Prior Authorization Criteria Document for Presbyterian Centennial Care

General Information and Definitions:

- Inclusion of a drug on this list does not mean that it will be covered.
- Prior Authorization (PA) - You or your doctor must get permission or an OK from Presbyterian Centennial Care before you fill your drug. If you don’t get permission, Presbyterian Centennial Care may not pay for the drug. You or your doctor can ask for permission by fax, phone, email or regular mail.
- Step Edit – You must first try certain drugs to treat a health problem before a different drug will be covered for the same health problem. For example, if drug A and Drug B both treat your health problem, we may not cover Drug B unless you try Drug A first. If Drug A does not work for you, the plan may then cover Drug B.
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<td>Zyvox (linezolid)</td>
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</tbody>
</table>
• **Abilify Discmelt (aripiprazole orally disintegrating tablet)**

Indications for Approval:

1. The patient must be unable to swallow tablets and is not currently taking other oral non-dissolving tablets or capsules, or has a significant history of “cheeking” despite monitored supervision.

AND

2. Must be initiated by a certified behavioral health provider (e.g. psychiatrist, CNP with psychiatry certification).
   a. **Schizophrenia Spectrum Disorder** (including schizoaffective disorder or schizophreniform disorder)
      - The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) other formulary atypical antipsychotics. Medication trials that fail due to lack of efficacy must be attempted at a maximal approved dose for a minimum of 4 weeks if no response, and a minimum of 12 weeks if partial response.
      
      OR
      - The patient has a current diagnosis of Metabolic Syndrome, Pre-Metabolic Syndrome, or Diabetes Mellitus and has failed ziprasidone or there is clinical documentation why ziprasidone is not clinically appropriate.
   b. **Bipolar I Disorder**
      - The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) formulary alternatives which could include preferred atypical antipsychotics (olanzapine, quetiapine, risperidone, or ziprasidone) and/or another formulary mood stabilizing medication (e.g. lithium, divalproex, or lamotrigine).
   c. **Major Depressive Disorder**
      - Abilify must be used as adjunctive or add on treatment, not as monotherapy.
      
      AND
      - The patient must have a documented trial and failure of at least three (3) other formulary antidepressants at a maximum tolerated dose for a minimum of 4 weeks.
      
      OR
      The patient must have a documented trial and failure of at least two (2) antidepressants and one (1) adjunctive agent at maximum tolerated doses for a minimum of 4 weeks.
   d. **Autistic Disorder**
• The patient must have a documented intolerance, side effects, or lack of efficacy to risperidone, or documentation that risperidone is not clinically appropriate.

e. Tourette’s Syndrome
• The treatment of tics associated with Tourette’s syndrome.

f. All other off-label indications:
• Use of atypical antipsychotics must be supported by a medical compendium.
  AND
• The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) formulary atypical antipsychotics.

Quantity Limit: 30 tablets for 30 days.
Approval: One year.
Approved by the P&T Committee 07/17/2013. Updated 04/15/2015, 01/18/2017 and 07/19/2017.

• **Abilify Maintena (aripiprazole)**
  **Indications for Approval:**
  1. Diagnosis of schizophrenia:
   • All FDA Approved indications
   • Member must have a documented trial and failure of or medical reason for avoiding use of Aristada and Invega Sustenna or Invega Trinza

  2. Diagnosis of bipolar disorder

  Approval Length: one year

  Quantity Limit: 1 vial or syringe per 28 days

  Approved by the P&T Committee 07/17/2019

• **Aciphex (rabeprazole)**
  **Step Edit Criteria:**
  The patient must have a claim history of a 30-day trial of omeprazole or pantoprazole within the past 545 days.

  Quantity Limit: 60 tablets for 30 days.

  Alternatives: omeprazole capsules, pantoprazole tablets.

  Approved by the P&T Committee 01/20/2016. Updated 10/18/17.

• **Actemra (tocilizumab)**
  **Indications for Approval:**
  1. The patient must have a current PPD (tuberculosis) negative skin test, negative QuantiFERON-TB Gold test, or documented treatment for latent tuberculosis prior to initiation of therapy.
AND
2. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23, or Prevnar) prior to initiation of therapy.
   AND
3. The appropriate Disease Specific Criteria below has been met.
   a. Juvenile Idiopathic Arthritis
      i. The patient must have had an adequate trial (three months or more) of methotrexate at a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (three months or more) of one of the following other disease modifying anti-rheumatic drugs (DMARDs) is required:
         ▪ Leflunomide
         ▪ Hydroxychloroquine
         ▪ Sulfasalazine
         ▪ Minocycline
         ▪ Gold Salt
      ii. The patient must have a documented trial and failure of both Humira (adalimumab) and one other formulary TNF-inhibitor.
   b. Rheumatoid Arthritis (RA)
      i. Documented presence of moderate to severe RA defined as: DAS-28 > 3.2 or CDAI > 10.1.
      ii. The patient must have had an adequate trial (three months or more) of methotrexate at a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (three months or more) of one of the following other disease modifying anti-rheumatic drugs (DMARDs) is required:
         ▪ Leflunomide
         ▪ Hydroxychloroquine
         ▪ Sulfasalazine
         ▪ Minocycline
         ▪ Gold Salt
      iii. The patient must have a documented trial and failure of both and Humira (adalimumab) and one other formulary TNF-inhibitor.
   c. Giant Cell Arteritis (adult patients)
      i. Have developed, or are at high risk for, adverse effects of prednisone.
      ii. Have had an adequate trial of methotrexate or cyclophosphamide.
4. Medical records or a typed summary documenting all of the above must be submitted with the prior authorization request.

**Continuation of Therapy:**
Documentation of clinical benefit is required.
Initial Approval Length: Six (6) months.
Reauthorization: One (1) year.
Specialty Pharmacy required.

<table>
<thead>
<tr>
<th>Code: J3262</th>
<th>1mg = 1 billable unit</th>
</tr>
</thead>
</table>

Approved by the P&T Committee 07/16/2014. Updated 7/19/2017.

- **Actoplus Met (pioglitazone/metformin)**
  Step Edit Criteria:
  The patient must have previous use of at least one of the medications (pioglitazone or metformin) that make up the combination medication within the past 120 days.
  Alternatives: pioglitazone, metformin.
  Approved by the P&T Committee 09/17/2008.

- **Actos (pioglitazone)**
  Step Edit Criteria:
  The patient must have a 30-day prescription fill of metformin in the past 545 days.
  Quantity Limit: 30 tablets for 30 days.
  Alternative: metformin
  Approved by the P&T Committee 09/15/2010.

- **Aczone 5% (dapsone topical gel)**
  Indications for Approval:
  Acne Vulgaris – patient must have a documented treatment failure of all of the following:
  - Benzoyl peroxide
  - A 30-day supply of an oral antibiotic indicated for the treatment of acne vulgaris such as doxycycline or minocycline.
  - A topical retinoid such as tretinoin topical cream or gel.
  Approval: One year.
  Alternatives: benzoyl peroxide/clindamycin topical, benzoyl peroxide/erythromycin topical, doxycycline, minocycline, tetracycline, tretinoin topical.
  Approved by the P&T Committee 07/15/2009.

- **Adcetris (brentuximab)**
  Refer to the [Oncology](#) criteria located within this document.
• **Afinitor (everolimus)**
  Refer to the [Oncology criteria](#) located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Revised 05/16/2012 and 11/05/2015.

• **Afinitor Disperz (everolimus)**
  Refer to the [Oncology criteria](#) located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 07/17/2013.

• **Albenza (albendazole)**
  **Indications for Approval:**
  All of the following must be met:
  1. All formulary alternatives must be trialed for the requested indication.
  2. Dose must be within recommended dosing for the condition
  Approved by the P&T Committee 01/16/2019.

