Prior Authorization Approval Criteria

Effective Date: 10/01/2016

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Prior Authorization Approval Criteria

Abilify Maintena
(aripiprazole long-acting injectable)

Generic name: aripiprazole long-acting injectable
Brand name: Abilify Maintena
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia

Usual dose range:
- Schizophrenia – adults
  - 400mg monthly (may be reduced to 300 mg in patients with adverse reactions or who are known CYP2D6 poor metabolizers)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation criteria
Schizophrenia:
  Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Documented tolerance to oral aripiprazole
  - Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
  - Either one of the following:
    - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
      - Risperidone extended release IM (Risperdal Consta)
      - Haloperidol decanoate or fluphenazine decanoate
    OR
    - Documented stabilization on oral aripiprazole (trial of 4-6 weeks)

Renewal criteria
Schizophrenia:
  - Must have documentation of adherence to therapy (>75% compliance)
  - Documentation of effectiveness of therapy
  - Documentation of continued need for long-acting injection (including a review of adherence with other oral medications)
Contraindications:
- Known hypersensitivity to aripiprazole.

Not approved if:
- Past history of neuroleptic malignant syndrome, seizures, or dementia-related psychosis
- Current history of orthostatic hypotension
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

Black box warning:
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

Additional considerations:
- In conjunction with first dose, give 14 consecutive days of concurrent oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic then discontinue
- Dosage adjustments are required for missed doses
- Dosage adjustments for patients who are CYP2D6 poor metabolizers and patients taking CYP2D6 inhibitors, CYP3A4 inhibitors, or CYP3A4 inducers for greater than 14 days
- Maximum dose is 400 mg monthly

Approval time frames:
- Initial – 6 months with a quantity limit of 1 vial/month
- Renewal – 1 year with a quantity limit of 1 vial/month

References:


Prior Authorization Approval Criteria
Abilify (aripiprazole)

Generic name: aripiprazole
Brand name: Abilify
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder
- Adjunctive treatment of major depressive disorder
- Treatment for irritability with autistic disorder
- Treatment of Tourette's disorder

Usual dose range:
- Schizophrenia – adults 10 mg-30mg/day
- Schizophrenia – adolescents 2 mg-30 mg/day
- Bipolar mania – adults 15 mg-30 mg/day
- Bipolar mania – pediatric patients 2 mg-30 mg/day
- Irritability associated with autistic disorder 2 mg-15 mg/day
- Tourette’s disorder 5 mg-10 mg/day (wt <50 kg)
  10 mg-20 mg/day (wt >50 kg)
- As an adjunct to antidepressants for the treatment of major depressive disorder – adults 2 mg-15 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
Schizophrenia:

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotic agents

Adolescents (13-17yrs)
- FDA indicated diagnosis
- Age 13 to 17 years of age
- Failure to respond (or intolerance) to an adequate trial (30 days) of one formulary atypical antipsychotic
Bipolar I disorder:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (at least 30 days with adequate blood levels) of each of the following:
  - Lithium OR valproic acid
  - Two formulary antipsychotic agents

**Adolescents (10-17yrs)**
- FDA indicated diagnosis
- Age 10 to 17 years of age
- Failure to respond (or intolerance) to an adequate trial (30 days) of one formulary atypical antipsychotic

Major depressive disorder:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (4-6 weeks of an adequate dose) of each of the following:
  - A Selective Serotonin Reuptake Inhibitor (SSRI) OR a Serotonin and Norepinephrine Reuptake Inhibitor (SNRI)
  - One additional formulary antidepressant (SSRI, SNRI, TCA, bupropion, mirtazapine) OR a combination trial of a SSRI or SNRI and quetiapine (unless BMI>35 or BMI>30 with multiple risk factors (HTN/DM/etc))
- Must be used as adjunctive or add-on treatment to antidepressant therapy and not as monotherapy

Irritability associated with autistic disorder:

**Children (6-17yrs)**
- FDA indicated diagnosis
- Age 6 to 17 years of age
- Failure to respond (or intolerance) to an adequate trial (30 days) of one formulary atypical antipsychotic

Tourette's disorder:

**Children (6-17yrs)**
- FDA indicated diagnosis
- Age 6 to 17 years of age
- Failure to respond (or intolerance) to an adequate trial (30 days) of haloperidol or another antidopaminergic drug (e.g., fluphenazine, risperidone)
Renewal criteria

All FDA indicated diagnoses:
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to aripiprazole

Not approved if:
- Past history of neuroleptic malignant syndrome, seizures, or dementia-related psychosis
- Current history of orthostatic hypotension
- Used for treatment of Bipolar Depression
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

Black box warning:
- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

Additional considerations:
- Maximum daily dose is 30 mg/day

Approval time frames:
- Initial – 6 months with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria

Adcirca (tadalafil)

Generic name: tadalafil
Brand name: Adcirca
Medication class: Phosphodiesterase Type 5 Inhibitor

FDA-approved uses:
• Pulmonary arterial hypertension

Usual dose range:
• Pulmonary arterial hypertension - adult 40 mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Pulmonary arterial hypertension (PAH):

Adults
• FDA indicated diagnosis
• 18 years of age or older
• Prescribed or recommended by a pulmonologist
• Confirmed World Health Organization (WHO) Group I PAH diagnosis
• Confirmed New York Heart Association (NYHA) functional Class II or III symptoms
• Failure to respond (or contraindication) to a calcium channel blocker (required only if there is a positive response to acute vasoreactivity testing)
• Failure to respond (or contraindication) to Revatio (PA required)

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Concomitant or intermittent use of nitrates

Not approved if:
• Patient exhibits only NYHA Class I symptoms
**Additional considerations:**

- **WHO Group I PAH diagnosis can be confirmed by the following:**
  - Mean pulmonary arterial pressure > 25 mmHg at rest or 30 mmHg during exercise
  - Normal pulmonary capillary wedge pressure
- **NYHA functional classes are determined by the following:**
  - Class I: No symptoms with ordinary physical activity.
  - Class III: Symptoms with less than ordinary activity. Marked limitation of activity. Comfortable at rest.
  - Class IV: Symptoms with any activity or even at rest.
- **Maximum daily dose is 40 mg/day**

**Approval time frames:**

- Initial – 1 year with MDL of 2/day
- Renewal – 1 year with MDL of 2/day

**References:**


**Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:**

Initial: 06/26/2014
Revision: June 2015, June 2016
Prior Authorization Approval Criteria
Ampyra (dalfampridine)

Generic name: dalfampridine
Brand name: Ampyra
Medication class: Potassium Channel blocker

FDA-approved uses:
- Improvement of walking ability in multiple sclerosis (MS) patients

Usual dose range:
- Improvement of walking ability in MS patients - adults  10 mg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Improvement of walking ability in MS patients:

Adults
- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 – 70 years of age
- Complete the 25 foot walk test in 8-45 seconds
OR
- If 25 foot walk test is < 8 seconds, the Expanded Disability Status Scale (EDSS) must be between 4.5-6.5

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Improvement in 25 foot walk time of ≥ 20% after one month of therapy

Contraindications:
- History of seizure disorders
- Moderate to severe renal impairment (CrCL ≤ 50mL/min)
- Hypersensitivity to Ampyra or 4-aminopyridine

Not approved if:
- Patient has any contraindications
- Patient is wheelchair bound

Additional considerations:
- Discontinue Ampyra if patient experiences a seizure
References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 11/11/14
Revision: November 2015
Prior Authorization Approval Criteria
Aranesp (darbepoetin alfa)

Generic name: darbepoetin alfa
Brand name: Aranesp
Medication class: Erythropoietic - Hematopoietic

FDA-approved uses:
• Treatment of anemia in Chronic Kidney Disease (CKD) patients on or not on dialysis
• Treatment of anemia due to myelosuppressive chemotherapy

Usual dose range:
• CKD on dialysis
  0.45mcg/kg IV* or SC weekly
  or 0.75mcg/kg IV* or SC every 2 weeks
• CKD not on dialysis
  0.45mcg/kg IV or SC every 4 weeks
• Cancer patients on chemotherapy
  2.25mcg/kg SC weekly or 500 mcg SC every 3 weeks

*IV route recommended for patients on hemodialysis*

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
CKD on/not on dialysis:

Adult and Pediatric:
• FDA indicated diagnosis
• 1 year of age and older
• Prescribed by a hematologist or nephrologist
• Hgb <10 g/dL in pre-pubertal children and pre-menopausal females OR
  Hgb <12 g/dL in adult males and post-menopausal females
• Failure to respond to an adequate trial (3 months) of iron supplementation
  o Ferritin level within normal limits:
    ▪ Male: 12-300 ng/mL
    ▪ Female: 12-150 ng/mL
• Documentation that other causes of anemia have been ruled out (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.)
Cancer patients on chemotherapy:

**Adults**

- FDA indicated diagnosis
- 18 years of age and older
- Documented intention of chemotherapy is palliative
- Documentation of Hgb < 10g/dL
- Failure to respond to an adequate trial (3 months) of iron supplementation
  - Ferritin level within normal limits:
    - Male: 12-300 ng/mL
    - Female: 12-150 ng/mL
- Documentation that other causes of anemia have been ruled out (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.)

**Renewal Criteria**

- Documentation of effectiveness of therapy by improvement of Hgb levels by at least 1 to 2 g/dL or a decrease in transfusion requirements
- Current Hgb <11g/dL in pre-menopausal females and in pre-pubertal patients OR Hgb <12g/dL in adult males and post-menopausal females
- For patients on chemotherapy, must be continuing to receive myelosuppressive chemotherapy

**Contraindications:**

- Uncontrolled hypertension
- Pure red cell aplasia (PRCA) that begins after treatment darbepoetin alfa or other erythropoietin protein drugs
- Serious allergic reactions to darbepoetin alfa

**Not approved if:**

- Patient is on other therapies (i.e. iron, cyanocobalamin, blood products, folate, or vitamin C) for the correction of anemia
- Patient has a previous acute coronary syndromes or acute myocardial infarction

**Black box warning:**

- ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence
- Chronic Kidney Disease: In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL. No trial has identified a hemoglobin target level, darbepoetin alfa dose, or dosing strategy that does not increase these risks. Use the lowest darbepoetin alfa dose sufficient to reduce the need for red blood cell (RBC) transfusions.
Cancer: ESAs shorten overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense darbepoetin alfa to patients with cancer. Use the lowest dose to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy. ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Discontinue following the completion of a chemotherapy course.

Additional considerations:
- Darbepoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being
- Not indicated for use in patients:
  - Receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
  - As a substitute for RBC transfusions in patients who require immediate correction of anemia
- Increases the risk for seizures in patients with CKD
- Maximum daily dose is 500mcg/week or 4.5mcg/kg/week

Approval time frames:
- Initial – 6 months with MDL of 500mcg/week or 4.5mcg/kg/week
- Renewal – 6 months with MDL of 500mcg/week or 4.5mcg/kg/week

References:

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 12/02/2013
Revision: 12/02/2014, December 2015
Prior Authorization Approval Criteria

Aubagio (teriflunomide)

Generic name: teriflunomide
Brand name: Aubagio
Medication class: Pyrimidine synthesis inhibitor

FDA-approved uses:
- Relapsing forms of multiple sclerosis (MS)

Usual dose range:
- Relapsing forms of multiple sclerosis – adults 7-14 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Relapsing forms of multiple sclerosis:
Adults
- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (6 months) of one of the following:
  - Copaxone (glatiramer acetate)
  OR
  - An interferon product:
    - Avonex (IFN Beta-1a)
    - Rebif (IFN Beta-1a)
    - Betaseron (IFN Beta-1b)
- Failure to respond (or intolerance) to an adequate trial (6 months) of Gilenya (fingolimod)- PA required

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Sever hepatic impairment
- Women who are pregnant or of childbearing potential not using reliable contraception
- Current treatment with leflunomide
Not approved if:
- Combined with Copaxone, Gilenya, Tecfidera, Tysabri, Rituxan or an interferon product
- Patient has any contraindications

Black box warning:
- Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide. A similar risk would be expected for teriflunomide.
- Concomitant use of teriflunomide with other potentially hepatotoxic drugs may increase the risk of severe liver injury
- Teriflunomide may cause major birth defects if used during pregnancy. Pregnancy must be excluded before starting teriflunomide

Additional considerations:
- Female patients of child bearing age must use a reliable form of contraception

Approval time frames:
- Initial – 6 months with MDL 1/day
- Renewal – 1 year with MDL 1/day

References:

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 11/11/14
Revision: November 2015
Prior Authorization Approval Criteria
Copaxone 40 mg (glatiramer acetate)

Generic name: glatiramer acetate
Brand name: Copaxone 40 mg
Medication class: immunomodulator

FDA-approved uses:
• Relapsing forms of multiple sclerosis (MS)

Usual dose range:
• Relapsing forms of multiple sclerosis – adults 40 mg three times a week

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Relapsing forms of multiple sclerosis:
Adults
• FDA indicated diagnosis
• Prescribed by (or in consultation with) a neurologist
• 18 years of age or older
• Experience severe intolerable injection site reactions to Copaxone 20mg such as:
  ▪ Pain requiring local anesthetic
  ▪ Oozing
  ▪ Lipoatrophy
  ▪ Swelling
  ▪ Ulceration
• Documentation that injection site reactions could not be managed with conventional techniques (site rotation, icing, or analgesics)

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Known hypersensitivity to glatiramer acetate or mannitol

Not approved if:
• Combined with Tecfidera, Gilenya, Tysabri, Rituxan or an interferon product
**Additional considerations:**

- Localized lipoatrophy may occur at injection sites

**Approval time frames:**

- Initial – 6 months with 12 syringes / 28 days
- Renewal – 1 year with 12 syringes / 28 days

**References:**

Prior Authorization Approval Criteria  
D.H.E. 45 (dihydroergotamine injection)

Generic name: dihydroergotamine injection solution  
Brand name: D.H.E. 45  
Medication class: Antimigraine; ergot alkaloid  

FDA-approved uses:  
- Cluster headache  
- Migraine

Usual dose range:  
- Cluster headache - adult: 1mg (1ml) IM/SC/IV; repeat at 1 h intervals to 3mg (2mg IV) per 24 h period; max 6mg per week  
- Migraine – adult: 1mg (1ml) IM/SC/IV; repeat at 1 h intervals to 3mg (2mg IV) per 24 h period; max 6mg per week

Criteria for use: (bullet points are all inclusive unless otherwise noted)  
Initiation Criteria  
All FDA approved indications:  
Adults  
- FDA indicated diagnosis  
- 18 years of age and older  
- Prescribed by a neurologist  
- Failure to respond (or intolerance) to an adequate trial (1 month) of each of the following:  
  - Ergotamine/caffeine (Cafergot)  
  - One formulary NSAID (i.e. diclofenac, ibuprofen, indomethacin, ketoprofen, meloxicam, naproxen, salsalate, or sulindac)  
  - Two of the following:  
    - Sumatriptan (Imitrex)  
    - Zolmitriptan (Zomig)  
    - Relpax (Note: Step Therapy required – failure of sumatriptan or zolmitriptan)  
  - One of the following:  
    - Butalbital/aspirin/caffeine (Fiorinal)  
    - Butalbital/acetaminophen/caffeine (Fioricet)  
    - Isometheptene/acetaminophen/dichloralphenazone (Midrin)  
  - Sumatriptan injection (Note: Step Therapy required – failure of oral or nasal sumatriptan)

Renewal Criteria  
- Documentation of effectiveness of therapy
Contraindications:
- Pregnancy Category X
- Coadministration with CYP3A4 inhibitors (see “Not approved if” section)
- Coadministration with vasoconstrictors (e.g. sumatriptan, propranolol, nicotine)
- Ischemic heart disease (angina pectoris, history of myocardial infarction, or silent ischemia)
- Peripheral arterial disease
- Uncontrolled hypertension
- Severely impaired hepatic or renal function

Not approved if:
- Currently taking ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole,itraconazole
- Pregnant or nursing (Category X)
- Requested for chronic daily administration (prophylaxis)

Black box warning:
- Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with potent CYP3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated

Additional considerations:
- Liver disease: dose reductions are suggested
- Maximum daily dose is 3mg/day
- Maximum weekly dose is 6mg/week

Approval time frames:
- Initial — 1 year with quantity limit of 10 ampules/month (10mL/month)
- Renewal — 1 year with quantity limit of 10 ampules/month (10mL/month)

References:
Prior Authorization Approval Criteria
Daytrana (methylphenidate extended release transdermal system)

Generic name: methylphenidate extended release transdermal system
Brand name: Daytrana
Medication class: CNS Stimulant

