FST) test results for each eye must be submitted
6. A maximum of 1 dose of  $1.5 \times 10^{11}$  vector genomes (vg) administered by subretinal injection in a total volume of 0.3 mL will be allowed per eye per lifetime

**HCPCS:** J3398

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**NPlate - romiplostim (Medical)**

1. Member must have a diagnosis of chronic (lasting at least 3-4 months) idiopathic thrombocytopenia purpura (ITP) **AND**
2. Must have a current platelet count less than  $30 \times 10^9/L$  **AND**
3. Must have had an insufficient response (defined as a platelet count of less than  $20 \times 10^9/L$ , or greater but with bleeding symptoms) to the following treatments:
  - a) Corticosteroids **AND**
  - b) Immunoglobulins (IVIG) or splenectomy **AND**
4. Must be administered under the care of a hematologist in an office setting, will not be covered via home care
5. NPlate should not be used to attempt to normalize platelet count
6. NPlate may be used in combination with other medical ITP therapies such as, corticosteroids, danazol, azathioprine, intravenous immunoglobulin (IVIG), and anti-D immunoglobulin.
7. If the patient's platelet count is greater than or equal to  $50 \times 10^9/L$ , medical ITP therapies may be reduced or discontinued.

**HCPCS:** J2796

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**Ocrevus – ocrelizumab (Medical)**

**\*\*This criteria only applies to Managed Medicaid (MMC)/Child Health Plus (CHP); no prior authorization is requested for lines of business other than MMC/CHP\*\***

1. Must be 18 years of age or older
2. Must be prescribed by or in consultation with a neurologist
3. Must have a diagnosis of a relapsing form of multiple sclerosis, including: clinically isolated syndrome, relapsing-remitting disease, active secondary progressive disease, or primary progressive disease
  - a. The member must have had a clinical exacerbation or evidence of worsening disease with an adequate trial (minimum 12 weeks each) of at least 2 different preferred agents (Avonex, Copaxone, Gilenya, Rebif, Tecfidera or Plegridy).
4. Member must not currently be on combination therapy with any other multiple sclerosis disease modifying agent such as Avonex, Rebif, Betaseron, Extavia, Copaxone, Aubagio, Tecfidera, Gilenya, Tysabri, or Lemtrada
5. The use of Ocrevus as a first line therapy for the treatment of multiple sclerosis will be assessed on a case by case basis through a letter of medical necessity based on severity of the disease. Coverage will be considered if any of the following are met: >2 attacks within the last 18 months, brain stem/cerebellar/or spinal cord disease, greater than 3 gadolinium enhancing lesions with significant clinical exacerbations and/or motor involvement, bilateral optic neuritis, and/or rapid cognitive decline.
6. Ocrevus will not be approved in patients with active hepatitis B virus infection
7. If criteria are met, approval duration will be as follows:

<u>Line of Business</u>	<u>Medical Initial approval</u>	<u>Medical Recert</u>
<b>Medicaid Managed Care (MMC) / Child Health Plus (CHP)</b>	6 months	12 months
<b>Medicare</b>	Outpatient Hospital – 3 years	Outpatient Hospital – 3 years
	Home Care or Office Based – 3 years	Home Care or Office Based – 3 years

8. The recommended dosage is 300mg via intravenous infusion, followed 2 weeks later by a second 300mg IV infusion and then 600mg via IV infusion every 6 months.

**Radicava – edaravone (Medical)**

1. Must be greater than 18 years of age AND
2. Must be prescribed by or in consultation with a provider that specializes in Amyotrophic lateral sclerosis (ALS) and/or neuromuscular disorders AND
3. Must have a diagnosis of ALS
4. Recommended dosing is:
  - a. 60mg administered as an IV infusion over 60 minutes.
  - b. Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period
 Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

**HCPCS:** J1301

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**Signifor LAR - pasireotide (Medical)**

1. Diagnosis of acromegaly
2. Prescribed by endocrinologist
3. Must fail to achieve full biochemical control (GH <2.5 ug/L and normal IGF1) on high dose treatment with Sandostatin LAR OR Somatuline Depot.
4. Initial approval will be for 12 months. Recertification for any further approval will require documentation of response to therapy, including:
  - a. Reduction or stabilization in tumor volume from baseline assessed by MRI after initial 6 months of therapy **OR**
  - b. Mean growth hormone (GH) less than 2.5 mcg/L and/or a normal insulin-like growth factor- 1 (IGF-1) level after at least 12 months of initial therapy
5. Quantity limit of 1 injection (maximum 60 mg) every 28 days.