• **Alecensa (alectinib)**
  Refer to the [Oncology criteria](#) located within this document.
  Quantity limit: 240 capsules for 30 days.
  Approved by the P&T Committee 01/17/2018.

• **Alimta (pemetrexed)**
  Refer to the [Oncology criteria](#) located within this document.
  Code: J9305
  10mg = 1 billable unit
  Approved by the P&T Committee 07/20/2011. Revised 11/05/2015.

• **Aliqopa (copanlisib)**
  Refer to the [Oncology criteria](#) located within this document.
  Approved by the P&T Committee 10/18/2017.

• **Alphagan P (brimonidine ophthalmic)**
  Step Edit Criteria:
  The patient must have a prescription claim history for brimonidine tartrate 0.2% ophthalmic solution within the past 180 days.
  Approved by the P&T Committee 04/19/2017.

Alrex (loteprednol etabonate 0.2%)
Step Edit Criteria:
The member must have a claim history within the past 120 days of a formulary ophthalmic corticosteroid.
Alternatives: dexamethasone ophthalmic, fluorometholone ophthalmic, prednisolone acetate ophthalmic, prednisolone sodium phosphate ophthalmic.
Approved by the P&T Committee 3/24/2010.

- **Alunbrig (brigatinib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit:
  - 30 mg tablets: 60 tablets for 30 days
  - 90 mg and 180 mg tablets: 30 tablets for 30 days
  Approval Length: Six (6) months.
  References:
  Approved by the P&T Committee 07/19/2017. Updated 04/18/2018.

- **Ambien CR (zolpidem)**
  Indications for Approval:
  Insomnia - Patient must have a documented treatment failure of all of the following:
  - Zolpidem oral tablets
  - A formulary benzodiazepine used for the treatment of insomnia.
  - Trazodone
  Quantity Limit: 30 tablets per 30 days.
  Alternatives: lorazepam, temazepam, trazodone, triazolam, zolpidem.
  Approved by the P&T Committee 07/15/2009.

- **Amerge (naratriptan)**
  Refer to the Triptans, Preferred Criteria located within this document.
  Quantity Limit: 18 tablets for 30 days.

- **Amicar solution (aminocaproic acid)**
  Indications for Approval:
The following criteria apply to patients greater than 12 years of age:
  - The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.
  Length of Approval: One (1) year.
  Approved by the P&T Committee 10/17/2018.

- **Amitiza (lubiprostone)**
  Step Edit Criteria:
The patient must have a claim history of an osmotic laxative (PEG-3350 or lactulose) within the past 120 days.

Quantity Limit: 60 capsules for 30 days.
Approved by the P&T Committee 05/18/2011. Updated 07/15/2015, 10/17/2018.

- **Amnesteem (isotretinoin capsules)**
  Refer to the [Isotretinoin](#) criteria located within this document.
  Approved by the P&T Committee 10/19/2016. Updated: 10/17/2018, 10/16/2019.

- **Ampyra (dalfampridine)**
  **Indication for Approval:**
  The patient must have a documented diagnosis of Multiple Sclerosis **AND must have documentation of ALL of the following:**
  - Patient must not have a history of seizures.
  - Patient must currently require a walking assistance device (cane, walker, etc.) for every day ambulation.
  - Patient must have a CrCl greater than 50mL/min. Note: Ampyra is contraindicated in patients with moderate to severe renal impairment.
  - Patient must have a baseline Timed 25-foot walk (T25FW) between 8 – 46 seconds.
  **Criteria for Continuation of Therapy:**
  - Must demonstrate a 20% improvement in T25FW initially at 3 months and maintain the initial 20% improvement in the T25FW at each 6 month interval. Approval will be discontinued if the T25FW declines.

Length of Approval: 3 months initially then at 6 month intervals.
Quantity Limit: 60 tablets for 30 days.
Exceptions: Any other medical conditions or exceptions to the above criteria for coverage for Ampyra will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.
Approved by the P&T Committee 07/21/2010.

**References:**

- **Androderm (testosterone transdermal patch)**
  Refer to the [Testosterone Products, Non-Preferred](#) Criteria located within this document.
  Approval: 1 year.
Quantity limit:
  Androderm 2mg
    ▪ 60 patches for 30 days
  Androderm 4mg
    ▪ 30 patches for 30 days
Approved by the P&T Committee 09/19/2007.
Revised 01/21/2009, 05/18/2011, 01/18/2012, 07/17/2013 and 10/15/2014.

- **AndroGel (testosterone 1% topical gel)**
  Refer to the [Testosterone products, Preferred](#) Criteria located within this document.
  Approval: 1 year.
  Quantity limit:
    ▪ 75gm for 30 days
Approved by the P&T Committee 09/19/2007.

- **Androxy (fluoxymestrone)**
  Indications for Approval
  1. Breast cancer, palliative treatment
  2. Postpartum breast engorgement
Approved by the P&T Committee 05/18/2011.

- **Antipsychotics, Non-Preferred**
  *Covered products are: Fanapt (iloperidone), Invega (paliperidone), Rexulti (bexpiprazole), Saphris (asenapine maleate), Vraylar (cariprazine)*
  Indications for Approval:
  - The medication requested must be used for the treatment of a medical condition approved by the U.S. Food and Drug Administration (FDA). If it is not approved by the FDA, its use must be supported in the medical compendia.
  - Must be initiated by a behavioral health practitioner or in consultation with a behavioral health practitioner for all indications:
    1. Schizophrenia
      - The patient must have a trial and failure of three (3) formulary atypical antipsychotics. Medication trials that fail due to lack of efficacy must be attempted at a maximal approved dose for a minimum of 4 weeks if no response, and a minimum of 12 weeks if partial response.
      OR
      - The patient has a current diagnosis of Metabolic Syndrome, Pre-Metabolic Syndrome, or Diabetes Mellitus and has failed ziprasidone
and aripiprazole or there is clinical documentation why they are not clinically appropriate.

2. Bipolar Disorder
   • The patient must have a documented intolerance, side effects or lack of efficacy to at least three (3) formulary alternatives which could include lithium, valproic acid, lamotrigine, and atypical antipsychotics.

3. Major Depressive Disorder
   • Medication is being used in combination with an antidepressant medication.
   AND
   • The patient has a trial and failure of at least one of each of the following:
     - Selective serotonin reuptake inhibitor.
     - Serotonin norepinephrine reuptake inhibitor (SNRI), mirtazapine, or bupropion.
     - Formulary preferred atypical antipsychotic used for the adjunctive treatment of major depressive disorder with an antidepressant.

Length of approval: 1 year
Approved by the P&T Committee 04/24/19. Updated 10/16/2019.

- **Anzemet (dolasetron) Tablets**
  Indications for Approval:
  The patient has a documented treatment failure with antiemetic regimens that include generic ondansetron or generic granisetron.
  - Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of complete response.
  Quantity Limit: 3 tablets for 30 days.
  Length of Approval: 6 months.
  Alternatives: ondansetron, granisetron (must have a documented failure of ondansetron tablets for formulary coverage of granisetron tablets).
  Approved by the P&T Committee 05/19/2010.
  References:
• **Apokyn (apomorphine)**
  Indications for Approval:
  All FDA-approved indications
  ▪ Acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) associated with advanced Parkinson’s disease.
  Specialty Pharmacy required.

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<th>Code: J0364</th>
<th>1mg = 1 billable unit</th>
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Approved by the P&T Committee 07/20/2011.

• **Apriso (mesalamine extended release)**
  Step Edit Criteria:
  The patient must have a claim history within the past 545 days of a 30-day trial of balsalazide or sulfasalazine.
  Quantity Limit: 120 capsules for 30 days.
  Alternatives: balsalazide, sulfasalazine
  Approved by the P&T Committee 01/18/2012.