FDA-approved uses:
- Attention Deficit Hyperactivity Disorder (ADHD) in children (ages 6-12) and adolescents (ages 13-17)

Usual dose range:
- ADHD – children and adolescent 10 mg – 30 mg /9 hours

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:

Children and Adolescents
- FDA indicated diagnosis
- Age 6 to 17 years of age
- Failure to respond (or intolerance) to each of the following
  - A formulary methylphenidate product
  - A formulary amphetamine product

OR
- Inability to take oral formulations

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to methylphenidate
- Patients with marked anxiety, tension, or agitation
- Patients with a diagnosis of glaucoma
- Patient with a tic disorder or a family history or diagnosis of Tourette's syndrome
- Patients currently using or within 2 weeks of using an MAO inhibitor
Not approved if:
• Patient has a history of drug dependence or alcoholism
• Patient has a contraindication to treatment (see Contraindications)

Black box warning:
• Should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Additional considerations:
• Maximum daily dose is 30 mg/9 hours.
• The patch should be applied 2 hours before an effect is needed and should be removed 9 hours after application.
• Dose should be titrated to effect. Dose titration, final dosage and wear time should be individualized according to the needs and response of the patient.
• The recommended titration schedules are based on the following table from the package insert:

<table>
<thead>
<tr>
<th>Upward Titration, if Response is Not Maximized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
</tr>
<tr>
<td>Patch Size</td>
</tr>
<tr>
<td>Nominal Delivered Dose (mg/9 hours)</td>
</tr>
<tr>
<td>Delivery Rate</td>
</tr>
</tbody>
</table>

Approval time frames:
• Initial – 1 year with MDL of 1 patch/day
• Renewal – 1 year with MDL of 1 patch/day

References:
1. Daytrana Prescribing Information (August 2015). Noven Pharmaceuticals, Inc., Miami, FL

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016
Prior Authorization Approval Criteria
EMSAM (selegiline transdermal system)

Generic name: selegiline transdermal system
Brand name: EMSAM
Medication class: antidepressant

FDA-approved uses:
• Major Depressive Disorder (MDD)

Usual dose range:
• Major Depressive Disorder
  o Adult patients ≤64 years old  6 mg to 12 mg/24 hours
  o Elderly patients ≥65 years old  6 mg/24 hours

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Major Depressive Disorder:
  Adults
  • FDA indicated diagnosis
  • 18 years of age or older
  • Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
    o Separate monotherapy trials of two different formulary Selective Serotonin Reuptake Inhibitors (SSRIs)
    o An additional formulary antidepressant agent (bupropion, mirtazapine, a tricyclic antidepressant, a Serotonin Norepinephrine Reuptake Inhibitor [SNRI], or a third SSRI)

Renewal Criteria
Major Depressive Disorder:
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Hypersensitivity to selegiline or to any component of the transdermal system
• Concomitant use in patients taking any of the following:
  o Other antidepressants that affect serotonin levels (SSRIs, TCA’s, SNRIs, MAOIs, or bupropion), some analgesics (meperidine, tramadol, methadone, or propoxyphene), dextromethorphan, St. John’s wort, mirtazapine, buspirone, or cyclobenzaprine
  o Agents that can increase risk of hypertensive crisis such as sympathomimetic agents (phenylpropanolamine or some weight loss products)
  o Carbamazepine or oxcarbazepine
Not approved if:
- Patient has any contraindications to the use of selegiline (see above contraindication section)

Black box warning:
- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

Additional considerations:
- EMSAM should be applied to dry, intact skin on the upper torso, upper thigh or the outer surface of the upper arm. Avoid re-application to the same site on consecutive days.
- EMSAM should be discontinued at least 10 days prior to elective surgery
- EMSAM is associated with hypertensive crises caused by the ingestion of foods containing high amounts of tyramine. A modified diet is not required at doses of 6 mg/24 hours but patients on doses of 9 mg/24 hours and 12 mg/24 hours should follow a tyramine restricted diet
- Maximum daily dose – 12 mg/24 hours

Approval time frames:
- Initial – 1 year with MDL of 1 patch/day
- Renewal – 1 year with MDL of 1 patch/day

References:
Prior Authorization Approval Criteria

Exjade (deferasirox)

Generic name: deferasirox
Brand name: Exjade
Medication class: Heavy metal chelator

FDA-approved uses:
- Hemosiderosis – thalassemia syndrome, non-transfusion dependent
- Transfusion hemosiderosis

Usual dose range:
- Hemosiderosis – thalassemia syndrome, non-transfusion dependent – adult and pediatric
  - Up to 20 mg/kg/day
- Transfusion hemosiderosis – adult and pediatric
  - Up to 40 mg/kg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Hemosiderosis – thalassemia syndrome, non-transfusion dependent (NTDT):

Adult and pediatric
- FDA indicated diagnosis
- 10 years of age or older
- Prescribed by a hematologist
- Documentation of the following:
  - Liver iron concentration > 10 mg/g evidenced by at least two values obtained in the previous 3 months
  - Serum ferritin level consistently ≥ 300 mcg/L evidenced by at least two lab values in the previous 3 months
  - Creatinine clearance ≥ 40 ml/min

Transfusion hemosiderosis:

Adult and pediatric
- FDA indicated diagnosis
- 2 years of age or older
- Prescribed by a hematologist
- Documentation of the following:
  - Serum ferritin level consistently ≥ 1000 mcg/L evidenced by at least two lab values in the previous 3 months
  - Creatinine clearance ≥ 40 ml/min
Renewal Criteria

- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy evidenced by the following:
  - For NTDT: decreased liver iron concentration compared to baseline but no less than 3 mg/g; and serum ferritin level no less than 300 mcg/L within the last month
  - For transfusion hemosiderosis: serum ferritin level remains consistently > 500 mcg/L demonstrated by at least two lab values in the previous 3 months

Contraindications:

- CrCl less than 40 mL/min or serum creatinine greater than 2 times the age-appropriate ULN
- Hypersensitivity to deferasirox or to any component of the product
- Malignancies, advanced
- Platelet counts less than 50 x 10⁹/L
- Poor performance status and high-risk myelodysplastic syndromes

Not approved if:

- Any contraindication is present

Black box warning:

- May cause renal impairment (including failure), hepatic impairment (including failure), and gastrointestinal hemorrhage. In some reported cases, these reactions were fatal. Therapy requires close patient monitoring, including laboratory tests of renal and hepatic function

Additional considerations:

- Maximum daily dose is 40 mg/kg/day

Approval time frames:

- Initial: 6 months with MDL of 40 mg/kg/day
- Renewal: 6 months with MDL of 40 mg/kg/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 12/18/2014
Revision: December 2015
Prior Authorization Approval Criteria

Fanapt (iloperidone)

Generic name: iloperidone
Brand name: Fanapt
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia in adults

Usual dose range:
- Schizophrenia – adults
  - Starting dose: 1 mg twice a day
  - Target dose: 6-12 mg twice a day

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
  Schizophrenia:
    Adults
    - FDA indicated diagnosis
    - 18 years of age or older
    - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotics agents

Renewal criteria
  Schizophrenia:
  - Must have documentation of adherence to therapy (>75% adherence)
  - Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to iloperidone. Reactions have included urticaria and pruritus.
Not approved if:

- Patient has dementia-related psychosis
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

Black box warning:

- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

Additional considerations:

- Fanapt must be titrated slowly from a low starting dose to avoid orthostatic hypotension.
- Maximum daily dose is 24 mg/day
- Dose should be reduced in patients taking CYP2D6 or CYP3A4 inhibitors

Approval time frames:

- Initial: 6 months with MDL of 2/day
- Renewal: 1 year with MDL of 2/day

References:

- Fanapt Prescribing Information (January 2016). Novartis Pharmaceuticals Corporation East Hanover, NJ.
Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria
Focalin (dexmethylphenidate)

Generic name: dexmethylphenidate
Brand name: Focalin
Medication class: CNS Stimulant

FDA-approved uses:
• Attention Deficit Hyperactivity Disorder (ADHD) in individuals aged 6-17 years of age

Usual dose range:
• ADHD – children and adolescent 2.5 mg – 10 mg twice a day

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:

Adolescents
• FDA indicated diagnosis
• Age 6 to 17 years of age
• Failure to respond (or intolerance) to each of the following
  ▪ A formulary methylphenidate product
  ▪ A formulary amphetamine product

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
• Documentation of effectiveness of therapy

Contraindications:
• Known hypersensitivity to methylphenidate
• Patients with marked anxiety, tension, or agitation
• Patients with a diagnosis of glaucoma
• Patient with a history of motor tics or a family history or diagnosis of Tourette's syndrome
• Patients currently using or within 2 weeks of using an MAO inhibitor

Not approved if:
• Patient has a history of drug dependence or alcoholism
• Patient has a contraindication to treatment (see Contraindications)
Black box warning:

- Should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Additional considerations:

- May lower seizure threshold, particularly in patients with seizure history or EEG abnormalities
- Serious cardiovascular events have been reported with stimulant products. Stimulants should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems
- Maximum daily dose is 20 mg/day

Approval time frames:

- Initial – 1 year with MDL of 2/day
- Renewal – 1 year with MDL of 2/day

References:

1. Focalin Prescribing Information (April 2015). Novartis Pharmaceuticals Corporation, East Hanover, NJ.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016
Prior Authorization Approval Criteria
Focalin XR (dexmethylphenidate extended release)

Generic name: dexmethylphenidate extended release
Brand name: Focalin XR
Medication class: CNS Stimulant

FDA-approved uses:
- Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 years of age and older

Usual dose range:
- ADHD – children 5 mg – 30 mg daily in the morning
- ADHD – adults 10 mg – 40 mg daily in the morning

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:
- FDA indicated diagnosis
- 6 years of age or older
- Failure to respond (or intolerance) to each of the following
  - A formulary methylphenidate product
  - A formulary amphetamine product
  - Focalin (dexmethylphenidate) immediate-release (PA required)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to methylphenidate
- Patients with marked anxiety, tension, or agitation
- Patients with a diagnosis of glaucoma
- Patient with a history of motor tics or a family history or diagnosis of Tourette's syndrome
- Patients currently using or within 2 weeks of using an MAO inhibitor

Not approved if:
- Patient has a history of drug dependence or alcoholism
- Patient has a contraindication to treatment (see Contraindications)
Black box warning:
• Should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Additional considerations:
• Focalin XR capsules may be swallowed whole, or capsule contents can be sprinkled on applesauce. Do not crush, chew, or divide capsules.
• For patients already using methylphenidate should be initiated on Focalin XR therapy at half (1/2) the current total daily dose of methylphenidate.
• Patients currently using dexamphetamine immediate release should be switch to the same daily dose of Focalin XR.
• Serious cardiovascular events have been reported with stimulant products. Stimulants should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems
• May lower seizure threshold, particularly in patients with seizure history or EEG abnormalities
• Maximum daily dose is
  o Children – 30 mg/day
  o Adults – 40 mg/day

Approval time frames:
• Initial – 1 year with MDL of 1/day
• Renewal – 1 year with MDL of 1/day

References:
1. Focalin XR Prescribing Information (April 2015). Novartis Pharmaceuticals Corporation, East Hanover, NJ.
Prior Authorization Approval Criteria
Gilenya (fingolimod)

Generic name: fingolimod
Brand name: Gilenya
Medication class: Spinogosine 1-phosphate receptor modulator

FDA-approved uses:
- Relapsing forms of multiple sclerosis (MS)

Usual dose range:
- Relapsing forms of multiple sclerosis – adults 0.5 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Relapsing forms of multiple sclerosis:
- Adults
  - FDA indicated diagnosis
  - Prescribed by (or in consultation with) a neurologist
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (6 months) of one of the following:
    - Copaxone (glatiramer acetate)
    - An interferon product
      - Avonex (IFN Beta-1a)
      - Rebif (IFN Beta-1a)
      - Betaseron (IFN Beta-1b)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure
- History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker
- Baseline QTc interval ≥500 msec
- Treatment with Class Ia or Class III anti-arrhythmic drugs

Not approved if:
• Combined with Copaxone, Aubagio, Tecfidera, Tysabri, Rituxan or an interferon product  
• Patient has any contraindications  

**Additional considerations:**  
• Patient must be observed for 6 hours after the initial dose and all other doses where the patient has not received the medication for two weeks or more.  
• Use with caution in individuals with cardiovascular disease  

**Approval time frames:**  
• Initial  – 6 months with MDL 1/day  
• Renewal  – 1 year with MDL 1/day  

**References:**  
• Gilenya ® [package insert], East Hanover, NJ: Novartis.; 2015.  
Prior Authorization Approval Criteria
Harvoni (ledipasvir/sofosbuvir)

Generic name: ledipasvir/sofosbuvir
Brand name: Harvoni
Medication class: Direct-acting antiviral; RNA polymerase inhibitor

FDA-approved uses:
• Hepatitis C, chronic, genotype 1, 4, 5 and 6

Usual dose range:
• Hepatitis C, chronic, genotype 1, 4, 5 and 6 – adult 90 mg/400 mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Hepatitis C virus infection:
Adults
• Hepatitis C virus (HCV) infection with a positive serum HCV RNA
• 18 years of age or older
• Prescribed by a gastroenterologist, hepatologist, infectious disease specialist or HIV specialist
• Confirmation of Genotype 1, 4, 5 or 6
• Confirmation that the patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
• Evidence of fibrosis stage 3 or 4 confirmed by one of the following:
  o Liver biopsy of stage 3 or higher
  o Noninvasive fibrosis score with a high probability of advanced fibrosis/cirrhosis (FIB-4 greater than or equal to 3.25)
  o Radiological imaging with findings suggestive of cirrhosis
    • If cirrhotic, must be deemed compensated by prescribing provider by documentation of all of the following:
      ▪ Total bilirubin less than or equal to 1.5 g/dL, unless attributable to atazanavir therapy
      ▪ INR less than or equal to 1.5
      ▪ No evidence of ascites or hepatic encephalopathy
    • Decompensated cirrhotic patients will only be considered for genotype 1 on a case-by-case basis
• If genotype 1, treatment-naïve and pretreatment HCV RNA level is less than 6 million IU/mL, then an 8-week course of therapy may be considered at the discretion of the provider
• If genotype 1 and treatment-experienced, then must confirm previous failures of only PEG-interferon and ribavirin.
Treatment-experienced patients of other genotypes will only be considered on a case-by-case basis.

- If genotype 1, treatment-experienced and cirrhotic, then confirmation of concomitant use with ribavirin
  - Must provide medical rationale if the patient is not a candidate for ribavirin
- HIV co-infection must have confirmation of both of the following:
  - Stable on antiretroviral therapy
  - HIV viral load less than 200 copies/mL within the past 3 months
- Documentation that patient is willing to adhere to treatment requirements
- Documentation of each of the following:
  - No alcohol/drug use (including medical/recreational marijuana) within the past 6 months
  - Pretreatment tox screen and agreement to monthly tox screens with confirmed negative results for alcohol/drug use (including medical/recreational marijuana) if the patient has a history of alcohol/drug abuse within the past 2 years
    - Note: pretreatment tox screen only required if there has been any documented alcohol/drug abuse (including medical/recreational marijuana) within the past 2 years

Renewal Criteria

- Must have documentation of adherence to therapy (> 80% adherence)
- If patient has history of alcohol/drug abuse, must have documentation of monthly tox screens with confirmed negative results for alcohol/drug use (including medical/recreational marijuana)
- Documentation of effectiveness of therapy by the following:
  - For non-cirrhotic patients:
    - If viral RNA level is undetectable at week 6, then 4 additional weeks will be approved (Total 12 weeks of therapy)
    - If viral RNA level is detectable at week 6 with less than a 3 log decrease from baseline, then therapy will be discontinued
  - For cirrhotic patients:
    - If viral RNA level is undetectable at week 6, then the remainder of the full course of therapy will be approved as follows:
      - For treatment naïve prior to therapy: 4 additional weeks will be approved (Total 12 weeks of therapy)
      - For genotype 1, treatment-experienced prior to therapy, with concomitant ribavirin: 4 additional weeks will be approved (Total 12 weeks of therapy)
      - For genotype 1, treatment-experienced prior to therapy, and not a candidate for ribavirin: 16 additional weeks will be approved (Total 24 weeks of therapy)
If viral RNA level is detectable at week 6 with less than a 3 log decrease from baseline, then therapy will be discontinued

**Contraindications:**
- Pregnancy and men whose female partners are pregnant (only when concomitantly used with ribavirin, which may cause birth defects or death of exposed fetus)

**Not approved if:**
- Any previous trial/failure of any direct-acting antiviral therapy for any genotype
- Less than 12 months since the last attempt of HCV treatment with PEG-interferon plus ribavirin
- Diagnosis of genotype 2 or 3
- Confirmed decompensated cirrhosis in genotype 4, 5 or 6
- Evidence of non-adherence to treatment of concurrent medical diseases (e.g. poorly controlled DM, severe HTN, heart failure, significant CAD, COPD, thyroid disease)
- Clinically significant liver disease from other causes
- Concurrent psychiatric illness without strong primary care physician and psychiatric support
- Alcohol or illicit drug use (including medical/recreational marijuana) within the past 6 months
- Not established with a primary care provider
- Known hypersensitivity to drugs used to treat HCV

**Additional considerations:**
- Maximum daily dose is 1 tablet per day

**Approval time frames:**
- Initial approval
  - 8 weeks with MDL of 1/day

- Renewal
  - May be approved for up to 16 additional weeks with MDL of 1/day depending on which “Renewal Criteria” above is met

**References:**

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 03/31/2015
Revision: March 2016
Prior Authorization Approval Criteria
Invega (paliperidone)

Generic name: paliperidone
Brand name: Invega
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia in adults and adolescents (ages 12-17)
- Treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers and/or antidepressants

Usual dose range:
- Schizophrenia/Schizoaffective disorder – adults 3-12 mg/day
- Schizophrenia – adolescents
  - Weight < 51kg 3-6 mg/day
  - Weight ≥ 51kg 3-12 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
  Schizophrenia/Schizoaffective disorder:
  Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
    - Risperidone
    - Two formulary antipsychotics agents

  Adolescents (12-17yrs)
  - FDA indicated diagnosis
  - 12 to 17 years of age
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
    - Risperidone
    - Two formulary antipsychotics agents

Renewal criteria
  Schizophrenia:
  - Must have documentation of adherence to therapy (>75% adherence)
  - Documentation of effectiveness of therapy
**Contraindications:**
- Known hypersensitivity to paliperidone, risperidone, or to any components in the formulation.

