Prior Authorization Approval Criteria

Effective Date: 10/01/2017

This document contains Prior Authorization Approval Criteria for the following medications:

1. Abilify Maintena (aripiprazole long-acting injectable)
2. Ampyra (dalfampridine)
3. Aubagio (teriflunomide)
4. Copaxone 40 mg (glatiramer)
5. Daytrana (methylphenidate extended release transdermal system)
6. Fanapt (iloperidone)
7. Focalin (dexamethylphenidate)
8. Focalin XR (dexamethylphenidate extended release)
9. Gilenya (fingolimod)
10. Hepatitis C Virus (HCV) Medications (Epclusa, Harvoni, Zepatier)
11. Invega (paliperidone)
12. Invega Sustenna (paliperidone palmitate)
13. Kapvay (clonidine extended release)
14. Latuda (lurasidone)
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17. Rozerem (ramelteon)
18. Saphris (asenapine)
19. Sensipar (cinalcacet)
20. Silenor (doxepin)
21. Somatropin
22. Sonata (zaleplon)
23. Strattera (atomoxetine)
24. Tecfidera (dimethyl fumarate)
25. Viibryd (vilazodone)
26. Zyprexa Relprevv (olanzapine pamoate extended release injection)
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 Risperdal Consta (Step Therapy required: trial of oral risperidone)
  - Documented stabilization on oral aripiprazole (trial of 4-6 weeks), evidenced by previous prior authorization approval by the plan or confirmed coverage by the previous plan (e.g. pharmacy has been filling through the previous plan)

Renewal criteria
- 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

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
Approval time frames:

- Initial – 3 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, November 2016
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 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, November 2016
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
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:

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016, July 2017
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:
  - 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**
- 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 (2016). Novartis Pharmaceuticals Corporation East Hanover, NJ.
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:**

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:
- Adults and children
  - 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 dexamethasphenidate 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
  - Children – 30 mg/day
  - Adults – 40 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, July 2017
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

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; Baseline QTc interval ≥450 msec in males and >470 msec in females should not be dosed in a 6 hour observation and should be referred back to neurologist to arrange 24 hour continuous monitoring
- 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:**

Prior Authorization Approval Criteria

Hepatitis C Virus (HCV) Medications

Preferred formulary agents: Epclusa, Harvoni, Zepatier

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

Initiation Criteria (PLEASE CHECK BOX or write N/A to confirm that point has been addressed)

- If requesting completion of therapy, then skip to “Renewal Criteria” section below
- Hepatitis C virus (HCV) infection with confirmation of one of the following:
  - HCV RNA level < 6 million copies
  - HCV RNA level > 6 million copies
- 18 years of age or older (12 years of age or older for Harvoni)
- Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist or HIV specialist
- Confirmation that prescriber and patient understand that patients who terminated previous HCV treatment with a direct-acting antiviral (DAA) medication due to nonmedical reasons will not be considered for retreatment
- Confirmation of one of the following:
  - Treatment-naïve
  - Treatment-experienced with one of the following:
    - Peginterferon (PEG-IFN)/ribavirin
    - DAA with or without PEG-IFN/ribavirin (please specify DAA drug name)
    
    Note: DAA-experienced patients will be evaluated on a case-by-case basis only (see “additional considerations” section below)
- Confirmation of one of the following:
  - No evidence of cirrhosis
  - Compensated cirrhosis
- Confirmation of one of the following:
  - HIV positive
  - HIV negative
- Confirmation of one of the following:
  - Patient is Black or African American
  - Patient is not Black or African American
- Confirmation that the patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Confirmation of one of the following:
  - No alcohol or drug use
  - If alcohol or drug use, then documentation that patient is receiving or enrolled in counseling or substance abuse treatment program for at least a month prior to initiating treatment
- Confirmation that patient is willing to adhere to treatment requirements
- Confirmation of genotype obtained within the last year (please select genotype below and complete the additional criteria)
Genotype 1 (a or b)
- If all of the following are confirmed, then Harvoni for 8 weeks is preferred
  - HCV RNA level < 6 million copies
  - Treatment-naïve
  - No evidence of cirrhosis
  - HIV negative
  - Not Black or African American
- If any of the above are not confirmed, then proceed to the appropriate Genotype 1 subtype section below

Genotype 1a
- Documentation of lab confirming presence or absence of NS5A resistance-associated substitutions (RAS)
  - If NS5A RAS present, then Harvoni for 12 weeks is preferred
    (Note: If treatment-experienced, then addition of ribavirin is required)
  - If NS5A RAS absent, then Zepatier for 12 weeks is preferred