• **Aranesp (darbepoetin alfa)**
  Refer to the Erythropoiesis-Stimulating Agents criteria located within this document.

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<th>Code: J0881</th>
<th>1mcg (0.001mg) = 1 billable unit</th>
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Approved by the P&T Committee 07/16/2008. Revised 07/20/2011 and 01/15/2014.

• **Aricept ODT (donepezil hydrochloride orally disintegrating tablets)**
  Indications for Approval:
  The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.
  Approval: one year.
  References:
  Approved by the P&T Committee 07/18/2018.

• **Aristada Initio (aripiprazole lauroxil)**
  Indications for Approval:
  The patient must be unable to establish Aristada treatment with oral aripiprazole forms despite good compliance as shown by pharmacy claims.
  Approved by the P&T Committee 07/17/2019.

• **Arixtra (fondaparinux)**
  Indications for Approval:
The patient will be undergoing total knee replacement, total hip replacement, hip fracture repair, pulmonary embolism treatment or deep venous thrombosis treatment.

AND

The patient has an allergy or Heparin Induced Thrombocytopenia (HIT) with documented antiplatelet antibody to low molecular weight heparin (LMWH).

OR

The patient has an allergy or HIT with documented antiplatelet antibody to unfractionated heparin (UFH).

Contraindications:

- Patients with creatinine clearance < 30 ml/min
- Patient with weight <50 kg (deep vein thrombosis prophylaxis)
- Evidence of active bleeding
- Bacterial endocarditis
- Thrombocytopenia with a positive test for antiplatelet antibody to fondaparinux
- Hypersensitivity to fondaparinux
- Epidural/spinal anesthesia

Dosing:

- Fondaparinux 2.5 mg SQ daily, initiated 6 hours postoperatively for thromboprophylaxis.
- Fondaparinux weight adjusted dosing for thromboembolism treatment: 5.0 mg, 7.5 mg, 10 mg for body weights of <50 kg, 50-100 kg, and >100 kg, respectively.
- Duration for thromboprophylaxis was up to 11 days. However, benefits of prolonged duration for VTE prophylaxis have been documented.
- Duration for thromboembolism treatment is at least 5 days and until oral anticoagulation is within the therapeutic range (INR 2-3).
- If platelet counts fall below 100,000 mm³, fondaparinux should be discontinued.
- Overdosage with fondaparinux is not reversible with protamine sulfate.

Approval: One time.
Alternative: Lovenox (Lovenox has a quantity limit: 30 syringes for 90 days).

- **Asacol (mesalamine)**
  Step Edit Criteria:
  
  The patient must have a claim history within the past 545 days of a 30-day trial of balsalazide or sulfasalazine.

  Alternatives: balsalazide, sulfasalazine

  Approved by P&T Committee 09/16/2009.

  Updated 01/18/2012.

- **Astagraf XL (tacrolimus XL)**
  Indications for Approval
All of the following must be met:
1. Drug is used for FDA approved indication.
2. Patient has tried and failed tacrolimus immediate release capsules despite good adherence
   a. Tacrolimus levels must be submitted showing poor control.
   b. Pharmacy claims show regular fills

Quantity Limit: 0.5 mg: 30 capsules for 30 days, 1 mg: 120 capsules for 30 days, 5 mg: 90 capsules for 30 days
Approved by the P&T Committee 04/24/2019

- **Atacand (candesartan cilexetil)**
  Step Edit Criteria:
  The patient must have a prescription claim history of a formulary angiotensin converting enzyme (ACE) inhibitor or ACE inhibitor/diuretic combination within the past six months.
  Alternatives: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, benazepril/HCTZ, captopril/HCTZ, enalapril/HCTZ, fosinopril/HCTZ, lisinopril/HCTZ, moexipril/HCTZ, quinapril/HCTZ. HCTZ= hydrochlorothiazide

- **Atacand HCT (candesartan cilexetil/hydrochlorothiazide)**
  Step Edit Criteria:
  The patient must have a prescription claim history of a formulary angiotensin converting enzyme (ACE) inhibitor or ACE inhibitor/diuretic combination within the past six months.
  Alternatives: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, benazepril/HCTZ, captopril/HCTZ, enalapril/HCTZ, fosinopril/HCTZ, lisinopril/HCTZ, moexipril/HCTZ, quinapril/HCTZ. HCTZ= hydrochlorothiazide

- **Austedo (deutetrabenazine)**
  Indications for Approval:
  1. The patient does not have untreated or inadequately treated depression.
  2. The patient is not actively suicidal.
  3. The patient does not have hepatic impairment.
  4. The patient is not taking monoamine oxidase inhibitors (MAOIs) or reserpine.
  5. The appropriate Disease Specific Criteria below have been met.
     a. **Chorea associated with Huntington disease**
        i. The medication is being prescribed by or in consultation with a neurologist.
        ii. The patient is ambulatory.
iii. Documentation of a baseline total maximal chorea score from the Unified Huntington Disease Rating Scale (UHDRS) must be provided.

iv. The member has a documented trial and failure, or intolerance to, or a medical reason for avoiding the use of tetrabenazine and one of the following: amantadine or riluzole.

b. Tardive Dyskinesia
   i. The medication is prescribed by or in consultation with a neurologist or psychiatrist.
   ii. The patient has documented diagnosis of tardive dyskinesia.
   iii. Trial and failure of one of the following: amantadine, anticholinergic medication (e.g. trihexyphenidyl, benztropine), or a benzodiazepine (e.g. clonazepam).
   iv. Documentation of a baseline Abnormal Involuntary Movement Scale (AIMS) must be provided.

Continuation of Therapy:
1. For all indications: Documentation showing the patient continues to be monitored for depression, suicidal ideation, and hepatic impairment.
2. Chorea associated with Huntington disease: Documented improvement in the total maximal chorea score from the UHDRS compared to baseline.
3. Tardive Dyskinesia: Documented improvement in AIMS compared to baseline.

Specialty Pharmacy Required.

Approval Length:
- Initial Approval - 6 months
- Renewal - 1 year

Quantity Limits:
- 6mg and 9mg - 90 tablets for 30 days
- 12mg – 120 tablets for 30 days.

Approved by the P&T Committee 10/18/2017. Updated 07/17/2019.

• **Avalide (irbesartan/HCTZ)**

Step Edit Criteria:
The patient must have a claim history of a formulary angiotensin converting enzyme (ACE) inhibitor, ACE inhibitor/diuretic combination, angiotensin receptor blocker (ARB), or ARB/diuretic combination.

Alternatives: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, benazepril/HCTZ, enalapril/HCTZ, fosinopril/HCTZ, lisinopril/HCTZ, moexipril/HCTZ, quinapril/HCTZ, losartan, losartan/HCTZ. HCTZ= hydrochlorothiazide.

Approved by the P&T Committee 04/16/2014.
• **Avandamet (rosiglitazone/metformin)**
  Step Edit Criteria:
  The patient must have previous use of at least one of the medications (Avandia or metformin) that make up the combination medication within the past 120 days.
  Alternatives: Avandia, metformin.
  Approved by the P&T Committee 09/17/2008.

• **Avandia (rosiglitazone)**
  Step Edit Criteria:
  The patient must have a 30-day prescription fill of metformin in the past 545 days.
  Alternative: metformin
  Approved by the P&T Committee 09/15/2010.

• **Avapro (irbesartan)**
  Step Edit Criteria:
  The patient must have a claim history of a formulary angiotensin converting enzyme (ACE) inhibitor, ACE inhibitor/diuretic combination, angiotensin receptor blocker (ARB), or ARB/diuretic combination.
  Alternatives: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, benazepril/HCTZ, enalapril/HCTZ, fosinopril/HCTZ, lisinopril/HCTZ, moexipril/HCTZ, quinapril/HCTZ, losartan, losartan/HCTZ. HCTZ=hydrochlorothiazide.
  Approved by the P&T Committee 04/16/2014.