**Not approved if:**
- Past history of dementia-related psychosis
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

**Black box warning:**
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

**Additional considerations:**
- At least 6 days should elapse between dosage increases
- The dose should be increased no more than 3 mg at a time
- Consideration may be given to individuals with hepatic impairment
- Maximum daily dose
  - Adults and adolescents (≥ 51kg) – 12 mg/day
  - Adolescents < 51kg – 6 mg/day
  - Mild renal impairment (CrCl 50-80mL/min) – 6 mg/day
  - Severe renal impairment (CrCl 10-50 mL/min) – 3 mg/day

**Approval time frames:**
- Initial – 6 months with MDL of 1/day
- Renewal – 1 year with MDL of 1/day
- Special approval notes – for 12 mg/day doses use 6 mg tablet with MDL of 2/day

**References:**
- Invega Prescribing Information (March 2016). Janssen Pharmaceuticals, Inc. Titusville, NJ.
Prior Authorization Approval Criteria
Invega Sustenna (paliperidone palmitate)

Generic name: paliperidone palmitate
Brand name: Invega Sustenna
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia
- Treatment of schizoaffective disorder as monotherapy and as adjunct to mood stabilizers or antidepressants

Usual dose range:
- Initial loading dose
  - Schizophrenia 234 mg on day 1, 156 mg on day 8
  - Schizoaffective disorder 234 mg on day 1, 156 mg on day 8
- Maintenance
  - Schizophrenia 39-234 mg every month
  - Schizoaffective disorder 78-234 mg every month

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
  Schizophrenia:
    Adults
    - FDA indicated diagnosis
    - 18 years of age or older
    - Documented tolerance to oral paliperidone or risperidone
    - Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
    - Either one of the following:
      - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
        - Risperidone extended release IM (Risperdal Consta)
        - Haloperidol decanoate or fluphenazine decanoate
      OR
      - Documented stabilization on oral paliperidone or risperidone (trial of 4-6 weeks)

Renewal criteria
  Schizophrenia:
    - Must have documentation of adherence to therapy (>75% compliance)
    - Documentation of effectiveness of therapy
• Documentation of continued need for long-acting injection (including a review of adherence with other oral medications)

**Contraindications:**
- Known hypersensitivity to paliperidone, risperidone, or to any components in the formulation

**Not approved if:**
- Past history of dementia-related psychosis
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

**Black box warning:**
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo

**Additional considerations:**
- To reduce the risk of hypersensitivity and first dose adverse effects patients should have a documented exposed to oral risperidone or paliperidone prior to initiation of paliperidone palmitate.
- Patients should not receive supplemental oral doses of antipsychotics after the first dose of IM paliperidone palmitate.
- Dose adjustments:
  - Moderate to severe renal impairment (CrCl < 50mL/min) – not recommended
  - Mild renal impairment (CrCl 50-80mL/min)
    - Initial loading dose – 156 mg on day 1 and 117 mg on day 7 then 78 mg monthly
- Maximum daily dose is 234 mg monthly

**Approval time frames:**
- Initial – 6 months with a quantity limit of 1 syringe/month
- Renewal – 1 year with a quantity limit of 1 syringe/month

**References:**

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria
Kapvay (clonidine extended release)

Generic name: clonidine extended release
Brand name: Kapvay
Medication class: antiadrenergic agent, centrally acting

FDA-approved uses:
- Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications in children and adolescents

Usual dose range:
- ADHD – children and adolescents ages 6 to 17
  0.1 mg – 0.4 mg/daily (taken twice daily, divided equally or split with the higher dose given at bedtime)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:
- Children and adolescents
  - FDA indicated diagnosis
  - Age 6 to 17 years of age
  - Failure to respond (or intolerance) to clonidine immediate release
  - Failure to respond (or intolerance) to each of the following
    - A formulary methylphenidate product
    - A formulary amphetamine product
    - Guanfacine extended-release
    OR
  - Diagnosis of drug abuse or dependence

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to clonidine

Not approved if:
- Patient has a known hypersensitivity to clonidine
Additional considerations:

- Dose should be initiated with one 0.1 mg tablet at bedtime, and the daily dosage should be adjusted in increments of 0.1 mg/day at weekly intervals until the desired response is achieved. Doses should be taken twice daily, with either an equal or higher split dosage given at bedtime.

<table>
<thead>
<tr>
<th>Total Daily Dose</th>
<th>Morning Dose</th>
<th>Bedtime Dose</th>
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<tbody>
<tr>
<td>0.1 mg/day</td>
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<td>0.2 mg/day</td>
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<td>0.3 mg/day</td>
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<tr>
<td>0.4 mg/day</td>
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- Tablet should not be crushed, chewed, or broken before swallowing
- When discontinuing, the dosage should be tapered in decrements of no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension
- Heart rate and blood pressure should be determined prior to initiation of therapy, following dosage increases, and periodically during therapy
- Maximum daily dose is 0.4 mg/day

Approval time frames:

- Initial – 1 year with MDL of 1-4/day (based on dose)
- Renewal – 1 year with MDL of 1-4/day (based on dose)

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016
Prior Authorization Approval Criteria  
Latuda (ilurasidone)

Generic name: ilurasidone  
Brand name: Latuda  
Medication class: Antipsychotic

FDA-approved uses:
- Schizophrenia
- Depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate

Usual dose range:
- Schizophrenia – adults: 40-160 mg/day
- Bipolar Depression – adults: 20-120 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
- Schizophrenia:
  Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotic agents

- Bipolar Depression:
  Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three of the following:
    o Lithium
    o Lamotrigine
    o Quetiapine immediate release
    o Concurrent trials of olanzapine and fluoxetine
    o One combination trial of lithium, lamotrigine, quetiapine immediate release, or olanzapine ± fluoxetine

***If patient has a BMI>35 or BMI>30 with multiple risk factors (HTN/DM/etc) then quetiapine, lithium and olanzapine are not required
Renewal criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Known hypersensitivity to Latuda or any components in the formulation
• Co-administration with a strong CYP3A4 inhibitor or inducer

Not approved if:
• Patient has dementia-related psychosis
• Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  o Clozapine
  o Two other antipsychotics

Black box warning:
• Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo

Additional considerations:
• Maximum daily dose is 160 mg/day; should be taken with food (at least 350 calories)
• Moderate (CrCl 30 - 50 mL/min) and severe (CrCl < 30 mL/min) renal impairment, the starting dose is 20 mg/day and maximum dose is 80 mg/day
• Moderate (Child Pugh score 7 to 9) hepatic impairment, the starting dose is 20 mg/day and the maximum dose is 80 mg/day
• Severe (Child Pugh score 10 to 15) hepatic impairment, the starting dose is 20 mg/day and the maximum dose is 40 mg/day
• FDA Pregnancy Category B (per approved label of 7/2013)

Approval time frames:
• Initial – 6 months with MDL of 1/day
• Renewal – 1 year with MDL of 1/day

References:
• Latuda Prescribing Information (July 2013). Sunovion Pharmaceuticals Inc. Marlborough, MA.


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria
Letairis (ambrisentan)

Generic name: ambrisentan
Brand name: Letairis
Medication class: Endothelin receptor antagonist

FDA-approved uses:  
• Pulmonary arterial hypertension

Usual dose range:  
• Pulmonary arterial hypertension – adult 10 mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Pulmonary arterial hypertension (PAH):
   Adults
   • FDA indicated diagnosis
   • 18 years of age or older
   • Prescribed or recommended by a pulmonologist
   • Confirmed World Health Organization (WHO) Group I PAH diagnosis
   • Confirmed New York Heart Association (NYHA) functional Class II or III symptoms:
   • Failure to respond (or contraindication) to a calcium channel blocker (required only if there is a positive response to acute vasoreactivity testing)
   • Failure to respond (or contraindication) to each of the following:
     o Revatio (PA required)
     o Adcirca (PA required)

Renewal Criteria
   • Must have documentation of adherence to therapy (>75% adherence)
   • Documentation of effectiveness of therapy

Contraindications:
   • Pregnancy
   • Idiopathic pulmonary fibrosis

Not approved if:
   • Patient exhibits only NYHA Class I symptoms
Black box warning:
• Do not administer to pregnant females. May cause fetal harm. Exclude pregnancy before start of treatment, monthly during treatment, and one month after stopping treatment. Prevent pregnancy during treatment and for one month after stopping treatment by using acceptable methods of contraception. For all female patients, this medication is available only through the Letairis REMS program.

Additional considerations:
• World Health Organization (WHO) Group I PAH diagnosis can be confirmed by the following:
  o Mean pulmonary arterial pressure > 25 mmHg at rest or 30 mmHg during exercise
  o Normal pulmonary capillary wedge pressure
• NYHA functional classes are determined by the following:
  o Class I: No symptoms with ordinary physical activity.
  o Class II: Symptoms with ordinary activity. Slight limitation of activity. Comfortable at rest.
  o Class III: Symptoms with less than ordinary activity. Marked limitation of activity. Comfortable at rest.
  o Class IV: Symptoms with any activity or even at rest.
• Maximum daily dose is 10 mg/day

Approval time frames:
• Initial – 1 year with MDL of 1/day
• Renewal – 1 year with MDL of 1/day

References:
• Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA: 2015.
Prior Authorization Approval Criteria
Leukine (sargramostim)

Generic name: sargramostim
Brand name: Leukine
Medication class: Granulocyte-macrophage colony stimulating factor; hematopoietic

FDA-approved uses:
- Allogeneic bone marrow transplantation; myeloid reconstitution in HLA-matched related donors
- Autologous bone marrow transplant; myeloid reconstitution following transplant in patients with non-Hodgkin’s lymphoma, Hodgkin’s disease, and acute lymphoblastic lymphoma
- Bone marrow transplant; delay or failure of myeloid engraftment
- Febrile neutropenia, in acute myelogenous leukemia following induction chemotherapy; prophylaxis
- Harvesting of peripheral blood stem cells
- Peripheral blood stem cell graft, autologous, myeloid reconstitution following transplant in patients mobilized with granulocyte macrophage colony stimulating factor (GM-CSF)

*Safety and efficacy has not been established in pediatric patients

Usual dose range:
- Allogeneic bone marrow transplantation; myeloid reconstitution in HLA-matched related donors
  - 250 mcg/m2/day IV over 2 hr; begin 2-4 hr after bone marrow infusion and continue until the absolute neutrophil count (ANC) is greater than 1500 cells/mM3 for 3 consecutive days; do not administer sooner than 24 hr after the last dose of chemotherapy/radiotherapy or until the post marrow infusion ANC is less than 500 cells/cubic millimeter

- Autologous bone marrow transplant; myeloid reconstitution following transplant in patients with non-Hodgkin’s lymphoma, Hodgkin’s disease, and acute lymphoblastic lymphoma
  - 250 mcg/m2/day IV over 2 hr; begin 2-4 hr after bone marrow infusion and continue until the absolute neutrophil count (ANC) is greater than 1500 cells/mm3 for 3 consecutive days; do not administer sooner than 24 hr after the last dose of chemotherapy/radiotherapy or until post-marrow infusion ANC less than 500 cells/mm3
• Bone marrow transplant; delay or failure of myeloid engraftment
  o 250 mcg/m2/day IV over 2 hr for 14 days; may repeat after 7 days off therapy, if needed; after another 7 days off therapy, a third course of 500 mcg/m2/day IV for 14 days may be administered

• Febrile neutropenia, in acute myelogenous leukemia following induction chemotherapy; prophylaxis
  o 250 mcg/m2/day IV over 4 hr; begin 4 days after completing induction chemotherapy (if day 10 bone marrow is hypoplastic; less than 5% blasts) and continue until the absolute neutrophil count is greater than 1500 cells/mm³ for 3 consecutive days or until a maximum of 42 days

• Harvesting of peripheral blood stem cells
  o 250 mcg/m2/day IV over 24 hr OR SQ once daily; continue through the peripheral blood progenitor cell collection period

• Peripheral blood stem cell graft, autologous, myeloid reconstitution following transplant in patients mobilized with granulocyte macrophage colony stimulating factor
  o 250 mcg/m2/day IV over 24 hr or SQ once daily; begin immediately following peripheral blood progenitor cell infusion and continue until the absolute neutrophil count is greater than 1500 cells/mm³ for 3 consecutive days

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
For All FDA-approved indications:
Adult
• FDA indicated diagnosis
• Prescription is written by an oncologist or hematologist
• Failure to respond (or contraindication) to Neupogen (PA required)
• Post-transplantation ANC < 1000/mm³
  o Note: this lab value is not required to approve for use in the diagnoses of febrile neutropenia or harvesting of peripheral blood stem cells

Renewal Criteria
• Must have documentation of adherence to therapy (> 75% adherence)
• Documentation of effectiveness of therapy
• ANC has not been greater than > 1500 cells/mm³ for more than 3 days

Contraindications:
• Individuals with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (≥ 10%)
• In patients with known hypersensitivity to GM-CSF, yeast-derived products, or any component of the product
Concomitant use with chemotherapy and radiotherapy

**Not approved if:**
- Any of the contraindications listed above are present

**Additional considerations:**
- Should not be administered simultaneously with cytotoxic chemotherapy or radiotherapy or within 24 hours preceding or following chemotherapy or radiotherapy
- Pediatric use: Benzyl alcohol is a constituent of liquid sargramostim and bacteriostatic water for injection diluent. Benzyl alcohol has been reported to be associated with a fatal “Gasping Syndrome” in premature infants and should not be administered to neonates.
- In patients with hepatic impairment, hepatic function should be monitored every other week during therapy
- In patients with renal impairment, renal function should be monitored every other week
- Treatment should be interrupted or the dose reduced by half if the ANC exceeds 20,000 cells/mm³

**Approval time frames:**

For the following indications:
- Allogeneic bone marrow transplantation; myeloid reconstitution in HLA-matched related donors
- Autologous bone marrow transplant; myeloid reconstitution following transplant in patients with non-Hodgkin’s lymphoma, Hodgkin’s disease, and acute lymphoblastic lymphoma
  - Initial: 30 days with an MDL of 250 mcg/m²
  - Renewal: 60 days with an MDL of 250 mcg/m²

For the following Indications:
- Febrile neutropenia, in acute myelogenous leukemia following induction chemotherapy; prophylaxis
- Peripheral blood stem cell graft, autologous, myeloid reconstitution following transplant in patients mobilized with granulocyte macrophage colony stimulating factor
  - Initial: Until ANC of > 1500 cells/mm³ is reached for 3 consecutive days or for a maximum of 42 days with an MDL of 250 mcg/m²
  - Renewal: Until ANC of > 1500 cells/mm³ is reached for 3 consecutive days or for a maximum of 42 days with an MDL of 250 mcg/m²
Bone marrow transplant; delay or failure of myeloid engraftment

- Initial: 14 days with an MDL of 250 mcg/m²
- Renewal: If engraftment has not occurred after 7 days off therapy, a second course may be given for 14 days with an MDL of 250 mcg/m². If a third course of therapy is needed, 14 days may be given with an MDL up to 500 mcg/m².