**HCPCS:** J2502

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**Soliris - eculizumab (Medical)**

1. Must be followed by a neurologist, hematologist or nephrologist as appropriate for diagnosis **AND**
2. Must have a diagnosis of generalized myasthenia gravis **AND**
  - a. Must be at 18 years of age or older
  - b. Must be followed by a neurologist. If geographically available, it is also recommended for patients to have been evaluated by a neuromuscular specialist.
  - c. Must be anti-acetylcholine receptor (AChR) antibody positive **AND**
  - d. Must have had serious side effects or drug failure with pyridostigmine **AND**
  - e. Must have had serious side effects or drug failure with at least 1 year of treatment with TWO immunosuppressant agents given alone or in combination such as: prednisone, azathioprine, mycophenolate mofetil, cyclosporine **OR**
  - f. Must have had serious side effects or drug failure with at least 1 year of treatment with ONE immunosuppressant agent and also required chronic plasma exchange or IVIG **AND**
  - g. Must have a baseline score of 6 or greater on the Myasthenia Gravis-Activities of Daily Living (MG-ADL) scale.
  - h. Initial approval will be for 6 months. Recertification after this initial 6-month period will require documentation of at least a 3-point improvement in the MG-ADL baseline score **AND**
  - i. Patients who are currently intubated will be excluded from coverage **OR**
3. Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by a flow cytometry or acid hemolysis test **AND**
  - a. Must be prescribed by a hematologist or nephrologist **AND**
  - b. For a diagnosis of PNH, must have had serious side effects or drug failure with Ultomiris **OR**
4. Must have a diagnosis of atypical hemolytic uremic syndrome (aHUS) confirmed by ADAMTS13 testing
  - a. Patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) will be excluded **AND**
  - b. Must be prescribed by a hematologist or nephrologist **AND**
  - c. For a diagnosis of aHUS, must have had serious side effects or drug failure with Ultomiris **OR**
5. Must have a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) confirmed by a positive Anti-AQP4 test
  - a. Must be at least 18 years of age
  - b. Must be prescribed by an ophthalmologist or neurologist
  - c. Must have had at least 2 neuromyelitis optica relapses in the last 12 months **OR**
  - d. Must have had at least 3 neuromyelitis optica relapses in the last 24 months with one of which being within the last 12 months
  - e. Must have had serious side effects or drug failure with Rituxan

**HCPCS:** J1300



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**Spravato – esketamine nasal spray (Medical)**

- 1) Member must have a diagnosis of treatment-resistant Single Episode or treatment-resistant Recurrent Major Depressive Disorder (MDD) without psychotic features
  - a) If Single Episode MDD, the episode must have lasted at least 2 years
  - b) The diagnosis must be confirmed by a mental health provider (psychiatrist, psychiatric nurse practitioner) using the DSM-5 criteria
- 2) Must be at least 18 years old
- 3) Spravato must be prescribed or recommended by a mental health provider
- 4) Must have had serious side effects or drug failure with at least 4 separate trials for MDD including:
  - a) Two antidepressants from different drug classes
  - b) Two evidence-based augmentation treatments (may be an antidepressant and a non-antidepressant used together OR two antidepressants used together)
  - c) All medications must be taken compliantly based on pharmacy fill history and each trial must last a sufficient period of time (usually 4-6 weeks)
- 5) Progress notes will be REQUIRED to document the patient's diagnosis of treatment-resistant Major Depressive Disorder, all previous therapies failed, and the medical necessity of Spravato
- 6) Spravato must be used in combination with an oral antidepressant
- 7) The patient's baseline depression symptoms must be measured and documented with an appropriate rating scale (such as PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D) as a tool for monitoring response to therapy
- 8) Spravato will not be covered if the patient has a history of substance or alcohol use disorder
- 9) Spravato will not be covered in patients with a current or prior diagnosis of psychosis
- 10) The prescriber must attest that Spravato will be administered at a treatment facility that is certified through the REMS program and that the member has been enrolled in the REMS program
- 11) Initial approval will be for 2 months
- 12) Recertification will require improvement in depression symptoms measured after 4-8 weeks of therapy with Spravato by the same rating scale used at baseline. Recertification will be approved for 1 year if improvement in symptoms is demonstrated and the REMS protocol continues to be followed.

**Sylvant - siltuximab (Medical)**

- 1) Must be prescribed by an oncologist or hematologist
- 2) Must have a diagnosis of Multicentric Castleman's disease (MCD) with pathological confirmation on biopsy of involved tissue **AND**
- 3) Must be human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative
- 4) Approval will be for 1 year at a time. Further approval will require submission of documentation supporting the absence of disease progression (defined as increase in symptoms, radiologic progression, or deterioration in performance status)
- 5) Recommended dosage is 11mg/kg given over 1 hour by intravenous infusion every 3 weeks

**HCPCS:** J2860

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**Tepezza –teprotumumab-trbw (Medical)**