• **Avastin (bevacizumab)**
  Refer to the Oncology criteria located within this document.
  Code:  J9035  
  10mg = 1 billable unit
  Approved by the P&T Committee 05/18/2011.
  Updated 03/20/2013, 10/15/2014, 01/21/2015 and 11/05/2015.

• **Avinza (morphine sulfate extended release capsules)**
  Refer to the Morphine Sulfate ER Capsules, Tablets (Avinza, Kadian) Criteria located within this document.
  Approved by the P&T Committee 09/19/2007.

• **Avodart (dutasteride)**
  Step Edit Criteria:
  The patient must have a claim history of finasteride within the past 4 months.
  Quantity Limit:  30 capsules for 30 days.
  Approved by the P&T Committee 07/20/2011.
• **Azedra (iobenguane I-131)**
  Indications for Approval:
  1. Documented diagnosis of iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL).
  2. Patient is 12 years of age or older.
  3. Documentation that symptoms of catecholamine excess are being managed with alpha and/or beta-adrenergic blockade.
  4. Documentation that member falls into one of the following categories:
     a) Unresectable progressive PPGL
     b) Symptoms from disease that are not amenable to locoregional methods of control (e.g., resection, radiation therapy, nonsurgical ablative therapy)
     c) Documentation that patient does not have rapidly progressing tumors*
  *Note: For patients with rapidly progressive tumors of bone-predominant extensive disease, chemotherapy is a preferred option even if iobenguane scan positive.

Length of Approval: 6 months

Quantity Limit: one dosimetric vial and two therapeutic vials.

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<tr>
<th>Dosimetric Vial Code: C9407</th>
<th>1 millicurie = 1 billable unit</th>
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<tbody>
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<td>Therapeutic Vial Code: C9407</td>
<td>1 millicurie = 1 billable unit</td>
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</tbody>
</table>

Approved by the P&T Committee 10/17/2018.

• **Balversa (erdafitinib)**
  Refer to the Oncology criteria located within this document.
  Approved by the P&T Committee: 07/17/2019.

• **Baraclude (entecavir)**
  Indications for Approval:
  1. Must be ≥2 years old
  2. There is insufficient evidence to support the use of entecavir in pregnant women
  3. Patient must be in one of the following phases of chronic Hepatitis B (CHB) infection (see Table 1)
     a. Immune-active CHB (HbeAg negative or HBeAg positive) with ALT >2 times ULN
        i. ULN defined as 30U/L for males and 19 U/L for females regardless of laboratory values
     b. Immune-active CHB with significant histological disease (significant inflammation or fibrosis on biopsy) and HBV DNA >2000IU/mL if HBeAG negative or >20000IU/mL if HBeAG positive
     c. If the patient has elevated ALT, but <2 times ULN, documents must show immune-active CHB AND cirrhosis AND HBV DNA >2000IU/mL
d. Immune-active CHB with ALT <2ULN and HBV DNA <2000IU/mL if HBeAG negative or <20000IU/mL if HBeAG positive, documents show ONE of the following high risk factors:
   i. >40 years of age, family history of hepatocellular carcinoma, previous treatment, OR extrahepatic manifestations

e. Immune-tolerant CHB, >40 years of age, and HBV DNA ≥1,000,000IU/mL, regardless of ALT

f. Compensated cirrhosis with low level viremia, HBV DNA <2000IU/mL
g. HBsAg-positive with decompensated cirrhosis

h. Children 2 to <18 years with both elevated ALT (>1.3times ULN, ULN is 30U/mL) and measurable HBV DNA levels (>10^6 IU/mL)

4. Patients with the following phases should NOT be treated
   a. Immune-Tolerant CHB (ALT ≤30U/L for men and ≤19U/L for women)
   b. Inactive chronic hepatitis B (HBeAg negative with normal ALT and low-level viremia (<2000 IU/mL))
   c. Children 2 to <18 years old with persistently normal ALT, regardless of HBV DNA levels

Continuation of Therapy Criteria:
   1. HBeAg-positive adults WITHOUT cirrhosis who seroconvert to anti-HBe
      a. Continue therapy for at least 12 months of persistently normal ALT levels and undetectable serum HBV DNA levels

2. HBeAg or HBsAG positive WITH cirrhosis

3. HBeAg-negative immune-active CHB

Table 1. Phases of Chronic Hepatitis B Infection

<table>
<thead>
<tr>
<th>Phase</th>
<th>ALT</th>
<th>HBV DNA</th>
<th>HBeAg</th>
<th>Liver Histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune-Tolerant Phase</td>
<td>Normal</td>
<td>Elevated, typically &gt;1 million IU/mL</td>
<td>Positive</td>
<td>Minimal Inflammation and fibrosis</td>
</tr>
<tr>
<td>HBeAg-positive, Immune Active phase</td>
<td>Elevated</td>
<td>Elevated ≥20,000 IU/mL</td>
<td>Positive</td>
<td>Moderate-to-severe inflammation or fibrosis</td>
</tr>
<tr>
<td>Inactive CHB Phase</td>
<td>Normal</td>
<td>Low or undetectable &lt;2000 IU/mL</td>
<td>Negative</td>
<td>Minimal necroinflammation but variable fibrosis</td>
</tr>
<tr>
<td>HBeAg-negative Immune reactivation phase</td>
<td>Elevated</td>
<td>Elevated ≥2000 IU/mL</td>
<td>Negative</td>
<td>Moderate-to-severe inflammation or fibrosis</td>
</tr>
</tbody>
</table>

Quantity limit: 30 tablets for 30 days.
Approval: One (1) year.
Specialty Pharmacy required
Approved by the P&T Committee 10/17/2018.
References:


- **Bavencio (avelumab)**
  Refer to the [Oncology criteria](#) located within this document.

<table>
<thead>
<tr>
<th>Code: J9023</th>
<th>10mg = 1 billable unit</th>
</tr>
</thead>
</table>

Approved by the P&T Committee 07/19/2017

- **Beleodaq (belinostat)**
  Refer to the [Oncology criteria](#) located within this document.

<table>
<thead>
<tr>
<th>Code: J9032</th>
<th>10mg = 1 billable unit</th>
</tr>
</thead>
</table>

Approved by the P&T Committee 10/15/2014. Updated 11/05/2015.

- **Belsomra (suvorexant)**
  Indications for Approval:
  Insomnia (patient must have a documented treatment failure of all of the following:
  - Zolpidem tablets
  - A formulary benzodiazepine used for the treatment of insomnia.
  - Trazodone

  Quantity Limit: 30 tablets for 30 days.

  Approved by the P&T Committee 04/19/2017

- **Benlysta (belimumab intravenous and subcutaneous injection)**
  Indications for Approval (all of the following must be met):
  1. Documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus (SLE).
  2. Prescriber is a rheumatologist.
  3. The member is concurrently taking and is compliant with standard therapy for SLE (e.g. corticosteroids, antimalarials, or immunosuppressives (alone or in combination).

  Exclusions (will not be approved in the following instances):
  - As monotherapy.
  - For patients with active central nervous system lupus.
  - For patients with active lupus nephritis.
  - For patients who are autoantibody negative.
- In combination with other biologics (other B-cell targeted therapy) and/or intravenous cyclophosphamide or if the member is currently receiving high dose prednisone ≥ 100mg/day.

Reauthorization Criteria: Documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline.