Harvesting of peripheral blood stem cells

- Initial: 7 days with an MDL of 250 mcg/m²
- Renewal: For the length of the collection period, with an MDL of 250 mcg/m²

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 12/02/2013
Revision: 12/02/2014, December 2015
Prior Authorization Approval Criteria
Lyrica (Pregabalin)

Generic name: pregabalin
Brand name: Lyrica
Medication class: anticonvulsant, neuropathic pain agent

FDA-approved uses:
- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunct therapy for adults with partial onset seizures
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injuries

Usual dose range:
- Neuropathic pain due to diabetic peripheral neuropathy-adult 50-100mg TID
- Postherpetic pain-adult 150-300mg/day
  (In divided doses of two to three times a day)
- Adjunct therapy for partial onset seizures-adult 150-600mg/day
  (In divided doses of two to three times a day)
- Fibromyalgia-adult 75-225mg BID
- Neuropathic pain due to spinal cord injury-adult 75-300mg BID

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Diabetic neuropathy/Fibromyalgia

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to each of the following:
  - Gabapentin
  - One formulary tricyclic antidepressant (TCA)*
  - Duloxetine (Step Therapy required)*
* see additional considerations
Neuropathy related to spinal cord injury

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to each of the following:
  - Gabapentin
  - One formulary TCA*
    * see additional considerations

Postherpetic neuralgia

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to each of the following:
  - Gabapentin
  - Lidocaine patch
  - One formulary TCA*
    * see additional considerations

Partial onset seizures (Adjunctive)

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or contraindication) to two different classes of formulary anticonvulsant drugs

**Renewal Criteria**
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

**Contraindications:**
- Hypersensitivity to pregabalin or any component of the formulation

**Not approved if:**
- Patient with severe cardiovascular disease, such as heart failure
Additional considerations:

- *Trials of duloxetine or a TCA are not required if the patient is already stable on an SSRI, SNRI or a TCA*
- Renal dosing is required for creatinine clearance less than 60ml/min
- Maximum daily dose is 600mg/day
- Must be tapered off over at least 1 week

Approval time frames:

- Initial – 1 year(s) with MDL of 3/day
- Renewal – 1 year(s) with MDL of 3/day
- Special approval notes – Approve by HICL if titration requested

References:

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2015
Revision:
Prior Authorization Approval Criteria
Neupogen (filgrastim)

Generic name: filgrastim
Brand name: Neupogen
Medication class: Colony Stimulating Factor, Hematopoietic

FDA-approved uses:
- Febrile neutropenia, in non-myeloid malignancies, in patients undergoing myeloablative chemotherapy followed by marrow transplantation; prophylaxis
- Febrile neutropenia, in non-myeloid malignancies following myelosuppressive chemotherapy; prophylaxis
- Febrile neutropenia, in patients with acute myeloid leukemia receiving chemotherapy; prophylaxis
- Harvesting of peripheral blood stem cells
- Neutropenic disorder, chronic (severe), symptomatic (except for neonates and autoimmune neutropenia of infancy)

Usual dose range:

Adult and Pediatric
- Febrile neutropenia, in non-myeloid malignancies, in patients undergoing myeloablative chemotherapy followed by marrow transplantation; Prophylaxis
  - 10 mcg/kg/day IV over 4 or 24 h or as a continuous 24-h SC infusion; start at least 24 hours after chemotherapy and bone marrow infusion

- Febrile neutropenia, in non-myeloid malignancies following myelosuppressive chemotherapy; Prophylaxis
  - 5 mcg/kg/day SC/IV; start at least 24 h after chemotherapy

- Febrile neutropenia, in patients with acute myeloid leukemia receiving chemotherapy; prophylaxis
  - 5 mcg/kg/day SC/IV; start at least 24 h after chemotherapy

- Harvesting of peripheral blood stem cells
  - 10 mcg/kg/day SC as a bolus or continuous infusion, given at least 4 days before first leukapheresis and continued until the last leukapheresis

- Neutropenic disorder, chronic (severe), symptomatic
  - idiopathic or cyclic neutropenia: 5 mcg/kg SC once daily
  - congenital neutropenia: 6 mcg/kg SC twice daily
Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Febrile neutropenia, in non-myeloid malignancies following myelosuppressive chemotherapy; prophylaxis

- FDA indicated diagnosis
- Prescription is written by an oncologist or hematologist
- Primary prophylaxis:
  - Risk of febrile neutropenia is >20% (see Table 1 in additional considerations)
  - OR
  - High-risk for febrile neutropenia by documentation of one of the following:
    - Age > 65
    - Poor performance status
    - Infection or open wounds
    - Renal or liver disease
    - Malnutrition
    - History of previous chemotherapy or radiation
    - History of febrile neutropenia
    - Other serious co-morbidities that cause immunosuppression such as HIV/AIDS

-OR-

- Secondary prophylaxis:
  - Documentation of chemo-induced febrile neutropenia in the past without receiving primary prophylaxis

For the following diagnoses:

- Febrile neutropenia, in non-myeloid malignancies, in patients undergoing myeloablative chemotherapy followed by marrow transplantation; prophylaxis
- Febrile neutropenia, in patients with acute myeloid leukemia receiving chemotherapy; prophylaxis
- Harvesting of peripheral blood stem cells
  - FDA indicated diagnosis
  - Prescription is written by an oncologist or hematologist

Neutropenic disorder, chronic (severe), symptomatic; idiopathic, cyclic and congenital neutropenia

- FDA indicated diagnosis
- Prescription is written by an oncologist or hematologist
- Patient’s ANC is < 1000/mm³

Renewal Criteria

- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy (ANC > 1,000/mm³)
Contraindications:

- Individuals with known hypersensitivity to E coli-derived proteins, filgrastim, or any component of the product
- Patient is receiving concurrent chemotherapy or radiation

Not approved if:

- The patient has any of the aforementioned contraindications
- Patient post-nadir ANC is > 10,000/ mm³

Additional considerations:

- Splenic rupture, including fatal cases, has occurred with filgrastim. Caution in patients with a history of an enlarged spleen or who experience upper left quadrant pain.
- Severe sickle cell crises, in some cases resulting in death, have been associated with filgrastim.
- Filgrastim has not been evaluated in patients receiving chemotherapy associated with delayed myelosuppression (i.e. nitrosoureas), with mitomycin C, or with myelosuppressive doses of antimetabolites such as 5-fluorouracil. In these patients, filgrastim should be avoided.

Table 1. Examples of Chemotherapy Regimens at High Risk for Febrile Neutropenia*

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder</td>
<td>MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)</td>
</tr>
<tr>
<td>Breast</td>
<td>Docetaxel + trastuzumab</td>
</tr>
<tr>
<td></td>
<td>Dose-dense AC followed by T (doxorubicin + cyclophosphamide followed by paclitaxel)</td>
</tr>
<tr>
<td></td>
<td>TAC (docetaxel, doxorubicin, cyclophosphamide)</td>
</tr>
<tr>
<td>Esophageal and gastric</td>
<td>Docetaxel-cisplatin-fluorouracil</td>
</tr>
<tr>
<td>Non-Hodgkin’s Lymphoma</td>
<td>ICE (ifosfamide, carboplatin, etoposide)</td>
</tr>
<tr>
<td></td>
<td>CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)</td>
</tr>
<tr>
<td></td>
<td>DHAP (dexamethasone, cisplatin, cytarabine)</td>
</tr>
<tr>
<td></td>
<td>BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Dacarbazine-based combinations</td>
</tr>
<tr>
<td>Myelodysplastic syndrome</td>
<td>Antithymocyte globulin, rabbit; cyclosporine</td>
</tr>
<tr>
<td>Ovarian</td>
<td>Topotecan</td>
</tr>
<tr>
<td></td>
<td>Paclitaxel or docetaxel</td>
</tr>
<tr>
<td>Sarcoma</td>
<td>MAID (mesna, doxorubicin, ifosfamide, cisplatin)</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Topotecan</td>
</tr>
<tr>
<td>Testicular</td>
<td>VeiP (vinblastine, ifosfamide, cisplatin)</td>
</tr>
<tr>
<td></td>
<td>VIP (etoposide, ifosfamide, cisplatin)</td>
</tr>
<tr>
<td></td>
<td>BEP (bleomycin, etoposide, cisplatin)</td>
</tr>
<tr>
<td></td>
<td>TIP (paclitaxel, ifosfamide, cisplatin)</td>
</tr>
</tbody>
</table>

*Does not include all high-risk regimens

Approval time frames:

Febrile neutropenia, in non-myeloid malignancies, in patients undergoing myeloablative chemotherapy followed by marrow transplantation; Prophylaxis

- Initial: 14 days with an MDL of 10 mcg/kg
- Renewal: 14 days with the daily dose being titrated against the neutrophil response as follows:

<table>
<thead>
<tr>
<th>Absolute Neutrophil Count</th>
<th>Dose Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When ANC &gt; 1000/mm³ for 3 consecutive days</td>
<td>Reduce to 5 mcg/kg/day</td>
</tr>
<tr>
<td>2. Then, if ANC remains &gt;1000/mm³ for 3 more consecutive days</td>
<td>Discontinue</td>
</tr>
<tr>
<td>3. Then, if ANC decreases to &lt;1000/mm³</td>
<td>Resume at 5 mcg/kg/day</td>
</tr>
</tbody>
</table>

Febrile neutropenia, in non-myeloid malignancies following myelosuppressive chemotherapy; Prophylaxis

- Initial: 14 days/cycle of chemotherapy, with an MDL of 5 mcg/kg
- Renewal: 14 days/cycle of chemotherapy, with an MDL of 5 mcg greater than the previously approved dose

Febrile neutropenia, in patients with acute myeloid leukemia receiving chemotherapy; Prophylaxis

- Initial: 30 days/cycle of chemotherapy, with an MDL of 5 mcg/kg
- Renewal: 30 days/cycle of chemotherapy, with an MDL of 5 mcg/kg

Harvesting of peripheral blood stem cells

- Initial: 7 days with an MDL of 10 mcg/kg
- Renewal: 7 days with an MDL of 10 mcg/kg

Neutropenic disorder, chronic (severe), symptomatic

- Idiopathic or cyclic neutropenia
  - Initial: 6 months with an MDL individualized to each patient; initial dose has an MDL of 5 mcg/kg
  - Renewal: 1 year with individualized dosing with no MDL

- Congenital neutropenia
  - Initial: 6 months with an MDL individualized to each patient, initial dose has an MDL of 12 mcg/kg
  - Renewal: 1 year with individualized dosing with no MDL
References:

- Kouroukis CT, Haynes AE. The prophylactic use of filgrastim in patients with hematological malignancies. Toronto (ON): Cancer Care Ontario (CCO); 2009 Sep 23. p: 19

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 12/02/2013
Revision: 12/02/2014, December 2015
Prior Authorization Approval Criteria
Nexavar (sorafenib)

Generic name: sorafenib
Brand name: Nexavar
Medication class: Tyrosine kinase inhibitor

FDA-approved uses:
• Liver carcinoma, unresectable
• Malignant tumor of thyroid gland, Metastatic or locally advanced, refractory to radioactive iodine
• Renal cell carcinoma, Advanced

Usual dose range:
• For all indications – adult 400 mg twice daily, 1 hour before or 2 hours after eating

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
For all FDA-approved indications:
Adults
• 18 years of age or older
• Prescribed by an oncologist

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy with evidence of no disease progression

Contraindications:
• Do not use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer

Not approved if:
• Any of the above contraindications are present

Additional considerations:
• Maximum daily dose is 800 mg/day
Approval time frames:

- Initial – 6 months with MDL of 4/day
- Renewal – 6 months with MDL of 4/day

References:

Prior Authorization Approval Criteria
Novarel (human chorionic gonadotropin)

Generic name: human chorionic gonadotropin
Brand name: Novarel
Medication class: Gonadotropin

FDA-approved uses:
- Cryptorchidism
- Hypogonadotropic hypogonadism, in male patients
- Ovulation induction (Important Note: See “Not approved if” section below)

Usual dose range:
- Cryptorchidism – pediatric
  - 4000 units IM 3 times weekly for 3 weeks;
  - OR 5000 units IM every second day for 4 doses;
  - OR 15 injections of 500 to 1000 units IM over a period of 6 weeks;
  - OR 500 units IM 3 times weekly for 4 to 6 weeks and if ineffective, an additional
    course 1 month later using 1000 units per dose
- Hypogonadotropic hypogonadism in male patients – adolescent
  - 500 to 1000 units IM 3 times weekly for 3 weeks followed by 500 to 1000 units
    IM 2 times weekly for 3 weeks;
  - OR 4000 units IM 3 times weekly for 6 to 9 months, following which the dosage
    may be reduced to 2000 units IM 3 times weekly for an additional 3 months

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Cryptorchidism:
  Pediatric
    - FDA indicated diagnosis
    - Males 4 to 9 years of age
    - Prescribed by an endocrinologist or urologist
    - Documentation to support that patient is not a candidate for surgical
      repositioning of the undescended testes (orchiopexy)

Hypogonadotropic hypogonadism, in male patients:
  Adolescent
    - FDA indicated diagnosis
    - Documentation that hypogonadism is secondary to pituitary deficiency
    - Males 13 to 17 years of age with confirmed delayed puberty
Prescribed by an endocrinologist

Failure to respond (or contraindication) to one of the following formulary testosterone medications:
- Androderm patch
- Depo-testosterone injection
- Testim gel

Renewal Criteria
- Must have documentation of adherence to therapy
- For cryptorchidism:
  - Documentation of ineffective response to the following regimen:
    - 4 to 6 weeks of 500 units IM 3 times weekly
    - If confirmed ineffective, then 1 month later a second course of therapy will be approved for up to 6 additional weeks of 1000 units IM 3 times weekly
    - Other regimens will not be approved for additional courses of therapy
- For hypogonadotropic hypogonadism:
  - Renewals will not be approved if a full-course of therapy is completed per the above “Usual dose range” regimens
  - If a full-course of therapy was not completed, then medical rationale must be provided to support the reason for discontinuation and the re-initiation of therapy

Contraindications:
- Precocious puberty
- Pregnancy; may cause fetal harm
- Prostate cancer or other androgen-dependent neoplasm
- Prior allergic reaction to human chorionic gonadotropin

Not approved if:
- Diagnosis is ovulation induction; medications used for infertility are excluded from coverage
- Diagnosis is male infertility or intended use is for spermatogenesis (increase in sperm production); medications used for infertility are excluded from coverage

Additional considerations:
- Maximum daily dose is 5000 units/day (see “Usual dose range” section above)
Approval time frames:

- Cryptorchidism
  - Initial – Up to 6 weeks depending on regimen (variable regimens depending on prescriber choice; see “Usual dosage range” above)
  - Renewal – see “Renewal Criteria” above

- Hypogonadotropic hypogonadism, in male patients
  - Initial – Up to 12 months depending on regimen (variable regimens depending on prescriber choice; see “Usual dosage range” above)
  - Renewal – see “Renewal Criteria” above

References:

Prior Authorization Approval Criteria
Orencia (abatacept)

Generic name: abatacept
Brand name: Orencia
Medication class: Antirheumatic, Immune Modulator

FDA-approved uses:
- Adult Rheumatoid Arthritis (moderate to severe)
- Juvenile Idiopathic Arthritis (moderate to severe)

Usual dose range:
Adult Rheumatoid Arthritis (moderate to severe)

- **IV infusion**
  - Following initial IV infusion (weight-based), repeat infusion (with same dose as initial) at weeks 2 and 4 after initial, and every 4 weeks thereafter.

<table>
<thead>
<tr>
<th>Patient Body Weight</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 60 kg</td>
<td>500 mg</td>
</tr>
<tr>
<td>60 to 100 kg</td>
<td>750 mg</td>
</tr>
<tr>
<td>More than 100 kg</td>
<td>1000 mg</td>
</tr>
</tbody>
</table>

- **SubQ:**
  - 125 mg once weekly
  - *Note: dose may be used w/without IV loading dose

Juvenile Idiopathic Arthritis (moderate to severe)

- **IV infusion**
  - >6 years and <75kg
    - 10 mg/kg initial, repeat dose (weight-based at each administration) at weeks 2 and 4 after initial, and every 4 weeks thereafter
  - >6 years and >75 kg
    - Initial and maintenance dose are weight-based at each administration. Repeat at weeks 2 and 4 after initial, and every 4 weeks thereafter.