Genotype 1b
- Zepatier for 12 weeks is preferred

Genotype 2
- Epclusa for 12 weeks is preferred

Genotype 3
- Treatment-naïve
  - Without cirrhosis
    - Epclusa for 12 weeks is preferred
  - With compensated cirrhosis, then RAS testing for Y93 is required
    - If RAS absent, then Epclusa for 12 weeks is preferred
    - If RAS present, then Epclusa plus ribavirin for 12 weeks is preferred
- Treatment-experienced
  - Without cirrhosis, then RAV testing for Y93H is required
    - If RAS absent, then Epclusa for 12 weeks is preferred
    - If RAS present, then Epclusa plus ribavirin for 12 weeks is preferred
  - With compensated cirrhosis
    - Epclusa plus ribavirin for 12 weeks is preferred

Genotype 4
- Zepatier for 12 weeks is preferred
  - If treatment-experienced where patient had on-treatment virologic failure (failure to suppress or breakthrough), then Technivie plus ribavirin for 12 weeks is recommended

Genotype 5 or 6
- Harvoni for 12 weeks is preferred
Renewal Criteria

- Must have documentation of adherence to therapy confirmed by patient receiving refills within one week of completing previous fill
- Documentation of HCV RNA level at week 4
  - If undetectable, then the remainder of the treatment course will be approved
  - If detectable (>25 copies), then HCV RNA will be reassessed in 2 weeks
    - If HCV RNA has increased > 1 log from nadir, then therapy will be discontinued

Contraindications:
- Ribavirin is contraindicated in pregnancy and men whose female partners are pregnant

Not approved if:
- Less than 12 months since the last attempt of HCV treatment
- Evidence of medication non-adherence to treatment of concurrent medical diseases (e.g. poorly controlled DM, severe HTN, heart failure, significant CAD, COPD, thyroid disease)
- Concurrent psychiatric illness without strong primary care physician and psychiatric support
- Known hypersensitivity to drugs used to treat HCV

Additional considerations:
- Preferred HCV medications may not be required when there are confirmed major drug-drug interactions that prevent their use and changing current medications is not appropriate
- Some preferred HCV medication regimens may require concomitant ribavirin
  - If contraindication to ribavirin is documented, then the preferred HCV medication regimen will not be required for use and other appropriate treatment regimens will be considered
- Treatment-experienced patients with previous failure of a DAA (i.e. Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Techniev, Viekira Pak, Viekira XR, Zepatier) will be considered on a case-by-case basis and must be in accordance with the AASLD/IDSA HCV guidelines
- Treatment of patients with decompensated cirrhosis will be considered on a case-by-case basis and must be in accordance with the AASLD/IDSA HCV guidelines
- Maximum daily limit (MDL) of all formulary HCV medications is 1 tablet per day
Approval time frames:

- Initial approval for all formulary HCV medications
  - 8 weeks with MDL of 1/day

- Renewal for all formulary HCV medications (if necessary)
  - 4 additional weeks with MDL of 1/day
  - Total course of 12 weeks

References:

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

Renewal criteria
- 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:**


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 06/28/2013
Revision: 06/28/2014, June 2015, June 2016, June 2017
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/Schizoaffective disorder:
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 Risperdal Consta (Step Therapy required: trial of oral risperidone)
  - Documented stabilization on oral paliperidone (trial of 4-6 weeks), evidenced by previous prior authorization approval by the plan or confirmed coverage by the previous plan (e.g. pharmacy has been filling through the previous plan)

Renewal criteria
- 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
Revision: 06/28/2014, June 2015, June 2016, June 2017
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 guanfacine extended-release
• Failure to respond (or intolerance) to each of the following
  ▪ A formulary methylphenidate product
  ▪ A formulary amphetamine product
  -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>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mg/day</td>
<td>0.1 mg</td>
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<tr>
<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>
<td>0.2 mg</td>
<td>0.2 mg</td>
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</tbody>
</table>

- 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:

Prior Authorization Approval Criteria
Latuda (lurasidone)

Generic name: lurasidone
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 – adolescents and 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:
  - Adolescents and adults
  - FDA indicated diagnosis
  - 13 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:
    - Lithium
    - Lamotrigine
    - Quetiapine immediate release
    - Concurrent trials of olanzapine and 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:
  - 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 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:**
on the long-term treatment of schizophrenia and management of antipsychotic-induced side effects. World J Biol Psychiatry 2013; 14: 2-44.