Approval Length:
- Initial approval - 6 months.
- Reauthorization – 12 months

Specialty Pharmacy required

Quantity Limit: Syringes and Autoinjectors - 4mL for 28 days.

| Code: J0490 | 10mg = 1 billable unit |

Approved by the P&T Committee 09/21/2011. Updated 10/18/2017.

- **Berinert (C1 esterase inhibitor, human)**
  **Indications for Approval** (all of the following must be met):
  1. Must meet ALL clinical criteria for hereditary angioedema (HAE).
  2. Must be at least 5 years old.
  3. Request is for acute “on-demand” treatment.

Approval: 6 months

Quantity Limit: 2 episodes in 28 days

Specialty Pharmacy required: Briova

| Code: J0597 | 10 units = 1 billable unit |

Approved by the P&T Committee 09/19/2012. Updated 10/16/2019

References:

- **Besponsa (inotuzumab ozogamicin)**
  Refer to the Oncology criteria located within this document.

Approved by the P&T Committee 10/18/2017.
• **Betaxolol 0.5% ophthalmic**
  Step Edit Criteria:
  The patient must have a prescription claim history for timolol maleate 0.5% ophthalmic solution within the past 180 days.
  Approved by the P&T Committee 04/19/2017

• **Betoptic S (betaxolol 0.25% ophthalmic)**
  Step Edit Criteria:
  The patient must have a prescription claim history for timolol maleate 0.5% ophthalmic solution within the past 180 days.
  Approved by the P&T Committee 04/19/2017.

• **Blincyto (blinatumomab)**
  Refer to the Oncology criteria located within this document.
  
  | Code: J9039 | 0.001mg = 1 billable unit |
  
  Approved by the P&T Committee 01/21/2015. Updated 11/05/2015.

• **Boniva (ibandronate) tablets**
  Step Edit Criteria:
  A documented trial and failure of alendronate.
  Quantity Limit: 1 tablet for 28 days.
  Approved by the P&T Committee 07/17/2013.

• **Bosulif (bosutinib)**
  Indications for Approval:
  1. Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase
     • Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).
  2. Philadelphia chromosome positive acute lymphoblastic leukemia
     • Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).
  Continuation Criteria:
  All of the following must be met:
  1. Documentation that the patient does not have evidence of disease progression must be submitted.
  2. Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.
  Quantity Limit:
• 100 mg = 90 tablets for 30 days
  ▪ 400 mg and 500 mg = 30 tablets for 30 days.

Approval Length: Six (6) months.
Specialty Pharmacy required.
Approved by the P&T Committee 11/28/2012. Revised 10/15/2014, 11/05/2015 and 04/18/2018.

• **Botox (onabotulinumtoxinA)**

Indications for Approval:

1. Blepharospasm (doses of 100 units or less).
2. Cervical Dystonia (doses of 300 units or less).
3. Cerebral Palsy (doses of 400 units or less).
4. Facial Nerve Disorder/Hemi-facial Spasm (doses of 100 units or less).
5. Severe Palmar Hyperhidrosis (doses of 100 units or less) that meets following criteria:
   ▪ Documented trial and failure of drying agents such as topical aluminum chloride (DrySol, Xerac AC, and Hypercare).
6. Severe Primary Axillary Hyperhidrosis (doses of 100 units or less) that meets the following criteria:
   ▪ Documented trial and failure of drying agents such as topical aluminum chloride (DrySol®, Xerac AC®, and Hypercare®).
7. Laryngeal Dystonia (doses of 100 units or less).
8. Limb Dystonia (doses of 100 units or less).
9. Migraine, Chronic; Prophylaxis (total dose of 155 units or less) that meets the following criteria:
   ▪ The requested medication is being prescribed by, or in consultation with, a neurologist.
   ▪ ≥ 15 days per month with headache lasting 4 hours a day or longer.
   ▪ Documented trials and failures with conventional abortive therapies which should include:
     a. NSAIDS, aspirin, or acetaminophen, butalbital
     b. Serotonin agonists (triptans)
   ▪ Documented trials and failures with prophylactic therapies to include failed trials of at least 2 of the medications below for at least 60 days:
     a. Anti-hypertensives: (e.g., metoprolol, propranolol, timolol, nadolol, verapamil, nimodipine)
     b. Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, venlafaxine, nortriptyline, protriptyline);
c. Anti-epileptic drugs (e.g., divalproex, topiramate, valproic acid, please note that gabapentin has been proven ineffective as prophylaxis for migraines):

- **NOTE:** Botox will not be approved for use in conjunction with CGRP medications for headache prophylaxis. Documentation must be provided that member will not receive a CGRP while receiving Botox.

10. Spasmodic Torticollis (doses of 300 units or less).
11. Spasticity resulting from an acquired or congenital brain disorder (doses of 400 units or less).
12. Strabismus (doses of 100 units or less).
13. Urinary incontinence treatment due to detrusor overactivity (doses of 200 units or less) associated with a neurologic condition (e.g. spinal cord injury, MS) in adults who have had an inadequate response to or are intolerant of two anticholinergic medications used for urinary incontinence such as oxybutynin and tolterodine.
14. Overactive bladder (OAB) (doses of 100 units or less) with symptoms of urinary incontinence, urgency and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.
15. Upper limb spasticity in the following muscle groups: elbow flexors, wrist flexors, finger flexors, and thumb flexors in accordance with approved dosages listed in prescribing information for each muscle group (maximum total dose of 400 units).

**Exception:** Any exceptions to the above conditions of coverage for Botox will be considered through the Pharmacy Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Approval: 1 year.

| Code: J0585  | 1 unit = 1 billable unit |

Approved by the P&T Committee 09/17/2008. Updated 11/16/2011, 03/20/2013, 07/15/2015, 10/18/2017 and 07/18/2019.

- **Braftovi (encorafenib)**
  
  Refer to the Oncology criteria located within this document.
  
  Length of Approval: 6 months
  
  Quantity limit:
  
  - 50 mg capsules - 120 capsules per 30 days
  - 75 mg capsules - 180 mg capsules per 30 days
  
  References:
  

Approved by the P&T Committee 07/18/2018.
• **Brilinta (ticagrelor)**
  Indications for Approval:
  1. Therapy must be initiated by a cardiologist
     AND
  2. Patient must have a documented diagnosis of Acute Coronary Syndrome
Approval Length: One year.
Quantity Limit: 60 tablets for 30 days.
Approved by the P&T Committee 11/28/2012. Updated 07/20/2016.
References:

• **Cabometyx (cabozantinib)**
  Indications for Approval:
     i. Documentation that the patient belongs to the poor- or intermediate risk group must be provided.
  2. Subsequent therapy for the treatment of advanced renal cell carcinoma.
     i. Documentation of previous therapies tried must be provided.
Quantity Limit: 30 tablets for 30 days.
Approval Length: Six (6) months.
Specialty Pharmacy required.
Updated by the P&T Committee 07/20/2016 and 04/18/2018.

• **CGRP (calcitonin gene-related peptide)**
  Indications for Approval:
  1. Chronic Migraine
All of the following must be met:

a) The requested medication is being prescribed by, or in consultation with, a neurologist or headache specialist.

b) The patient is ≥ 18 years of age.

c) Documentation that the patient has ≥ 15 headache days per month, with ≥ 8 migraine days per month.

d) The patient has tried and failed a 3 month trial of at least two prophylactic medications from at least two of the following categories:
   • Anticonvulsants (e.g. divalproex, valproate, topiramate)
   • Beta-blockers (e.g. metoprolol, propranolol, timolol)
   • Antidepressants (e.g. amitriptyline, venlafaxine)

e) Member has been evaluated for and does not have medication overuse headache.

f) The patient has a documented trial and failure of Botox® (onabotulinumtoxinA).