<table>
<thead>
<tr>
<th>Patient Body Weight</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-100 kg</td>
<td>750 mg</td>
</tr>
<tr>
<td>&gt;100 kg</td>
<td>1000 mg</td>
</tr>
</tbody>
</table>
Criteria for use:

Initiation Criteria

Rheumatoid Arthritis (moderate to severe)

Adult
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by a rheumatologist
- Failure to respond to one of the following:
  - Leflunomide
  - Methotrexate
- Failure to respond to one of the following:
  - Hydroxychloroquine
  - Sulfasalazine
- Failure to respond (or contraindication) to each of the following:
  - Enbrel (Step therapy required)
  - Humira (Step therapy required)
  - Remicade (PA required)

Juvenile Idiopathic Arthritis (moderate to severe)

Pediatric
- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by a rheumatologist
- Failure to respond to at least one formulary NSAID
- Failure to respond to one of the following:
  - Leflunomide
  - Methotrexate
- Failure to respond (or contraindication) to each of the following:
  - Enbrel (Step therapy required)
  - Humira (Step therapy required)
  - Remicade (PA required)

Renewal Criteria:
- Must have documentation of adherence to therapy (>75% adherence)

Contraindications:
- Hypersensitivity to abatacept or any formulation constituents

Not approved if:
- Above contraindication is present
**Additional considerations:**

- Max dose is 125 mg SUBQ weekly and 1000 mg IV every 4 weeks

**Approval time frames:**

**IV Infusion**
- Initial – 6 months with MDL 1000 mg every 4 weeks (after initial loading dose at weeks 0, 2, and 4)
- Renewal – 1 year with MDL 1000 mg every 4 weeks

**Subcutaneous**
- Initial – 6 months with MDL of 125 mg/week
- Renewal – 1 year with MDL of 125 mg/week

**References:**

Prior Authorization Approval Criteria
Paxil CR (paroxetine extended release)

Generic name: paroxetine extended release
Brand name: Paxil CR
Medication class: antidepressant

FDA-approved uses:
- Major depressive disorder (MDD)
- Panic disorder, with or without agoraphobia
- Social anxiety disorder (social phobia)
- Premenstrual dysphoric disorder

Usual dose range:
- Major depressive disorder – adults 25 - 62.5 mg/day
- Panic disorder – adults 12.5 - 75 mg/day
- Social anxiety disorder – adults 12.5 – 37.5 mg/day
- Premenstrual dysphoric disorder – adults 12.5 - 25 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
All FDA indicated diagnoses:
   Adults
      • FDA indicated diagnosis
      • 18 years of age or older
      • Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
         o Paroxetine immediate release,
         o One other formulary Selective Serotonin Reuptake Inhibitor (SSRI)
         o An additional antidepressant agent (bupropion, mirtazapine, venlafaxine, a tricyclic antidepressant, or a third SSRI)

Renewal Criteria
All FDA indicated diagnoses
   • Must have documentation of adherence to therapy (>75% adherence)
   • Documentation of effectiveness of therapy
Contraindications:

- Concomitant use in patients taking MAOIs, pimozide, thioridazine
- Hypersensitivity to paroxetine or to any of the inactive ingredients in Paxil CR

Not approved if:

- Patient is currently using MAOIs, pimozide, or thioridazine
- Patient has a diagnosis of bipolar disorder and is not on a mood stabilizer

Black box warning:

- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

Additional considerations:

- A gradual reduction in dose rather than abrupt cessation is recommended whenever possible
- Prescribe with care in patients with a history of seizure
- Maximum daily dose
  - Major depressive disorder – 62.5 mg/day
  - Panic disorder – 75 mg/day
  - Social anxiety disorder – 37.5 mg/day
  - Premenstrual dysphoric disorder – 25 mg/day

Approval time frames:

- Initial – 1 year with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

References:

- Paxil CR Prescribing Information (June 2014). GlaxoSmithKline, Research Triangle Park, NC.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:

Initial: 07/10/2013
Prior Authorization Approval Criteria
Pristiq (desvenlafaxine)

Generic name: desvenlafaxine
Brand name: Pristiq
Medication class: antidepressant

FDA-approved uses:
• Major Depressive Disorder (MDD)

Usual dose range:
• Major Depressive Disorder – adults 50 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Major Depressive Disorder:
Adults
• FDA indicated diagnosis
• 18 years of age or older
• Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
  o Venlafaxine
  o One formulary Selective Serotonin Reuptake Inhibitor (SSRI)
  o An additional formulary antidepressant agent (bupropion, mirtazapine, a tricyclic antidepressant, another SSRI, or another SNRI)

Renewal Criteria
Major Depressive Disorder:
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Hypersensitivity to Pristiq or venlafaxine
• Concomitant use in patients taking MAOIs

Not approved if:
• Patient is currently using MAOIs
• Patient currently taking another SSRI/SNRI with no plan to discontinue therapy
**Black box warning:**
- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

**Additional considerations:**
- A gradual reduction in dose rather than abrupt cessation is recommended whenever possible
- Prescribe with care in patients with a history of seizure
- Patients should have regular blood pressure monitoring, since increases in blood pressure were observed in clinical studies
- Hyponatremia may occur as a result of treatment, discontinue therapy in patients with symptomatic hyponatremia
- Maximum daily dose – 50 mg/day

**Approval time frames:**
- Initial – 1 year with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

**References:**

**Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:**
Initial: 07/10/2013
Prior Authorization Approval Criteria
Remicade (infliximab)

Generic name: infliximab
Brand name: Remicade
Medication class: TNF – α Blocker

FDA-approved uses:
• Ankylosing spondylitis
• Crohn’s disease
• Fistulizing Crohn’s Disease
• Plaque Psoriasis
• Psoriatic Arthritis
• Rheumatoid arthritis
• Ulcerative Colitis

Usual dose range:
• Ankylosing spondylitis:
  o 5 mg/kg IV over 2 hours given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hours every 6 weeks
• Crohn’s disease/Fistulizing Crohn’s disease/ Plaque psoriasis/ Psoriatic arthritis/ Ulcerative colitis:
  o 5 mg/kg IV over 2 hours given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hours every 8 weeks.
• Rheumatoid arthritis:
  o 3 mg/kg IV over 2 hours given at weeks 0, 2, and 6 followed by a maintenance dose of 3 mg/kg IV over 2 hours every 8 weeks.

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Ankylosing spondylitis:

Adults
• FDA indicated diagnosis
• 18 years of age or older
• Prescribed by a rheumatologist
• Failure to respond (or intolerance) to each of the following:
  o An NSAID
  o Enbrel (Step therapy)
  o Humira (Step therapy)
Crohn’s disease/Fistulizing Crohn’s Disease:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by a gastroenterologist
- Failure to respond (or intolerance) to each of the following:
  - One corticosteroid
  - Sulfasalazine or mesalamine
  - Humira (Step therapy)
  - Azathioprine, 6-mercaptopurine or methotrexate

**Adolescents (6-17)**
- FDA indicated diagnosis
- Prescribed by a rheumatologist
- Failure to respond (or intolerance) to each of the following:
  - One corticosteroid
  - Sulfasalazine or mesalamine
  - Azathioprine, 6-mercaptopurine or methotrexate

Plaque Psoriasis/Psoriatic arthritis:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by a rheumatologist
- Failure to respond (or intolerance) to each of the following:
  - One corticosteroid
  - Methotrexate
  - Enbrel (Step therapy)
  - Humira (Step therapy)

Rheumatoid arthritis

**Adult**
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by a rheumatologist
- Failure to respond (or intolerance) to each of the following:
  - Sulfasalazine, hydroxychloroquine or leflunomide
  - Methotrexate
  - Enbrel (Step therapy)
  - Humira (Step therapy)

Ulcerative Colitis:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
Prescribed by a gastroenterologist
Failure to respond (or intolerance) to each of the following:
- One corticosteroid
- Sulfasalazine or mesalamine
- Azathioprine or 6-mercaptopurine
- Humira (Step therapy)

Adolescents (6-17)
- FDA indicated diagnosis
- Prescribed by a gastroenterologist
- Failure to respond (or intolerance) to each of the following:
  - One corticosteroid
  - Sulfasalazine or mesalamine
  - Azathioprine or 6-mercaptopurine

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Moderate to severe (NYHA Class III/IV) heart failure
- Hypersensitivity to murine proteins or any other component of Remicade

Not approved if:
- Any of the contraindications listed above are present
- Infection is present at time of use

Black box warning:
- Tuberculosis, invasive fungal infections, bacterial, viral, and other opportunistic infections have been witnessed in patients taking Remicade. Monitor patients being administered the medication and evaluate for tuberculosis risk factors.
- Patients should be tested for tuberculosis before and during therapy with Remicade
- Lymphoma and other malignancies have been reported in patients treated with TNF – α blockers, including Remicade

Additional considerations:
- Monitor patient for signs of infection or hypersensitivity reaction
- Auto-antibody formation has been witnessed, leading to the formation of lupus like symptoms
- Increased risk of infection in ages > 65 and co-administration of other immunosuppressants
Neurologic disorders such as seizure, optic neuritis, and systemic vasculitis have been reported.

Pregnancy Category: B

Women should not breast-feed while on Remicade

Remicade has not been studied in children < 6 years of age

**Approval time frames:**
- Initial – 6 months; MDL is weight-based per request
- Renewal – 1 year; MDL is weight-based per request

**References:**
Prior Authorization Approval Criteria

Revatio (sildenafil)

Generic name: sildenafil
Brand name: Revatio
Medication class: Phosphodiesterase Type 5 Inhibitor

FDA-approved uses:
- Pulmonary arterial hypertension

Usual dose range:
- Pulmonary arterial hypertension - adult 5 mg – 20 mg TID

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Pulmonary arterial hypertension (PAH):

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed or recommended by a pulmonologist
- Confirmed World Health Organization (WHO) Group I PAH diagnosis
- Confirmed New York Heart Association (NYHA) functional Class II or III symptoms
- Failure to respond (or contraindication) to a calcium channel blocker (required only if there is a positive response to acute vasoreactivity testing)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Concomitant or intermittent use of nitrates
- Concomitant use with evitegravir/cobicistat/tenofovir/emtricitabine (Stribild) or HIV protease inhibitors

Not approved if:
- Patient exhibits only NYHA Class I symptoms
Additional considerations:

- World Health Organization (WHO) Group I PAH diagnosis can be confirmed by the following:
  - Mean pulmonary arterial pressure > 25 mmHg at rest or 30 mmHg during exercise
  - Normal pulmonary capillary wedge pressure
- NYHA functional classes are determined by the following:
  - Class I: No symptoms with ordinary physical activity.
  - Class III: Symptoms with less than ordinary activity. Marked limitation of activity. Comfortable at rest.
  - Class IV: Symptoms with any activity or even at rest.
- Maximum daily dose is 60 mg/day

Approval time frames:

- Initial – 1 year with MDL of 3/day
- Renewal – 1 year with MDL of 3/day

References:

Prior Authorization Approval Criteria

Risperdal Consta
(risperidone long-acting injection)

Generic name: risperidone long-acting injection
Brand name: Risperdal Consta
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia
- Maintenance treatment of bipolar I disorder as monotherapy or as adjunctive therapy to lithium or valproate

Usual dose range:
- Schizophrenia/Bipolar disorder – adults
  - Initial 25 mg every 2 weeks
  - Maintenance 25-50 mg every 2 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria
  Schizophrenia/Bipolar Disorder:
    Adults
    - FDA indicated diagnosis
    - 18 years of age or older
    - Documentation of response to oral risperidone therapy
    - Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted

Renewal criteria
  All FDA indicated diagnoses:
  - Documentation of adherence to therapy (>75% compliance)
  - Documentation of effectiveness of therapy
  - Documentation of continued need for long-acting injection (including a review of adherence with other oral medications)

Contraindications:
- Known hypersensitivity to risperidone
Not approved if:

- Past history of dementia-related psychosis
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

Black box warning:

- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo

Additional considerations:

- Tolerability should be established with oral risperidone prior to initiation initial injection of Risperdal Consta
- Oral risperidone should be continued for 3 weeks following initial injection and then discontinued
- Upward dose increases should not be made more frequently than every 4 weeks
- Maximum daily dose is 50 mg every 2 weeks

Approval time frames:

- Initial – 6 months with a quantity limit of 2 syringes/month
- Renewal – 1 year with a quantity limit of 2 syringes/month

References:

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria
Rozerem (ramelteon)

Generic name: ramelteon
Brand name: Rozerem
Medication class: Nonbenzodiazepine hypnotic

**FDA-approved uses:**
- Insomnia

**Usual dose range:**
- Insomnia - adult 8 mg at bedtime

**Criteria for use:** (bullet points are all inclusive unless otherwise noted)

**Initiation Criteria**

**Insomnia:**

- **Adults**
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial of each of the following:
    - Melatonin [Over-the-counter (OTC)]
    - Trazodone or diphenhydramine (OTC)
    - Either of the following:
      - Zolpidem or zolpidem extended-release or eszopiclone
      - Diagnosis of drug abuse or dependence

**Renewal Criteria**
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

**Contraindications:**
- Known hypersensitivity to ramelteon
- Concomitant use of fluvoxamine

**Not approved if:**
• Patient is currently taking other medications that can cause wakefulness (e.g. stimulants)
• Patient is currently taking fluvoxamine

Additional considerations:
• Do NOT take with meals
• Maximum daily dose is 8mg/day

Approval time frames:
• Initial – 1 year with MDL of 1/day
• Renewal – 1 year with MDL of 1/day

References:
• Rozerem Prescribing Information (November 2010). Takeda Pharmaceuticals America, Inc., Deerfield, IL.
Prior Authorization Approval Criteria
Saphris (asenapine)

Generic name: Saphris
Brand name: asenapine
Medication class: antipsychotic

FDA-approved uses:
- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy or adjunctive treatment to lithium or valproate

Usual dose range:
- Schizophrenia – adults 5-10 mg twice a day sublingually
- Bipolar Mania – adults 5-10 mg twice a day sublingually
- Bipolar Mania – pediatric patients (10-17 years) 2.5-10 mg twice a day sublingually

Criteria for use: (bullet points are all inclusive unless otherwise noted)
Initiation criteria

Schizophrenia:

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotics agents

OR
- Patient requires orally disintegrating formulation
- Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:
  - Risperidone ODT
  - Olanzapine ODT

Bipolar I Disorder:

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (at least 30 days with adequate blood levels) of each of the following:
  - Lithium OR valproic acid
  - Two formulary antipsychotic agents

OR
- Patient requires orally disintegrating formulation
- Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:
  - Risperidone ODT
Renewal criteria

All FDA indicated diagnoses:
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to asenapine, or to any components in the formulation.