1. Member must be at least 18 years old
2. Must be prescribed by an endocrinologist or ophthalmologist
3. Must have a diagnosis of Graves' disease with active thyroid eye disease (TED)
4. Must have a baseline score of at least 4 on the 7-point Clinical Activity Score (CAS)
5. Prescriber must attest that the member's thyroid level has been normalized before beginning treatment
6. FDA approved dosing is 10 mg/kg for the first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions
7. Approval will be for 24 weeks to allow for 8 infusions total
8. Retreatment will not be covered as there is no published literature available to support the use of Tepezza in patients who have already received a 24-week treatment
9. The 7-point CAS Score includes the following criteria:
  1. Spontaneous retrobulbar pain
  2. Pain on eye movements
  3. Eyelid erythema
  4. Conjunctival injection
  5. Chemosis
  6. Swelling of the caruncle
  7. Eyelid edema or fullness

**Trogarzo – ibalizumab-uiyk (Medical)**

1. Must be prescribed by an infectious disease specialist or certified HIV provider
2. Must be on current, stable antiretroviral therapy for at least 6 months consisting of 2 agents from different classes
3. Must have documented resistance (defined as laboratory confirmation or intolerable toxicities) to at least one ARV from each of three classes (NRTI, NNRTI, PI)
4. Must demonstrate inability to achieve or maintain suppression of viral replication on current ARV regimen, defined as persistent HIV RNA level of > 200 copies/mL
5. Must have full, laboratory confirmed susceptibility to at least one ARV agent (other than ibalizumab) that will be used concomitantly in the patient's optimized background ARV regimen
6. Must not have used immunomodulatory therapy, systemic steroids, or systemic chemotherapy within the previous 12 weeks
7. Dosing is a 2000 mg IV loading dose followed by 800 mg every 14 days, starting 14 days after the loading dose

**HCPCS:** J1746

**Ultomiris – ravulizumab-cwvz injection (Medical)**

1. Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by a flow cytometry or acid hemolysis test **AND**
  - a. Must be prescribed by a hematologist
2. Must have a diagnosis of atypical hemolytic uremic syndrome (aHUS) confirmed by ADAMTS13 testing
  - a. Patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) will be excluded **AND**
3. Must be prescribed by a hematologist or nephrologist
4. All other non-FDA approved indications will be excluded from coverage

**HCPCS:** J1303

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### POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time period will be as follows:

<u>Line of Business</u>	<u>Medical Initial approval</u>	<u>Medical Recert</u>
<b>Medicaid Managed Care (MMC) / Child Health Plus (CHP)</b>	6 months	12 months
<b>Commercial / Exchange</b>	Outpatient Hospital – 6 months	Outpatient Hospital – 6 months
	Home Care or Office Based – 2 years	Home Care or Office Based – 2 years
<b>Medicare</b>	Outpatient Hospital – 6 months	Outpatient Hospital – 6 months
	Home Care or Office Based – 2 years	Home Care or Office Based – 2 years

- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
2. Prior-authorization is contract dependent.
  3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will

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- likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
- The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
  - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
  5. Prescription homeopathic medications including, but not limited to: Arnica Gel, Psorizide Forte, Sleep Medicine, Hylira Gel and Vertigoheel are only covered when they are FDA approved for safety and efficacy. Most prescription homeopathic medications have their sales regulated by the FDA but are not FDA approved for safety and efficacy for any particular condition.
  6. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
  7. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent, if the preferred drug is not found in claims history.
  8. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

#### UPDATES:

Date	Revision
3/20	Revised
2/20	Revised
12/19	Revised
11/19	Revised/P&T Approval
8/19	Revised
6/19	Revised
5/19	Revised/P&T Approval
2/19	Revised/P&T Approval
1/19	Revised
12/18	Revised
11/18	Revised/P&T Approval
9/18	Revised/P&T Approval
8/18	Revised
3/18	Revised
1/18	Revised
11/17	Revised/P&T Approval
8/17	Revised
6/17	Revised
5/17	Revised
4/17	Revised
3/17	Revised
2/17	Revised

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### References:

In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria

#### **Amevive –**

1. Lowe NJ, Gonzalez J, Bagel J et al. Repeat courses of intravenous alefacept in patients with chronic plaque psoriasis provide consistent safety and efficacy. *Int J Dermatol* 2003; 42: 224-30.
2. Perrlmutter A, Cather J, Franks B, Jaracz E. Alefacept revisited: Our 3 year clinical experience in 200 patients with chronic plaque psoriasis. *J Am Acad Dermatol*. Jan 2008; 58(1):116-24.
3. Menter A et al. The efficacy of multiple courses of alefacept in patients with moderate to severe chronic plaque psoriasis. *J Amer Acad Dermatol*. Jan 2006;54:61-3.

#### **Cimzia –**

1. Gary R. Lichtenstein , Stephen B. Hanauer , William J. Sandborn , and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's Disease in Adults. . ACG Practice Guidelines 2009. *Amer J of Gastroenterology* Accessed March 2009
2. Swaminath A and Kornbluth A. Optimizing Drug Therapy in Inflammatory Bowel Disease. *Current Gastroenterology Reports*. 2007;9:513-520
3. Velayos FS, Sandborn WJ. Positioning Biologic Therapy for Crohn's Disease and Ulcerative Colitis. *Current Gastroenterology Reports*. 2007;9:521-527