   *Note: CGRP medications will not be approved for use in conjunction with Botox for headache prophylaxis. Documentation that member has not received a Botox injection for headache prophylaxis in the past 4 months must be provided.*

2. **Episodic Migraine**

All of the following must be met:

a) The requested medication is being prescribed by, or in consultation with, a neurologist or headache specialist.

b) The patient is ≥ 18 years of age.

c) The patient has 4 to 14 migraine days per month.

d) The patient has been evaluated for and does not have medication overuse headache.

g) The patient has tried and failed a 3 month trial of at least two prophylactic medications from at least two of the following categories:
   • Anticonvulsants (e.g. divalproex, valproate, topiramate)
   • Beta-blockers (e.g. metoprolol, propranolol, timolol)
   • Antidepressants (e.g. amitriptyline, venlafaxine)

Initial Length of Approval: 3 months.
Quantity limit: Quantity will be limited to maximum FDA approved doses for the requested medication.

*Specialty Pharmacy required.

**Continuation of Therapy Criteria:**
All of the following must be met:

1. The requested medication is being prescribed by, or in consultation with, a neurologist or headache specialist.

2. Documentation that the patient has experienced a reduction of 2 or more migraine days per month must be submitted.

3. Patient has not received a Botox injection for headache prophylaxis in the past 4 months.

4. Patient will not be initiating Botox for headache prophylaxis while using the requested CGRP medication.
Continuation of Therapy Length of Approval: 1 year.

References:

Approved by the P&T Committee 07/18/2018.

- **Calquence (acalabrutinib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 60 capsules for 30 days.
  Approved by the P&T Committee 01/17/2018.

- **Campath (alemtuzumab)**
  Refer to the Oncology criteria located within this document.
  | Code: J9010 | 10mg = 1 billable unit |
  Approved by the P&T Committee 05/20/2009. Revised 11/05/2015.

- **Campral (acamprosate)**
  Indications for Approval:
  Alcohol dependence – the following must be met:
  1. A documented trial and failure with either naltrexone tablets or disulfiram.
     OR
     Severely impaired liver function (ALT or AST value more than 3 times normal values) i.e. acute hepatitis or liver failure.
     AND
  2. Patient is engaged in a comprehensive management program that includes a psychosocial component of the therapy (e.g., psychosocial behavioral interventions* focused on relapse prevention) during the entire course of therapy.
  Approval: 3 months.
  Quantity Limit: 180 tablets for 30 days.
  Alternatives: disulfiram, naltrexone tablets.
  * Intervention examples include, but are not limited to; an intensive outpatient program, individual or group counseling for substance abuse and dependence, or regular attendance at Alcoholics Anonymous (AA).
Approved by the P&T Committee 1/20/2010.

- **Caprelsa (vandetanib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limits:
  - 100mg – 60 tablets for 30 days
  - 300mg – 30 tablets for 30 days
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Revised 10/15/2014 and 11/05/2015.

- **Casodex (bicalutamide)**
  Step Edit Criteria:
  The patient must have a claim history of a 30-day trial of flutamide in the past 180 days.
  Alternative: flutamide.

- **Cayston (aztreonam)**
  Indications for Approval (all of the following must be met):
  1. The patient must have cystic fibrosis.
  2. The patient must have *Pseudomonas aeruginosa* in the lungs.
  3. The patient must be > 7 years of age.
  4. FEV1 must be between 25% - 75% predicted.
  Continuation of Therapy Criteria:
  1. Must have improved FEV1
  2. Must have a decrease in the sputum density of *P. aeruginosa*.
  Quantity Limit: 84mL for 56 days.
  Approval Length: 6 months
  Specialty Pharmacy required.
  Approved by the P&T Committee 01/18/2017

- **CeeNU (lomustine)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Cellcept oral suspension (mycophenolate mofetil)**
  Indications for Approval
  The following criteria apply to patients greater than 12 years of age:
  - The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.
Length of Approval: One (1) year.
Approved by the P&T Committee 10/17/2018.

- **Cerebral Stimulant/ADHD Treatment for Adults Age 19 and Above**

  *Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.*

  Indications for Approval:

  1. **Attention Deficit Hyperactivity Disorder (ADHD)**

     Medical records documenting all of the following must be provided:

     a. The existence of at least 5 inattentive symptoms or at least 5 hyperactive-impulsive symptoms for at least 6 months.

     **Inattentive Symptoms:**

     - Fails to give close attention to details or makes careless mistakes in schoolwork, at work, or during other activities.
     - Has difficulty sustaining attention in tasks or play activities.
     - Does not seem to listen when spoken to directly.
     - Does not follow through on instructions and fails to finish school work, chores, or duties in the workplace.
     - Difficulty organizing tasks and activities.
     - Avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort.
     - Loses things necessary for tasks or activities.
     - Is easily distracted by extraneous stimuli.
     - If forgetful of daily activities.

     **Hyperactive-Impulsive Symptoms:**

     - Often fidgets with or taps hands or feet or squirms in seat.
     - Often leaves seat in situations when remaining in seat is expected.
     - Often runs about and climbs in situations where it is inappropriate.
     - Often unable to play or engage in leisure activities quietly.
     - Is often “on the go” acting as if driven by a motor.
     - Often talks excessively.
     - Often blurts out an answer before the question is completed.
     - Often has difficulty waiting his or her turn.
     - Often interrupts or intrudes on others.

     b. Presence of inattentive or hyperactive-impulsive symptoms prior to 12 years of age.

     c. Inattentive or hyperactive-impulsive symptoms are present in two or more settings (e.g. at home, school, work; with friends or relatives; in other activities). Documentation of settings is required.

     d. Symptoms impair or compromise normal functioning.
e. Symptoms are not better explained by another mental disorder (e.g. schizophrenia, mood disorder, anxiety disorder, dissociative disorder, personality disorder, or substance abuse.

f. The diagnosis has been verified using a standardized rating scale (e.g. Conners’ Adult ADHD Rating Scale, Wender Adult ADHD Rating Scale, or Adult ADHD Self-Report scale.

2. Narcolepsy
All of the following are required:

a. The medication must be prescribed by a sleep specialist or neurologist.

b. Diagnosis of narcolepsy with cataplexy

OR

c. Diagnosis of narcolepsy without cataplexy and diagnosis has been confirmed by the following sleep studies:
   ▪ Polysomnogram
   ▪ A mean sleep latency of ≤ 8 minutes and two or more sleep-onset random eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT).

3. Depression
One of the following is required:

a. Documentation of treatment resistant depression (for augmentation of antidepressant therapy). Treatment resistant depression is defined as a trial of two antidepressant medications at a therapeutic dose for an adequate duration without remission of symptoms.

b. Documentation that the patient is with advanced illness and the medication is being used to rapidly treat symptoms of depression (i.e. apathy, fatigue).

4. Multiple Sclerosis (MS) Fatigue

Length of Approval: One (1) year.

Approved by the P&T Committee 11/15/2015. Updated 07/20/2016.

References:

• **Cinryze (C1 esterase inhibitor, human)**

  **Indications for Approval**

  All of the following must be met:
  
  1. Must meet ALL clinical criteria for hereditary angioedema (HAE).
  3. Must be aged 6-11 years of age OR greater than 12 years of age with a documented contraindication or documented failure of BOTH Takhzyro AND Haegarda.

  Approval: 6 months

  Quantity Limit: 8 treatments (according to FDA and weight) for 28 days

  Specialty Pharmacy required: Briova

  References:
  

  **Code:** J0598
  
  10 units = 1 billable unit

  Approved by the P&T Committee 09/19/2012. Updated 07/18/2018, 10/16/2019.

• **Cinvanti (aprepitant)**

  **Indications for Approval:**

  1. The patient must be receiving Cinvanti in combination with a 5-HT3 antagonist and dexamethasone.

  AND

  2. Must meet **one** of the following criteria:

     • The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential.
     • The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination.