Not approved if:
- Past history of dementia-related psychosis
- Patient has severe hepatic impairment
- Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

Black box warning:
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

Additional considerations:
- Maximum daily dose is 10 mg twice a day

Approval time frames:
- Initial – 6 month(s) with MDL of 2/day
- Renewal – 1 year(s) with MDL of 2/day
- Special approval notes – for renewals of patients requiring orally disintegrating formulation verify that they still need ODT formulation

References:
- Saphris Prescribing Information (March 2015). Merck & Co. Inc., Whitehouse Station, NJ.
- Dixon L, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at:

Prior Authorization Approval Criteria
Sensipar (cinalcact)

Generic name: cinalcact
Brand name: Sensipar
Medication class: Calcimimetic

FDA-approved uses:
- Primary hyperparathyroidism / Parathyroid Carcinoma
- Secondary hyperparathyroidism

Usual dose range:
- Primary hyperparathyroidism/Parathyroid carcinoma:
  - Initial: 30 mg po BID
  - Maintenance: up to 90 mg QID
- Secondary hyperparathyroidism:
  - Initial: 30 mg po once daily
  - Maintenance: 60 mg, 90 mg, 120 mg, 180 mg once daily based on intact parathyroid hormone (iPTH) [see renewal criteria for lab values]

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Primary hyperparathyroidism/Parathyroid carcinoma:
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by endocrinologist or oncologist
- Hypercalcemia associated with parathyroid carcinoma confirmed by a serum calcium level ≥ 8.4 mg/dL
- Confirmation that patient is not a candidate for parathyroidectomy

Secondary hyperparathyroidism:
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by endocrinologist or nephrologist
- Patient is on dialysis
- Failure to respond (or contraindication) to one of the following:
  - Calcitriol
  - Calcium acetate (PhosLo)
- Documentation of iPTH > 300 pg/mL and serum calcium ≥ 8.4 mg/dL
Renewal Criteria

- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy
  - Serum calcium levels ≥ 8.4 mg/dL
  - iPTH > 150 pg/mL

Contraindications:

- Hypersensitivity to any ingredients
- Patients with hypocalcemia

Not approved if:

- Any of the above contraindications are present

Additional considerations:

- Lowers seizure threshold
- Maximum total daily dose is 360 mg/day

Approval time frames:

- Initial – 6 months with MDL of 4/day
- Renewal – 6 months with MDL of 4/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/03/2014
Revision: June 2015, June 2016
Prior Authorization Approval Criteria

Seroquel XR (quetiapine XR)

Generic name: quetiapine XR
Brand name: Seroquel XR
Medication class: Antipsychotic

FDA-approved uses:
- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder
- Acute treatment of depressive episodes associated with bipolar disorder
- Maintenance treatment of bipolar I disorder as either monotherapy or adjunct therapy to lithium or divalproex
- Adjunctive therapy for the treatment of major depressive disorder in adults

Usual dose range:
- Schizophrenia – adults 400 mg-800 mg/day
- Bipolar Disorder – manic and mixed episodes – adults 400 mg-800 mg/day
- Bipolar Disorder – manic episodes – pediatric (10-17 yrs) 400 mg-600 mg/day
- Bipolar Depression – adults 300 mg/day
- As an adjunct to antidepressants for the treatment of major depressive disorder – adults 150 mg-300 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation criteria

Schizophrenia:
- Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotic agents OR
  - Documentation of stabilization on quetiapine immediate release

Bipolar disorder – manic and mixed episodes:
- Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Failure to respond (or intolerance) to an adequate trial (at least 30 days with adequate blood levels) of each of the following:
    - Lithium OR valproic acid
    - Two additional formulary atypical antipsychotic agents OR
  - Documentation of stabilization on quetiapine immediate release
Bipolar depression:
   Adults
   • FDA indicated diagnosis
   • 18 years of age or older
   • Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three of the following:
     o Lithium
     o Lamotrigine
     o Quetiapine immediate release
     o Concurrent trials of olanzapine and fluoxetine
     o One combination trial of lithium, lamotrigine, quetiapine immediate release, or olanzapine ± fluoxetine
   ***If patient has a BMI>35 or BMI>30 with multiple risk factors (HTN/DM/etc) then quetiapine, lithium and olanzapine are not required

Major depressive disorder:
   Adults
   • FDA indicated diagnosis
   • 18 years of age or older
   • Failure to respond (or intolerance) to an adequate trial (4-6 weeks of an adequate dose) of each of the following:
     o A Selective Serotonin Reuptake Inhibitor (SSRI),
     o A Serotonin and Norepinehrine Reuptake Inhibitor (SNRI),
     o One additional formulary antidepressant (SSRI, SNRI, TCA, bupropion, mirtazapine)
   • Must be used as adjunctive or add-on treatment to antidepressant therapy and not as monotherapy

Renewal criteria
   All FDA indicated diagnoses:
   • Must have documentation of adherence to therapy (>75% adherence)
   • Documentation of effectiveness of therapy

Contraindications:
   • Known hypersensitivity to quetiapine or to any components in the formulation

Not approved if:
   • Past history of dementia-related psychosis
   • Current history of orthostatic hypotension
   • Used to treat insomnia
   • Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
o Clozapine
o Two other antipsychotics

**Black box warning:**

- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

**Additional considerations:**

- Maximum daily dose is 800 mg/day

**Approval time frames:**

- Initial – 6 months with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

**References:**

- Seroquel XR Prescribing Information (October 2013). AstraZeneca Pharmaceuticals, Wilmington, DE.


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Prior Authorization Approval Criteria
Silenor (doxepin)

Generic name: doxepin
Brand name: Silenor
Medication class: tricyclic antidepressant

FDA-approved uses:
- Insomnia

Usual dose range:
- Insomnia - adult 3 mg - 6 mg at bedtime

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Insomnia:
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial of each of the following:
  ▪ Doxepin (10 mg capsule for patients <65 years of age and doxepin concentrate if ≥65 years of age)
  ▪ Trazodone
  ▪ Either of the following:
    • Zolpidem or zolpidem extended-release or eszopiclone
    -OR-
    • Diagnosis of drug abuse or dependence

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- Known hypersensitivity to doxepin or other dibenzoxepines
- Concomitant use in patients taking MAOIs
- Use in patients with uncontrolled narrow-angle glaucoma
- Severe urinary retention
Not approved if:
- Patient is currently taking other medications that can cause wakefulness (e.g. stimulants)
- Patient is currently using MAOIs
- Patient has a diagnosis of narrow-angled glaucoma
- Patient has a diagnosis of severe sleep apnea
- Patient has severe urinary retention

Additional considerations:
- Start dosing at 3 mg/day for patients who are elderly, have severe hepatic impairment, or history of urinary retention
- Do NOT take with meals
- Maximum daily dose is 6 mg/day

Approval time frames:
- Initial – 1 year with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

References:
Prior Authorization Approval Criteria
Somatropin

Generic name: somatropin
Brand name: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope
Medication class: Pituitary Hormone/ Growth Hormone Modifier

FDA-approved uses:
- Growth hormone deficiency
- Noonan’s syndrome
- Prader-Willi syndrome
- Renal function impairment with growth failure
- Short stature disorder, Idiopathic
- Short stature disorder - Turner syndrome
- Short-stature homeobox-containing gene (SHOX) deficiency
- Small for gestational age baby, with no catch-up growth by age 2 to 4 years

Usual dose range:

Adult Dosing
- Growth hormone deficiency: weight-based dosing schedule: initial, not more than 0.04 mg/kg/week SUBQ given as a daily divided dose; increase at 4 to 8 week intervals
- Growth hormone deficiency: alternative dosing schedule: initial, 0.2 mg/day (range, 0.15 to 0.3 mg/day) SUBQ; increase by 0.1 to 0.2 mg/day every 1 to 2 months according to patient response

Pediatric Dosing
- Growth hormone deficiency: 0.15 to 0.3 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- Noonan’s syndrome: up to 0.462 mg/kg/week SUBQ, divided into equal daily doses
- Prader-Willi syndrome: 0.24 mg/kg/week SUBQ, divided into equal daily doses given 6 to 7 days/week
- Renal function impairment with growth failure: up to 0.35 mg/kg/week SUBQ, divided into equal daily doses; may continue up to time of renal transplantation
- Short stature disorder, Idiopathic: up to 0.47 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- Short stature disorder - Turner syndrome: up to 0.47 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- Short-stature homeobox-containing gene (SHOX) deficiency: 0.35 mg/kg/week SUBQ, divided into equal daily doses given 6 to 7 days/week
- Small for gestational age baby, with no catch-up growth by age 2 to 4 years: up to 0.48 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Growth hormone deficiency

[Important consideration: Acquired growth hormone deficiency with confirmation of known etiology (e.g. brain tumor, pituitary/hypothalamus tumor, radiation therapy, etc.) may not require the following criteria to be met]

Adult

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Confirmed panhypopituitarism (deficiencies of TSH, ACTH, and gonadotropins), pituitary or hypothalamic disease by documentation of one of the following:
  - Subnormal serum IGF-1 concentration based on age and sex
  - Subnormal serum growth hormone response to potent stimuli
    - Preferred: Insulin tolerance test (ITT) (Peak GH≤5.0 µg/L)
    - GHRH + arginine (ARG) or the glucagon test
      - Peak GH ≤ 11.0 µg/L in patients with BMI < 25 kg/m²
      - Peak GH ≤ 8.0 µg/L in patients with BMI > 25 and < 30 kg/m²
      - Peak GH ≤ 4.0 µg/L in patients with BMI ≥ 30 kg/m²

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Signs of growth deficiency by confirmation of ≤10th percentile per pediatric growth chart
- Documentation of the following:
  - Failure of two standard growth hormone stimulation tests (with arginine, clonidine, glucagon, insulin, levodopa, or propranolol)
    - Failure defined as a peak measured GH level of less than 10 ng/ml after stimulation
  - Documentation of both of the following:
    - Decrease in one of the following lab values:
      - Insulin-like growth factor-1 (IGF-I)
      - Insulin-like growth factor binding protein-3 (IGFBP-3)
      - Bone age
    - Failure of one standard growth hormone stimulation test
Noonan’s syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Prader-Willi syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Renal function impairment with growth failure

Pediatric

- FDA indicated diagnosis
- Prescribed by (or under the care of) a nephrologist
- Confirmation that patient is pre-transplant
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Short stature disorder, Idiopathic

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender
- Predicted height is <63 inches for male
- Predicted height is <59 inches for female
- Documentation of epiphyses not closed (X-ray)

Short stature disorder - Turner syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Short-stature homeobox-containing gene (SHOX) deficiency:

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
Confirmed by genetic testing
Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Small for gestational age baby, with no catch-up growth by age 2 to 4 years

Pediatric
• FDA indicated diagnosis
• Prescribed by an endocrinologist
• Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Renewal Criteria

Adult (only for the diagnosis of growth hormone deficiency)
• Improvement of IGF-1 levels to determine dose, waist/hip ratios, thyroid function tests, lipids, body weight
  o Therapy should be discontinued when:
    ▪ Patient has reached satisfactory adult height
    ▪ When the patient ceases to respond
  o Adults may require life-long therapy as determined by a GH ≤ 3 ng/ml after a year of therapy

Pediatric (for all FDA-approved indications)
• Height determination, documentation that epiphyseal is not closed, improved growth velocity
  o Therapy should be discontinued when:
    ▪ When epiphyses have fused
    ▪ When the patient ceases to respond
  o Growth of 5 cm/year or more is expected, if growth rate does not exceed 2.5 cm in a 6-month period, dose adjustments should be considered for an additional 6 months; if there is still no satisfactory response, discontinuation of therapy should be considered

Contraindications:
• Acute critical illness
• Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment, there have been reports of sudden death
  o Use may be appropriate if severe respiratory impairment is being treated
• Active malignancy
• Active proliferative or severe non-proliferative diabetic retinopathy
• Children with closed epiphyses (X-ray)
• Known hypersensitivity to somatropin or m-cresol
• Pregnancy/Breast feeding
Not approved if:
• Any of the contraindications listed above are present

Additional considerations:
• If patient meets the above “Initiation Criteria” for somatropin therapy for any diagnosis, the plan will only approve a preferred product. Other products may be considered if the patient has tried and failed, has intolerance, or has documented medical rationale to support why they are unable to use the plan-preferred product
• For pediatric growth hormone deficiency: once a maintenance dose has been reached, monitoring should be done every 6-12 months on IGF-1; thyroid lab values only need to be monitored for the first 6-12 months of therapy to ensure they remain within normal limits
• Bone age may be advanced in cases of concomitant precocious puberty, thus it would not be expected to be low as stated in the above initiation criteria for pediatric growth hormone deficiency

Approval time frames:
• Initial – 6 months; MDL is weight-based per request
• Renewal – 6 months; MDL is weight-based per request

References:
• Rogol AD, Geffner M, Hoppin AG. Diagnostic approach to short stature. In: UpToDate, Rose, BD (Ed), UpToDate, Waltham, MA, 2005.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 11/05/2013
Revision: 11/05/2014, November 2015
Prior Authorization Approval Criteria
Somatuline Depot (lanreotide acetate)

Generic name: lanreotide acetate
Brand name: Somatuline Depot
Medication class: Somatostatin analog

FDA-approved uses:
- Acromegaly
- Gastroenteropancreatic neuroendocrine tumor

Usual dose range:
- Acromegaly – adult 60 – 120 mg deep SUBQ every 4 weeks
- Gastroenteropancreatic neuroendocrine tumor – adult 120 mg deep SUBQ every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Acromegaly/Gastroenteropancreatic neuroendocrine tumor:
- Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Prescribed by an endocrinologist or oncologist
  - Inadequate response or contraindication to surgery and/or radiation (see additional considerations*)
  - Failure to respond (or contraindication) to octreotide acetate (PA may be required)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy
  - For acromegaly: serum IGF-1 level within normal age-adjusted range (see table in additional considerations)
  - For gastroenteropancreatic neuroendocrine tumor: stable or decrease in tumor size

Contraindications:
- None established
Not approved if:
• The above criteria are not met

Additional considerations:
• *Surgery is contraindicated for:
  o Patients with unstable medical conditions
  o Patients at risk of anesthesia complications due to airway trouble
  o Patients with systemic conditions: cardiomyopathy, severe hypertension, uncontrolled diabetes
• Serum IGF-1 level within normal age-adjusted range

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Female</th>
<th>Male</th>
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<tr>
<td>19 – 20</td>
<td>217 – 475 ng/mL</td>
<td>281 – 510 ng/mL</td>
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<td>21 – 30</td>
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<td>75 – 263 ng/mL</td>
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<tr>
<td>71 – 80</td>
<td>54 – 205 ng/mL</td>
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</table>
• Maximum daily dose is 120 mg/day

Approval time frames:
• Initial – 6 months with MDL of 1 syringe/month
• Renewal – 6 months with MDL of 1 syringe/month

References:
Prior Authorization Approval Criteria
Somavert (pegvisomant)

Generic name: pegvisomant
Brand name: Somavert
Medication class: Growth Hormone Receptor Antagonist

FDA-approved uses:
• Acromegaly

Usual dose range:
• Acromegaly – adult
  o Initiation: 40 mg SQ once
  o Maintenance: 10 mg SQ daily with possible titration up to 30 mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Acromegaly
Adults
• FDA indicated diagnosis
• 18 years of age and older
• Prescribed by an endocrinologist
• Inadequate response OR contraindication to surgery and/or radiation (see additional considerations*)
• Failure to respond (or contraindication) to one of the following:
  o Bromocriptine
  o Cabergoline (PA may be required)
• Failure to respond (or contraindication) to octreotide (PA required)

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Normal liver function tests (LFTs)
  o ALT ≤ 48 unit/L
  o AST ≤ 42 unit/L
• Documentation of effectiveness of therapy
  o Serum IGF-1 level within normal age-adjusted range (see table in additional considerations)

Contraindications:
• Hypersensitivity to pegvisomant, polyethylene glycol, latex, or any other component of the formulation
Not approved if:
- LFTs > 3x the normal upper limit
- Patient has hepatitis or hepatic injury

Additional considerations:
- *Surgery is contraindicated for:
  - Patients with unstable medical conditions
  - Patients at risk of anesthesia complications due to airway trouble
  - Patients with systemic conditions: cardiomyopathy, severe hypertension, uncontrolled diabetes
- Serum IGF-1 level within normal age-adjusted range

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- Monitoring of tumor growth
- Can oppose insulin or carbohydrate metabolism by decreasing insulin sensitivity
- Can cause growth hormone deficiency

Approval time frames:
- Initial – 6 months with MDL of 3 vials/day
- Renewal – 6 months with MDL of 3 vials/day

References:
Prior Authorization Approval Criteria
Sonata (zaleplon)

Generic name: zaleplon
Brand name: Sonata
Medication class: Nonbenzodiazepine hypnotic

FDA-approved uses:
• Insomnia

Usual dose range:
• Insomnia - adult 10 mg - 20 mg at bedtime

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Insomnia:
Adults
• FDA indicated diagnosis
• 18 years of age or older
• Failure to respond (or intolerance) to an adequate trial of each of the following:
  ▪ Zolpidem or zolpidem extended-release or eszopiclone
  ▪ Trazodone

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Known hypersensitivity to zaleplon

Not approved if:
• Patient is currently taking other medications that can cause wakefulness (e.g. stimulants)

Additional considerations:
• Start dosing at 5 mg/day for patients who are elderly and have severe hepatic impairment
• Do NOT take with meals
• A gradual reduction in dose rather than abrupt cessation is recommended whenever possible
• Maximum daily dose is 20 mg/day (10 mg/day for elderly adults)

Approval time frames:
• Initial – 1 year with MDL of 2/day
• Renewal – 1 year with MDL of 2/day

References:
• Sonata Prescribing Information (April 2013). CorePharma, LLC, Middlesex, NJ.
Prior Authorization Approval Criteria
Sovaldi (sofosbuvir)

Generic name: sofosbuvir
Brand name: Sovaldi
Medication class: Direct-acting antiviral; RNA polymerase inhibitor