Prior Authorization Approval Criteria
Lyrica (Pregabalin)

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

FDA-approved uses:
- Neuropathic pain associated with diabetic peripheral neuropathy
- Postherpetic neuralgia
- Adjunct therapy for partial onset seizures
- Fibromyalgia
- 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:
  o Gabapentin
  o One formulary tricyclic antidepressant (TCA)*
  o 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: December 2016
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
• 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
Revision: 07/10/2014, July 2015, July 2016, July 2017
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
      - 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 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:

<p>Prior Authorization Approval Criteria</p><p>Saphris (asenapine)</p><p><strong>Generic name:</strong> Saphris</p><p><strong>Brand name:</strong> asenapine</p><p><strong>Medication class:</strong> antipsychotic</p><p><strong>FDA-approved uses:</strong></p><ul><li>Treatment of schizophrenia</li><li>Acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy or adjunctive treatment to lithium or valproate</li></ul><p><strong>Usual dose range:</strong></p><ul><li>Schizophrenia – adults 5-10 mg twice a day sublingually</li><li>Bipolar Mania – adults 5-10 mg twice a day sublingually</li><li>Bipolar Mania – pediatric patients (10-17 years) 2.5-10 mg twice a day sublingually</li></ul><p><strong>Criteria for use:</strong> (bullet points are all inclusive unless otherwise noted)</p><p><strong>Initiation criteria</strong></p><p><strong>Schizophrenia:</strong></p><p><strong>Adults</strong></p><ul><li>FDA indicated diagnosis</li><li>18 years of age or older</li><li>Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotics agents</li><li>OR</li><li>Patient requires orally disintegrating formulation</li><li>Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:</li><li> • Risperidone ODT</li><li> • Olanzapine ODT</li></ul><p><strong>Bipolar I Disorder:</strong></p><p><strong>Pediatrics and Adults</strong></p><ul><li>FDA indicated diagnosis</li><li>10 years of age or older</li><li>Failure to respond (or intolerance) to an adequate trial (at least 30 days with adequate blood levels) of each of the following:</li><li> • Lithium OR valproic acid</li><li> • Two formulary antipsychotic agents</li><li>OR</li><li>Patient requires orally disintegrating formulation</li><li>Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:</li><li> • Risperidone ODT</li><li> • Olanzapine ODT</li></ul>
Renewal criteria

- 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:**


Prior Authorization Approval Criteria
Sensipar (cinalcacet)

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

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

Usual dose range:
- Primary hyperparathyroidism/Parathyroid carcinoma:
  - Up to 90 mg four times daily
- Secondary hyperparathyroidism:
  - Up to 180 mg once daily

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
- 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 have decrease from baseline or remained stable since previous request
  - iPTH has decreased from baseline or remained stable since previous request
**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 – 1 year with MDL of 4/day

**References:**
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
  - Therapy should be discontinued when:
    - Patient has reached satisfactory adult height
    - When the patient ceases to respond
  - 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
  - Therapy should be discontinued when:
    - When epiphyses have fused
    - When the patient ceases to respond
  - 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
  - Use may be appropriate if severe respiratory impairment is being treated
- 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.
- Caution when using in the presence of active malignancy.

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, November 2016
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:


Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/10/2013
Revision: 07/10/2014, July 2015, July 2016, July 2017
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 guanfacine extended-release
- Failure to respond (or intolerance) to both of the following
  - A formulary methylphenidate product
  - A formulary amphetamine product
-OR-
  - Diagnosis of drug abuse or dependence

Adults
- FDA indicated diagnosis
- 6 years of age or older
- Failure to respond (or intolerance) to both of the following
  - A formulary methylphenidate product
  - A formulary amphetamine product
-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
  - Children and adolescents up to 70 kg – 1.4 mg/kg/day
  - 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:**

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016, July 2017
Generic name: dimethyl fumarate
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 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:

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
• 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. Forest Pharmaceuticals, St. Louise, MO: 2017.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/10/2013
Revision: 07/10/2014, July 2015, July 2016, July 2017
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
  - Dose is based on correspondence to oral olanzapine dose
  - Initial dose 210 mg or 300 mg every 2 weeks or 405 mg every 4 weeks
  - 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 Risperdal Consta (Step Therapy required: trial of oral risperidone)
    OR
    ▪ Documented stabilization on oral olanzapine (trial of 4-6 weeks)

Renewal criteria
- 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 Relprevv Prescribing Information (2017). Lilly USA, LLC. Indianapolis, IN.
guideline for the treatment of patients with schizophrenia. Available at:
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-
• Lauriello J, Lambert T, Andersen S, Lin D, Taylor CC, McDonnell D. An 8-week, double-blind, randomized,
placebo-controlled study of olanzapine long-acting injection in acutely ill patients with schizophrenia. J Clin
• Kane JM, Detke HC, Naber D, Sethuraman G, Lin DY, Bergstrom RF et al. Olanzapine long-acting injection: a
24-week, randomized, double-blind trial of maintenance treatment in patients with schizophrenia. Am J