  Quantity Limit: 72mL (4 vials) for 30 days.

  Approval Length: Six (6) months.

  **Code:** J0185

  1mg = 1 billable unit
• **Ciprodex Otic (ciprofloxacin/dexamethasone)**
  Step Edit Criteria: (for patients 12 years of age and older)
  - Patient must have a claim history of ofloxacin 0.03% otic in the past 100 days.
  - Quantity limit of 7.5ml (1 bottle) every 30 days.
  - Alternative: ofloxacin 0.03% otic
  Approved by the P&T Committee 01/16/2013. Updated 11/05/2015.

• **Claravis (isotretinoin capsules)**
  Refer to the [Isotretinoin criteria](#) located within this document.
  Approved by the P&T Committee 10/19/2016. Updated: 10/17/2018.

• **Codeine and Tramadol Medications in Children**
  *Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.*
  **Indications for Approval:**
  1. Patient must be greater than 12 years of age. Codeine and tramadol containing medications will not be covered for any indication in patients under 12 years of age.
  2. For patients 12 to 18 years of age documentation must be provided confirming that patient does not have any of the following medical conditions:
     - Obesity
     - Obstructive Sleep Apnea
     - Severe Lung Disease
  3. Tramadol will not be covered for the treatment of postoperative pain management of tonsillectomy and/or adenoidectomy.
  **Approval:** Up to 3 months.
  **References:**
  Approved by the P&T Committee 04/18/2018.

• **Combipatch Transdermal (estradiol/norethindrone)**
  Step Edit Criteria:
  - The patient must have a 90 day trial of a formulary estrogen and progesterone medication within the past 180 days.
  **Alternatives:** Activella, estradiol vaginal, estradiol tablets, estropipate, Femhrt, medroxyprogesterone, Menest, Prefest, Premarin, Premarin vaginal, Premphase, Prempro.
• **Cometriq (cabozantinib)**
  Refer to the Oncology criteria located within this document.
  Approved by the P&T Committee 01/16/2013. Updated 11/05/2015.

• **Concurrent Medication-Assisted Treatment and Central Nervous System Depressants**

  **Indications for Approval**
  All of the following must be met:
  1. The patient has been diagnosed with opioid type dependence or combinations of opioid type abuse with other (F11.XX). Buprenorphine will not be covered for the treatment of pain.
  2. A treatment plan agreed to, and signed by the patient must be submitted by the requesting provider.
  3. Prescriber certifies that the patient has been informed of the increased risks associated with using CNS depressants in conjunction with methadone or buprenorphine containing products
  4. Patient has a full assessment that includes a complete list of drugs, including over-the-counter medications
  5. Current urine toxicology screen and a New Mexico Board of Pharmacy Prescription Monitoring Program (PMP) report must be submitted
     a. Inappropriate results must be addressed and plan to address future aberrations

For Concurrent use of Benzodiazepines the additional documentation is required:
  1. Documents must show that the individual is agreeable to engage in a plan to address their use of benzodiazepines before beginning treatment
  2. Benzodiazepine use is clearly addressed with a diagnosis AND
     a. A taper plan is included with a period of time agreed on by clinician and individual OR
     b. If patient is unable to be tapered, documents showing other non-benzodiazepine alternatives or non-pharmacologic tried AND a plan to stabilize benzodiazepine use
  3. Uncontrolled use of benzodiazepines in a person presenting for MAT is contraindicated
  4. If a person who is stable and experiences a major stressful event, a short-term (up to 14 days per 90 days) prescription for benzodiazepines to help stabilize the patient will be allowed-no prior authorization will be required
  5. If a person who is stable experiences an acute need for a muscle relaxant, a short-term (up to 14 days per 90 days) prescription will be allowed without a prior authorization

Approved by the P&T Committee: 04/26/2019
**Continuous Glucose Monitors (CGM) and supplies**

**Indications for Approval:**

Diabetes Mellitus Type 1 or 2 AND meets the following criteria:

1. The patient is currently using Blood Glucose Monitor (BGM) AND is testing four or more times per day; AND
2. The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; AND
3. The beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; AND
4. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met
5. DexCom will only be covered for
   a. Patients ≤ 17 years of age OR
   b. ≥75 years of age OR
   c. Have a medical reason why Freestyle Libre® cannot be used

**Continuation of Therapy Criteria:**

Treating practitioner must submit documentation that an in-person visit with the beneficiary has occurred every six months or more frequently to assess adherence to their CGM regimen and diabetes treatment plan.

Approval Length: 1 year

Quantity Limits Apply (reference formulary for device specific limits)

Approved by the P&T Committee PENDING

**References:**

1. National Coverage Determination (NCD) for Home Blood Glucose Monitors (40.2)


**Copaxone 40mg/mL (glatiramer acetate)**

**Step Edit Criteria:**

The patient must have a claim history of Glatopa 20mg/mL (glatiramer acetate 20mg/mL) within the past 180 days.

Specialty Pharmacy required.

Quantity Limit: 12mL for 28 days.

Approved by the P&T Committee 01/17/2018.
• **Copiktra (duvelisib)**  
   Refer to the **Oncology** criteria located within this document.  
   Quantity limit: 60 tablets for 30 days  
   Approval: 6 months  
   Approved by the P&T Committee 01/17/2019

• **Crinone (progesterone gel)**  
   Indications for Approval:  
   To reduce the risk of spontaneous preterm birth in pregnant women with a short cervix (≤ 20mm before 24 weeks) on ultrasound examination in the current pregnancy and no history of preterm birth.  
   Approved by the P&T Committee 01/20/2016.

• **Crysvita (burosumab-twza)**  
   Indications for Approval:  
   All of the following must be met:  
   1. Crysvita is prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders (i.e., endocrinologist or nephrologist).  
   2. Patient is ≥ 1 year of age.  
   3. The patient has a diagnosis of X-linked hypophosphatemia (XLH) confirmed by one of the following:  
      • Genetic testing  
      • Elevated FGF23 level > 30 pg/mL  
   4. Patient has a documented baseline serum phosphorus level that is below the normal range for patient’s age.  
   5. Patient has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR)  
   6. Documented presence of clinical signs and symptoms of the disease (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures)  
   7. Patient is not receiving oral phosphate or active vitamin D analogs.  
   8. Patient does not have severe renal impairment (eGFR < 30 mL/min/1.73 m²).  
   Initial Length of Approval: 6 months  
   Quantity limit:  
   Pediatric patients - Up to a maximum of three 30 mg vials (90 mg) every 2 weeks  
   Adult patients – Up to a maximum of three 30 mg vials (90 mg) every 4 weeks  
   **Continuation of Therapy Criteria:**  
   All of the following must be met:  
   1. Patient has experienced normalization of serum phosphate while on therapy.  
   2. Patient has experienced a positive clinical response to Crysvita evidenced by increased serum phosphorus levels, a reduction in serum total alkaline phosphate activity, improvement in symptoms (e.g., increased height velocity, reduction of generalized bone pain) and/or improvement in radiographic imaging of Rickets/osteomalacia.  
   **Continuation of Therapy Length of Approval: 1 year**
References:

Approved by the P&T Committee 07/18/2018.

- **Cyramza (ramucirumab)**
  Indication for Approval:
  1. As a single agent or in combination with paclitaxel, for the treatment of advanced gastric or gastro-esophageal junction adenocarcinoma, with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy.
  2. In combination with docetaxel, for treatment of metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza.
  3. In combination with FOLFIRI, for the treatment of metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.

  Code: J9308 5mg = 1 billable unit

  Approved by the P&T Committee 07/16/2014. Updated 01/21/2015.