FDA-approved uses:
- Hepatitis C, chronic, genotype 1, 2, 3 or 4

Usual dose range:
- Hepatitis C, chronic, genotype 1, 2, 3 or 4 – adult 400 mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Hepatitis C virus infection:
- Adults
  - Hepatitis C virus (HCV) infection with a positive serum HCV RNA
  - 18 years of age or older
  - Prescribed by a gastroenterologist, hepatologist, infectious disease specialist or HIV specialist
  - Confirmation of Genotype 2 or 3
    - Patients with liver carcinoma awaiting liver transplantation will only be considered on a case-by-case basis
  - Confirmation of concomitant use with ribavirin
  - For genotypes 1 or 4, must have contraindication to Harvoni (ledipasvir 90mg/sofosbuvir 400mg)
  - Evidence of fibrosis stage 3 or 4 confirmed by one of the following:
    - Liver biopsy of stage 3 or higher
    - Noninvasive fibrosis score with a high probability of advanced fibrosis/cirrhosis (FIB-4 greater than or equal to 3.25)
    - Radiological imaging with findings suggestive of cirrhosis
      - If cirrhotic, must be deemed compensated by prescribing provider by documentation of all of the following:
        - Total bilirubin less than or equal to 1.5 g/dL, unless attributable to atazanavir therapy
        - INR less than or equal to 1.5
        - No evidence of ascites or hepatic encephalopathy
  - HIV co-infection must have confirmation of both of the following:
    - Stable on antiretroviral therapy
    - HIV viral load less than 200 copies/mL within the past 3 months
  - Documentation that patient is willing to adhere to treatment requirements
• Documentation of each of the following:
  o No alcohol/drug use (including medical/recreational marijuana) within the past 6 months
  o Pretreatment tox screen and agreement to monthly tox screens with confirmed negative results for alcohol/drug use (including medical/recreational marijuana) if the patient has a history of drug/alcohol abuse within the past 2 years
  • Note: pretreatment tox screen only required if there has been any documented alcohol/drug abuse (including medical/recreational marijuana) within the past 2 years

Renewal Criteria
• Must have documentation of adherence to therapy (> 80% adherence)
• If patient has history of alcohol/drug abuse, must have documentation of monthly tox screens with confirmed negative results for alcohol/drug use (including medical/recreational marijuana)
• Documentation of effectiveness of therapy by the following:
  o If viral RNA level is undetectable at week 3, then the remainder of the full course of therapy will be approved
  o If viral RNA level is detectable at week 3 with less than a 3 log decrease from baseline, then therapy will be discontinued
  o If viral RNA level is detectable at week 3 with greater than or equal to a 3 log decrease from baseline, then 4 additional weeks will be approved and another viral RNA level will be required at week 7
    ▪ If viral RNA level is undetectable at week 7, then the remainder of the full course of therapy will be approved
    ▪ If viral RNA level is detectable at week 7, then therapy will be discontinued

Contraindications:
• Pregnancy and men whose female partners are pregnant (due to required concomitant use with ribavirin, which may cause birth defects or death of exposed fetus)

Not approved if:
• Any previous trial/failure of any direct-acting antiviral therapy for any genotype
• Less than 12 months since the last attempt of HCV treatment with PEG-interferon plus ribavirin
• Diagnosis of genotype 5 or 6
• Confirmed decompensated cirrhosis
• Evidence of non-adherence to treatment of concurrent medical diseases (e.g. poorly controlled DM, severe HTN, heart failure, significant CAD, COPD, thyroid disease)
• Clinically significant liver disease from other causes
• Concurrent psychiatric illness without strong primary care physician and psychiatric support
• Alcohol or illicit drug use (including medical/recreational marijuana) within the past 6 months
• Not established with a primary care provider
• Known hypersensitivity to drugs used to treat HCV

Additional considerations:
• Maximum daily dose is 1 tablet per day

Approval time frames:
• Initial approval
  o For genotypes 2 or 3 – 4 weeks with MDL of 1/day

• Renewal
  o Genotype 2
    ▪ If “Renewal Criteria” is met, then may be approved for up to 8 additional weeks with MDL of 1/day
  o Genotype 3
    ▪ If “Renewal Criteria” is met, then may be approved for up to 20 additional weeks with MDL of 1/day

References:
• Sovaldi Prescribing Information. Gilead Sciences, Foster City, CA: 2015.
Prior Authorization Approval Criteria
Sporanox (itraconazole)

Generic name: itraconazole
Brand name: Sporanox
Medication class: Antifungal

FDA-approved uses:
- Aspergillosis, pulmonary and extrapulmonary
- Blastomycosis, pulmonary and extrapulmonary
- Candidiasis, oropharyngeal and esophageal
- Histoplasmosis, chronic cavitary pulmonary disease and disseminated non-meningeal
- Onychomycosis, toenail and fingernail

Usual dose range:
- Aspergillosis – adult 200 – 400 mg daily
- Blastomycosis – adult 200 – 400 mg daily
- Candidiasis – adult 100 – 200 mg (oral solution) daily for 2 to 4 weeks and 2 weeks after resolution of symptoms
- Histoplasmosis – adult 200 – 400 mg daily
- Onychomycosis
  - Toenail – adult 200 mg daily for 12 weeks
  - Fingernail – adult 200 mg BID for 1 week, then 3 weeks off, then 200 mg BID for 1 week

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Aspergillosis, pulmonary and extrapulmonary:
- Adults
  - FDA indicated diagnosis
  - 18 years of age or older

Blastomycosis, pulmonary and extrapulmonary:
- Adults
  - FDA indicated diagnosis
  - 18 years of age or older
Candidiasis, oropharyngeal and esophageal:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or contraindication) to an adequate trial (200 – 400 mg daily for 7 days) of fluconazole

Histoplasmosis, chronic cavitory pulmonary disease and disseminated non-meningeal:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older

Onychomycosis, toenails and fingernails:

**Adults**
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or contraindication) to an adequate trial of terbinafine:
  - For fingernails: 250 mg daily for 6 weeks
  - For toenails: 250 mg daily for 12 weeks

Renewal Criteria
- Documentation of improved disease state, but still has indicators of active disease (positive cultures, positive radiologic imaging, or positive serum assay) since initial approval

Contraindications:
- Hypersensitivity to itraconazole or any other component of the product
- Concomitant use with cisapride, colchicine (in patients with renal or hepatic impairment), disopyramide, dofetilide, dronedarone, eplerenone, ergot alkaloids (such as dihydroergotamine, ergometrine (ergonovine), ergotamine, methylergometrine (methylergonovine)), felodipine, irinotecan, lovastatin, lurasidone, methadone, oral midazolam, nisoldipine, pimozide, quinidine, ranolazine, simvastatin, or triazolam
- Renal or hepatic impairment
- Pregnancy or wanting to become pregnant
- Ventricular dysfunction, e.g. congestive heart failure (CHF) or history of CHF

Not approved if:
- Any of the above contraindications are present
Black box warning:

- Should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration of itraconazole capsules or tablets, discontinue administration. If signs or symptoms of CHF occur during administration of itraconazole oral solution, continued itraconazole use should be reassessed. Coadministration of itraconazole with cisapride, colchicine (in patients with renal or hepatic impairment), disopyramide, dofetilide, dronedarone, eplerenone, ergot alkaloids (such as dihydroergotamine, ergometrine (ergonovine), ergotamine, methylergometrine (methylergonovine)), felodipine, irinotecan, lovastatin, lurasidone, methadone, oral midazolam, nisoldipine, pimozide, quinidine, ranolazine, simvastatin, or triazolam and in patients with renal or hepatic impairment is contraindicated. Itraconazole, a potent CYP3A4 inhibitor, may increase plasma concentration of drugs metabolized by this pathway. Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death may occur.

Additional considerations:

- Maximum daily dose is 400 mg/day

References:

Prior Authorization Approval Criteria
Strattera (atomoxetine)

Generic name: atomoxetine
Brand name: Strattera
Medication class: Norepinephrine reuptake inhibitor, non-CNS stimulant

FDA-approved uses:
• Attention Deficit Hyperactivity Disorder (ADHD)

Usual dose range:
• ADHD – children and adolescents up to 70 kg  0.5-1.2 mg/kg/day
• ADHD – children and adolescents over 70 kg and adults 40-80 mg/day

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:

Children and adolescents
• FDA indicated diagnosis
• 6 years of age or older
• Failure to respond (or intolerance) to each of the following
  ▪ A formulary methylphenidate product
  ▪ A formulary amphetamine product
  ▪ Guanfacine extended-release

OR
• Diagnosis of drug abuse or dependence

Renewal Criteria
• Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
• Documentation of effectiveness of therapy

Contraindications:
• Hypersensitivity to atomoxetine or other constituents of product.
• Use within 2 weeks after discontinuing MAOI or other drugs that affect brain monoamine concentrations
• Narrow angle glaucoma
• Pheochromocytoma or history of pheochromocytoma
• Severe cardiovascular disorders that might deteriorate with clinically important increases in HR and BP

Not approved if:
• Patient has a contraindication to treatment (see Contraindications)
• Patient has severe liver injury

**Black box warning:**
• Increased risk of suicidal ideation in children or adolescents. Patients started on therapy should be monitored closely.

**Additional considerations:**
• Dosing adjustment are required in patients with hepatic impairment, concurrently taking a strong CYP2D6 inhibitor, and in patients known to be CYP2D6 poor metabolizers
• Patients with known heart disease or hypertension should avoid use
• Patients with decreased appetites, or decreased growth rates should use with caution
• Adult patients with BPH should use with caution
• May be dosed as a single daily dose (in the morning) or as 2 divided doses (in the morning and late afternoon/early evening)
• Maximum daily dose
  o Children and adolescents up to 70 kg – 1.4 mg/kg/day
  o Children and adolescents over to 70 kg and adults – 100 mg/day

**Approval time frames:**
• Initial – 1 year with MDL of 2/day (based on dosing)
• Renewal – 1 year with MDL of 2/day (based on dosing)

**References:**
1. Strattera Prescribing Information (May 2015). Lilly USA, LLC Indianapolis, IN.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016
Prior Authorization Approval Criteria
Sutent (sunitinib)

Generic name: sunitinib
Brand name: Sutent
Medication class: Antineoplastic agent; tyrosine kinase inhibitor

FDA-approved uses:
• Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
• Advanced renal cell carcinoma (RCC)
• Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

Usual dose range:
• Gastrointestinal stromal tumor- adult
  50 mg daily for 4 weeks, followed by 2 weeks off (repeat every 6 weeks)
• Advanced renal cell carcinoma- adult
  50 mg daily for 4 weeks, followed by 2 weeks off (repeat every 6 weeks)
• Advanced neuroendocrine tumor, pancreatic- adult
  37.5 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Gastrointestinal Stromal Tumor (GIST):
Adults
• FDA indicated diagnosis confirmed via imaging or biopsy
• 18 years of age or older
• Prescribed by an oncologist
• Confirmation of ECHO for baseline LVEF > 50% in the past 3 months
• Failure (or contraindication) to Gleevec (imatinib) [PA may be required]

Advanced Renal Cell Carcinoma (RCC):
Adults
• FDA indicated diagnosis confirmed via biopsy
• 18 years of age or older
• Prescribed by an oncologist
• Confirmation of ECHO for baseline LVEF > 50% in the past 3 months
• Failure to respond (or contraindication) to Nexavar (sorafenib) [PA required]
Advanced Pancreatic Neuroendocrine Tumor (pNET):

Adults
- FDA indicated diagnosis confirmed via imaging
- 18 years of age or older
- Prescribed by an oncologist
- Confirmation of ECHO for baseline LVEF > 50% in the past 3 months

Renewal Criteria
- Documentation of effectiveness of therapy
- Confirmation of LVEF > 50% and/or LVEF has not decreased significantly (>20%) from baseline
- Imaging confirms no evidence of disease progression

Contraindications:
- Hypersensitivity to any component of sunitinib
- Patient has recent ECHO revealing an LVEF < 40% OR a diagnosis of congestive heart failure (CHF).

Not approved if:
- If any of the above contraindications are present

Black box warning:
- Hepatotoxicity has been observed in clinical trials and post-marketing experience. This hepatotoxicity may be severe, and deaths have been reported.

Additional considerations:
- CHF is a rare, but serious adverse event that has been observed in clinical trials. It would be advised to consider routine ECHOs in patients that are at risk for heart failure.
- A dose reduction should be considered in patients with a LVEF <50%
- Dose adjustments should be made in 12.5 mg increments
- Available in 12.5 mg, 25 mg, and 50 mg capsules
- Maximum daily dose is 50 mg/day (pNET)

Approval time frames:
- Initial – 6 months with MDL of 1/day
- Renewal – 6 months with MDL of 1/day
References:

Prior Authorization Approval Criteria
Tarceva (erlotinib)

Generic name: erlotinib
Brand name: Tarceva
Medication class: Antineoplastic Agent, Tyrosine Kinase Inhibitor

FDA-approved uses:
- Non-small cell lung cancer (NSCLC)
  - First-line therapy for metastatic tumors with epidermal growth factor receptor (EGFR) mutations
  - Second or Third-line therapy for locally advanced or metastatic cancer after failure of at least two prior chemotherapy regimens.
  - Maintenance treatment for locally advanced or metastatic cancer with no disease progression after four cycles of platinum-based therapy
- Pancreatic Cancer (PC)
  - First line treatment for locally advanced, unresectable, or metastatic cancer

Usual dose range:
- NSCLC - adult 150 mg PO daily
- PC – adult 100 mg PO daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
NSCLC:

First-Line treatment
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by an oncologist
- Clinically documented locally advanced or metastatic cancer
- EGFR(+) mutation
  - Exon 19 deletions or L858R mutation on exon 21
Second or Third-Line treatment
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by an oncologist
- Clinically documented locally advanced or metastatic cancer
  - Failure (or intolerance) to an adequate trial of at least one combination of the following chemotherapy regimen:
    - Platinum-based doublet regimen (+/- bevacizumab) as follows:
      - Cisplatin or carboplatin + one of the following:
        - Gemcitabine, pemetrexed, paclitaxel, docetaxel, vinorelbine or vinblastine
        [PA may be required]

Maintenance treatment
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by an oncologist
- Clinically documented locally advanced or metastatic cancer
- Already received adequate trial (4-6 cycles depending on which chemo regimen is initiated) of first-line platinum-based chemotherapy regimen
  - Documentation that disease has not progressed

PC:
Adults
- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by an oncologist
- Clinically documented locally advanced, unresectable or metastatic cancer
- Confirmation that medication is being used in combination with gemcitabine

Renewal Criteria
- Documentation that disease progression has not occurred during therapy
  - Confirmed by PET-CT scan

Contraindications:
- Hypersensitivity to erlotinib

Not approved if:
- Any of the contraindications listed above are present
Additional considerations:

- Tissue histology must be determined before prescribing
- Caution in use of both CYP3A4 inducers/inhibitors and CYP1A inhibitors
- Monitor hepatic and renal function
- Maximum daily dose is:
  - NSCLC: 150 mg/day
  - PC: 100 mg/day

Approval time frames:

- Initial – 6 months with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

References:

Prior Authorization Approval Criteria

Tecfidera (dimethyl fumerate)

Generic name: dimethyl fumerate
Brand name: Tecfidera
Medication class: immunomodulator

FDA-approved uses:
- Relapsing forms of multiple sclerosis (MS)

Usual dose range:
- Relapsing forms of multiple sclerosis – adults 240 mg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Relapsing forms of multiple sclerosis:

Adults
- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (6 months) of one of the following:
  - Copaxone (glatiramer acetate)
  OR
  - An interferon product:
    - Avonex (IFN Beta-1a)
    - Rebif (IFN Beta-1a)
    - Betaseron (IFN Beta-1b)
- Failure to respond (or intolerance) to an adequate trial (6 months) of Gilenya (fingolimod)- PA required

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- None

Not approved if:
- Combined with Copaxone, Aubagio, Gilenya, Tysabri, Rituxan or an interferon product
Additional considerations:

- Tecfidera has not been studied in patients with low lymphocyte counts
- Recommended titration schedule is 120 mg twice daily for 7 days, then 240 mg twice daily
  - Slower titration may reduce the incidence of flushing

Approval time frames:

- Initial – 6 months with MDL 2/day
- Renewal – 1 year with MDL 2/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 11/11/14
Revision: November 2015
Prior Authorization Approval Criteria

Tracleer (bosentan)

**Generic name:** bosentan  
**Brand name:** Tracleer  
**Medication class:** Endothelin receptor antagonist

**FDA-approved uses:**  
- Pulmonary arterial hypertension

**Usual dose range:**  
- Pulmonary arterial hypertension – adult  
  Up to 125 mg BID

**Criteria for use:** (bullet points are all inclusive unless otherwise noted)

**Initiation Criteria**  
**Pulmonary arterial hypertension (PAH):**  
**Adults**  
- FDA indicated diagnosis  
- 18 years of age or older  
- Prescribed or recommended by a pulmonologist  
- Confirmed World Health Organization (WHO) Group I PAH diagnosis  
- Confirmed New York Heart Association (NYHA) functional Class II, III or IV symptoms  
- Failure to respond (or contraindication) to a calcium channel blocker (required only if there is a positive response to acute vasoreactivity testing)  
- If NYHA Class II or III, then failure to respond (or contraindication) to each of the following:  
  - Revatio (PA required)  
  - Adcirca (PA required)  
- If NYHA Class IV, then failure to respond (or contraindication) to epoprostenol (PA required)

**Renewal Criteria**  
- Must have documentation of adherence to therapy (>75% adherence)  
- Documentation of effectiveness of therapy

**Contraindications:**  
- Pregnancy  
- Concomitant use with cyclosporine A or glyburide

**Not approved if:**  
- Patient exhibits only NYHA Class I symptoms
Black box warning:

- Risks of hepatotoxicity and teratogenicity. Elevations of ALT and AST and liver failure have been reported. Measure ALT and AST prior to initiation of treatment and then monthly. Discontinue if ALT and AST elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin ≥ 2 x ULN. Likely to cause major birth defects if used during pregnancy. Must exclude pregnancy before and during treatment. Females of childbearing potential must use two reliable forms of contraception during treatment and for one month after stopping medication. This medication available only through a restricted distribution program called the Tracleer Access Program (T.A.P.)

Additional considerations:

- World Health Organization (WHO) Group I PAH diagnosis can be confirmed by the following:
  - Mean pulmonary arterial pressure > 25 mmHg at rest or 30 mmHg during exercise
  - Normal pulmonary capillary wedge pressure
- NYHA functional classes are determined by the following:
  - Class I: No symptoms with ordinary physical activity.
  - Class III: Symptoms with less than ordinary activity. Marked limitation of activity. Comfortable at rest.
  - Class IV: Symptoms with any activity or even at rest.
- Maximum daily dose is 250 mg/day

Approval time frames:

- Initial – 1 year with MDL of 2/day
- Renewal – 1 year with MDL of 2/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/26/2014
Revision: June 2015, June 2016
Prior Authorization Approval Criteria
Ventavis (iloprost)

Generic name: iloprost
Brand name: Ventavis
Medication class: Prostacyclin

FDA-approved uses:
- Pulmonary arterial hypertension

Usual dose range:
- Pulmonary arterial hypertension – adult
  - Inhale 2.5 mcg via AAD nebulizer; if tolerated inhale 5 mcg via nebulizer 6 – 9 times daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Pulmonary arterial hypertension (PAH):
  Adults
  - FDA indicated diagnosis
  - 18 years of age or older
  - Prescribed or recommended by a pulmonologist
  - Confirmed World Health Organization (WHO) Group I PAH diagnosis
  - Confirmed New York Heart Association (NYHA) functional Class II, III or IV symptoms
  - Failure to respond (or contraindication) to a calcium channel blocker (required only if there is a positive response to acute vasoreactivity testing)
  - If NYHA Class II or III, then failure to respond (or contraindication) to each of the following:
    o Revatio (PA required)
    o Adcirca (PA required)
    o Letairis (PA required)
    o Tracleer (PA required)
  - If NYHA Class IV, then failure to respond (or contraindication) to epoprostenol (PA required)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence)
- Documentation of effectiveness of therapy

Contraindications:
- None established
Not approved if:

- Patient exhibits only NYHA Class I or II symptoms

Additional considerations:

- World Health Organization (WHO) Group I PAH diagnosis can be confirmed by the following:
  - Mean pulmonary arterial pressure > 25 mmHg at rest or 30 mmHg during exercise
  - Normal pulmonary capillary wedge pressure
- NYHA functional classes are determined by the following:
  - Class I: No symptoms with ordinary physical activity.
  - Class III: Symptoms with less than ordinary activity. Marked limitation of activity. Comfortable at rest.
  - Class IV: Symptoms with any activity or even at rest.
- Avoid coadministration of other inhaled medications simultaneously with Ventavis
- Exacerbation of hypotension has been reported; give 2.5 mcg dose initially to evaluate response
- Inhalation via Prodose® AAD® System or I-neb® AAD® System
- Do not administer in patients with a systolic blood pressure of < 85
- Maximum daily dose is 45 mcg/day

Approval time frames:

- Initial
  - 10 mcg/ml vials: 1 year with MDL of 4.5 ml/day
  - 20 mcg/ml vials: 1 year with MDL of 2.25 ml/day
- Renewal
  - 10 mcg/ml vials: 1 year with MDL of 4.5 ml/day
  - 20 mcg/ml vials: 1 year with MDL of 2.25 ml/day

References:

Prior Authorization Approval Criteria
Vfend (voriconazole)

**Generic name:** voriconazole
**Brand name:** Vfend
**Medication class:** Antifungal; Triazole

**FDA-approved uses:**
- Invasive aspergillosis
- Pulmonary aspergillosis*
- Candidemia (nonneutropenic patient)
- Candidiasis of the esophagus
- Disseminated candidiasis
- Mycosis, serious infection with *Scedosporium apiospermum* and *Fusarium* species

*clinically recognized indication, but not FDA approved

**Usual dose range:**

**Adult/Agedolent**
- Invasive Aspergillosis  Initial/Maintenance: 200 mg every 12 hours.
- Pulmonary Aspergillosis  Initial/Maintenance: 200 mg every 12 hours.
- Candidemia (nonneutropenic patient)  Initial: 400 mg every 12 hours for 2 doses. Maintenance: 200 mg every 12 hours for 2 weeks after clearance of candidemia from blood and resolution of symptoms)
- Candidiasis of the esophagus  Initial/Maintenance: 200 mg every 12 hours (minimum of 14 days and until 7 days after resolution of symptoms).
- Disseminated candidiasis  Initial/ Maintenance: 200 mg every 12 hours (minimum of 14 days following last positive culture).
- Mycosis, Serious infection with *Scedosporium apiospermum/Fusarium* spp.  Initial/Maintenance: 200 mg every 12 hours.

**Dose Modification**
- Patients < 40 kg: DECREASE maintenance dose to 100 mg every 12 hours.
- Poor response to initial therapy:
  - Patient > 40 kg: INCREASE maintenance dose to 300 mg every 12 hours.
  - Patient < 40 kg: INCREASE maintenance dose to 150 mg every 12 hours.
Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Invasive Aspergillosis:
- FDA indicated diagnosis
- 12 years of age and older

Pulmonary Aspergillosis:
- FDA indicated diagnosis
- 12 years of age and older
- Patient is severely immunocompromised, documented with having a hematopoietic stem cell transplant (HSCT), hematologic malignancy (leukemia, lymphoma, and multiple myeloma), HIV/AIDS diagnosis, or a high-risk solid organ transplant (heart, lung, liver, pancreas, or small bowel).

-OR-
- Failure to respond (or contraindication) to an adequate trial (600 mg daily for 3 days followed by 400 mg daily for a minimum of 4 days) of itraconazole [PA required]

Candidemia (nonneutropenic patient)/Disseminated Candidiasis:
- FDA indicated diagnosis
- 12 years of age and older
- Failure to respond (or contraindication) to an adequate trial (400 mg daily for 7 days) of fluconazole

Candidiasis of the Esophagus
- FDA indicated diagnosis
- 12 years of age and older
- Failure to respond (or contraindication) to an adequate trial of each of the following:
  - Fluconazole (200-400 mg daily for 7 days)
  - Itraconazole (200 mg daily for 7 days) [PA required]

Mycosis, serious infection with Scedosporium apiospermum and Fusarium species:
- FDA indicated diagnosis
- 12 years of age and older

Renewal Criteria
- The patient does not have any FDA labeled contraindications that may have arisen since the initial approval
- Documentation of improved disease state, but still has indicators of active disease (positive cultures, positive radiologic imaging, or positive serum assay) since initial approval
Contraindications:
- Known hypersensitivity to voriconazole or its excipients.
- Coadministration with CYP3A4 substrates: terfenadine, astemizole, cisapride, pimozide or quinidine increases plasma concentrations of these drugs and can lead to QT prolongation and rare occurrences of torsade de pointe.
- Coadministration with sirolimus significantly increases sirolimus concentration.
- Coadministration with rifampin, carbamazepine and long-acting barbiturates likely decrease plasma voriconazole concentrations significantly.
- Coadministration with rifabutin due to significant increases in rifabutin plasma concentrations and significant decreases in voriconazole plasma concentration.
- Coadministration with ergot alkaloids (ergotamine and dihydroergotamine) may increase the plasma concentration of ergot alkaloids, which may lead to ergotism.

Not approved if:
- Any of the above contraindications are present

Additional considerations:
- Pregnancy category D (Women of child bearing age should use effective contraception during treatment). Should not use with an existing known pregnancy.
- Dose adjustments/monitoring are warranted with:
  - Hepatic cirrhosis: mild to moderate (Child-Pugh Class A and B). Use same loading dose, use half the maintenance dose.
  - Inadequate response
  - Concomitant efavirenz use
  - Concomitant phenytoin use

Approval time frames:

**Invasive Aspergillosis/Pulmonary Aspergillosis**
- Initial -3 month(s) with MDL of 600 mg/day
- Renewal -3 month(s) with MDL of 600 mg/day
*Duration of therapy suggested by guidelines is 6-12 weeks for Aspergillosis*

**Candidemia/Disseminated Candidiasis**
- Initial -3 month(s) with MDL of 400 mg/day
- Renewal -3 month(s) with MDL 400 mg/day
*Duration of therapy suggested by guidelines is 2 weeks after resolution of symptoms*

**Candidiasis of the Esophagus**
- Initial -21 days with MDL of 400 mg/day
- Renewal -21 days with MDL of 400 mg/day
*Duration of therapy suggested by guidelines is 14-21 days*

**Mycosis, serious infection with Scedosporium apiospermum and Fusarium species:**
- Initial -3 month(s) with MDL of 400 mg/day
- Renewal -3 month(s) with MDL of 400 mg/day
References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/03/2014
Revision: June 2015, June 2016
Prior Authorization Approval Criteria
Viibryd (vilazodone)

Generic name: vilazodone
Brand name: Viibryd
Medication class: antidepressant

FDA-approved uses:
• Major Depressive Disorder (MDD)

Usual dose range:
• Major Depressive Disorder – adults 20-40 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
Major Depressive Disorder:
Adults
• FDA indicated diagnosis
• 18 years of age or older
• Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
  o Separate monotherapy trials of two different formulary Selective Serotonin Reuptake Inhibitors (SSRIs)
  o An additional formulary antidepressant agent (bupropion, mirtazapine, a tricyclic antidepressant, a Serotonin Norepinephrine Reuptake Inhibitor [SNRI], or a third SSRI)

Renewal Criteria
Major Depressive Disorder:
• Must have documentation of adherence to therapy (>75% adherence)
• Documentation of effectiveness of therapy

Contraindications:
• Concomitant use in patients taking MAOIs

Not approved if:
• Patient is currently using MAOIs
• Patient currently taking another SSRI/SNRI with no plan to discontinue therapy
**Black box warning:**
- Children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

**Additional considerations:**
- A gradual reduction in dose rather than abrupt cessation is recommended whenever possible
- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- Prescribe with care in patients with a history of seizure
- Maximum daily dose – 40 mg/day
- Take with food

**Approval time frames:**
- Initial – 1 year with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

**References:**
- Viibryd Prescribing Information (March 2015). Forest Pharmaceuticals, St. Louise, MO.
Prior Authorization Approval Criteria

Vyvanse (lisdexamfetamine dimesylate)

Generic name: lisdexamfetamine dimesylate
Brand name: Vyvanse
Medication class: CNS stimulant

FDA-approved uses:
- Attention Deficit Hyperactivity Disorder (ADHD) in children and adults
- Moderate to Severe Binge Eating Disorder (BED)

Usual dose range:
- ADHD – children, adolescents and adults 30-70 mg once daily
- Binge Eating Disorder 50-70 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria
ADHD:

Children and adolescents
- FDA indicated diagnosis
- 6 years of age or older
- Failure to respond (or intolerance) to each of the following
  ▪ A formulary methylphenidate product
  ▪ A formulary amphetamine product

Binge Eating Disorder:

Adults
- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to each of the following
  ▪ Two formulary SSRIs
  ▪ Topiramate
  ▪ Atomoxetine (PA required)

Renewal Criteria
- Must have documentation of adherence to therapy (>75% adherence or >75% of the school year)
- Documentation of effectiveness of therapy
Contraindications:

- Hypersensitivity to amphetamines or other constituents of product. Anaphylactic reactions, Stevens - Johnson syndrome, angioedema, and urticaria have been observed in postmarketing reports.
- Use within 2 weeks after discontinuing MAO inhibitor, hypertensive crisis can occur.
- Advanced arteriosclerosis, symptomatic cardiovascular disease, and moderate to severe hypertension.
- Hyperthyroidism
- Patients with marked anxiety, tension, or agitation
- Patients with a diagnosis of glaucoma

Not approved if:

- Patient has a contraindication to treatment (see Contraindications)
- Patient has a history of drug dependence or alcoholism

Black box warning:

- Should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Additional considerations:

- Serious cardiovascular events have been reported with stimulant products. Stimulants should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems.
- Maximum daily dose is 70 mg/day

Approval time frames:

- Initial – 1 year with MDL of 1/day
- Renewal – 1 year with MDL of 1/day

References:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016
Prior Authorization Approval Criteria

Zyprexa Relprevv
(olanzapine pamoate extended release injection)

Generic name: olanzapine pamoate extended release injection
Brand name: Zyprexa Relprevv
Medication class: Antipsychotic

FDA-approved uses:
• Treatment of schizophrenia

Usual dose range:
• Schizophrenia – adult
  o Dose is based on correspondence to oral olanzapine dose
  o Initial dose 210 mg or 300 mg every 2 weeks or 405 mg every 4 weeks
  o Maintenance 150 mg, 210 mg or 300 mg every 2 weeks or 300 mg or 405 mg every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation criteria

Schizophrenia:
 Adults
  • FDA indicated diagnosis
  • 18 years of age or older
  • Documented tolerance to oral olanzapine
  • Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
  • Either one of the following:
    ▪ Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of each of the following:
      • Risperidone extended release IM (Risperdal Consta)
      • Haloperidol decanoate or fluphenazine decanoate
    OR
    ▪ Documented stabilization on oral olanzapine (trial of 4-6 weeks)

Renewal criteria

Schizophrenia:
• Must have documentation of adherence to therapy (>75% compliance)
• Documentation of effectiveness of therapy
• Documentation of continued need for long-acting injection (including a review of adherence with other oral medications)

**Contraindications:**

Known hypersensitivity to olanzapine or to any components in the formulation

**Not approved if:**

• Past history of dementia-related psychosis
• Combining with another antipsychotic unless patient has tried maximum tolerated doses of all of the following as monotherapy:
  - Clozapine
  - Two other antipsychotics

**Black box warning:**

• Patients are at risk for severe sedation (including coma) and/or delirium after each injection and must be observed for at least 3 hours in a registered facility with ready access to emergency response services.
• Because of this risk, Zyprexa Relprevv is available only through a restricted distribution program called Zyprexa Relprevv Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment
• Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo

**Additional considerations:**

• Medication can only be administered in a registered healthcare facility with ready access to emergency response services, and the patient will be monitored for at least 3 hours after injection for delirium/sedation syndrome prior to release
• Establish tolerability with oral olanzapine prior to initiating treatment
• Plasma concentrations remain in the therapeutic effective range and oral supplementation is generally not necessary
• Maximum dose is 405mg every 4 weeks or 300mg every 2 weeks

**Approval time frames:**

• Initial
  - 6 months with the following quantity limits:
    - 2 vials/month for 150 mg, 210 mg, or 300 mg injection
    - 1 vial/month for 405 mg injection

• Renewal
  - 1 year with the following quantity limits:
    - 2 vials/month for 150 mg, 210 mg, or 300 mg injection
    - 1 vial/month for 405 mg injection
References:

- Zyprexa Relprev Prescribing Information (September 2015). Lilly USA, LLC. Indianapolis, IN.