- **CytoGam (Cytomegalovirus Immune Globulin)**
  Indications for Approval:
  1. Prevention of cytomegalovirus (CMV) disease in members undergoing transplantation of kidney, lung, liver, pancreas, or heart.
  2. Prevention of CMV in recipients of a bone marrow allograft.
  3. Treatment of CMV pneumonitis in combination with ganciclovir in recipients of a bone marrow allograft.

  Approval Length: One year (for all above diagnoses).

  Code: J0850 1 vial = 1 billable unit

  Approved by the P&T Committee 05/21/2008.

- **Daliresp (roflumilast)**
  Indications for Approval (must meet all of the following):
  1. Patient must be 18 years of age or older.
  2. Patient must have a diagnosis of severe COPD with chronic bronchitis (GOLD Stage III or worse) and documentation of continued exacerbations in the last 6 months.
  3. Severe COPD is defined by the GOLD guidelines as FEV1 < 50% predicted.
4. Patient must be currently receiving two standard treatments for severe COPD (i.e. long-acting B-agonist, long-acting anticholinergic, short-acting anticholinergic).

Quantity Limit: 30 tablets for 30 days.

References:
2. Daliresp® (roflumilast) prescribing information; February 2011.

Approved by the P&T Committee 01/18/2012.

- **Darzalex (daratumumab)**
  Refer to the Oncology criteria located within this document.

  Approval: 6 months

  Approved by the P&T Committee: 10/16/2019.

  | Code: J9145 | 10 mg = 1 billable unit |

- **Daurismo (glasdegib)**
  Refer to the Oncology criteria located within this document.

  Quantity limit:
  - 100 mg tablets: 30 tablets for 30 days
  - 25 mg tablets: 60 tablets for 30 days

  Approval: 6 months

  Approved by the P&T Committee 01/17/2019

- **Delatestryl (testosterone enanthate injection)**
  Refer to the Testosterone products, Preferred Criteria located within this document.

  Approval: 1 year.

  | Code: J3121 | 1mg = 1 billable unit |

  Approved by the P&T Committee 09/16/2009. Revised 05/18/2011 and 10/15/2014.

- **Delzicol (mesalamine)**
  Step Edit Criteria:
  - The patient must have a claim history of a 30-day trial of balsalazide or sulfasalazine within the past 120 days.
  - Alternatives: balsalazide, sulfasalazine

  Approved by the P&T Committee 11/06/2013.

- **Depen (penicillamine tablets)**
  Indications for Approval:
  - The appropriate Disease Specific Criteria below has been met:
  - a. **Wilson’s Disease**
  - The patient has a documented diagnosis of Wilson’s Disease.
b. **Cystinuria**
   All of the following must be met:
   
i. The patient has a documented diagnosis of cystinuria.
   
ii. The patient has a documented trial and failure of conservative therapy which includes the following: high fluid intake, sodium and protein restriction, and urinary alkalinization (e.g., use of postassium citrate).
   
iii. The patient must have had an adequate trial and failure (3 months or more) or intolerance to Thiola (tioprinin).

**Cystinuria Continuation of Therapy Criteria:**
   Documentation that there has been a decrease in stone formation must be provided.

Quantity limit: 240 tablets per 30 days.

Length of Approval:
   - Wilson’s Disease: 1 year.
   - Cystinuria: 6 months

References:

Approved by the P&T Committee 07/18/2018.

- **Depo-Testosterone (testosterone cypionate injection)**
  Refer to the [Testosterone products, Preferred](#) Criteria located within this document.

  Approval: 1 year.

| Code: J1071 | 1mg = 1 billable unit |

Approved by the P&T Committee 09/16/2009. Revised 05/18/2011 and 10/15/2014.

- **Detrol/Detrol LA (tolterodine/tolterodine ER)**
  Step Edit Criteria:
   The patient must have a prescription claim history of generic oxybutynin, oxybutynin XL, or oxybutynin transdermal (Oxytrol® for Women) within the past 545 days.

  Quantity Limit: 30 tablets for 30 days.

  Alternatives: oxybutynin, oxybutynin XL, oxybutynin transdermal (Oxytrol® for Women).

  Approved by the P&T Committee 10/15/2014.

- **Dexferrum (iron dextran)**
  Refer to the [Intravenous Iron](#) criteria located within this document.

| Code: J1750 | 50mg = 1 billable unit |

Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- **Diastat (diazepam) Rectal Gel**
Step Edit Criteria (for patients 18 years old and up):

The patient must have a claim history within the past 120 days of a 30-day fill of an anti-epileptic agent.

Quantity Limit: 5 for 30 days.

Approved by the P&T Committee 05/19/2010. Updated 04/15/2015.

- **Differin 0.1% (adapalene) OTC Gel**
  See the [Retinoids, Topical](#) criteria located within this document.
  Approved by the P&T Committee 10/18/2017.

- **Dificid (fidaxomicin)**
  Indications for Approval:
  1. A diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)
  2. A documented trial and failure of oral vancomycin* in a tapered and/or pulsed regimen

  * Compounded vancomycin oral suspension is available on all of the PHP formularies.

  Quantity Limit: 20 tablets for 30 days.
  Approved by the P&T Committee 07/20/2011.

  Criteria based on:
  Cohen SH, Gerding DN, Johnson S, Kelly C, Loo VG, McDonald LC, Pepin J, and Wilcox MH. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol.* 2010; 31(5).

- **Diovan HCT (valsartan/hydrochlorothiazide)**
  Step Edit Criteria:
  The patient must have a claim history within the past 180 days of a formulary ACE Inhibitor, or ACE inhibitor/diuretic combination.

  Alternatives: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, benazepril/HCTZ, enalapril/HCTZ, fosinopril/HCTZ, lisinopril/HCTZ, moexipril/HCTZ, quinapril/HCTZ. HCTZ= hydrochlorothiazide

- **Dipeptidyl Peptidase 4 (DPP-4) Inhibitors**
  *Note: Commercial and Health Ins. Exch plans cover alogliptin, alogliptin/metformin, Januvia and Janumet. Medicaid plans cover alogliptin and alogliptin/metformin.*
  Step Edit Criteria:
  The member must have a 30-day prescription fill of metformin within the past 545 days.
• **Dolophine (methadone tablets)**
  Indications for Approval:
  For the treatment of pain.
  Exclusions:
  Methadone is excluded from coverage for use in drug treatment programs (Medical Assistance Division [MAD] Policy Manual 8.324.4.14).
  Quantity Limit: 180 tablets for 30 days.
  Approval: 6 months
  Approved by the P&T Committee 05/19/2004

• **Duetact (pioglitazone/glimepiride)**
  Step Edit Criteria:
  The patient must have previous use of at least one of the medications (pioglitazone or glimepiride) that make up the combination medication within past 120 days.
  Alternatives: pioglitazone, glimepiride.
  Approved by the P&T Committee 09/17/2008.

• **Duragesic Patch (fentanyl transdermal)**
  Step Edit Criteria:
  The patient must have a claim history of morphine sulfate extended release tablets (MS Contin) within the past 90 days.
  Approved by the P&T Committee 09/19/2007. Updated by P&T Committee 07/15/2009.

• **Dysport (abobotulinumtoxinA)**
  Indications for Approval:
  1. Cervical Dystonia
  2. Upper limb spasticity in the following muscle groups: biceps brachii, brachialis, brachioradialis, flexor carpi radialis or ulnaris, flexor digitorum profundus or superficialis, pronator teres in accordance with approved dosages listed in prescribing information for each muscle group.
  3. Lower limb spasticity in the following muscle groups: flexor digitorum longus, flexor hallucis longus, gastrocnemius medial head or gastrocnemius lateral head, soleus, tibialis posterior in accordance with approved dosages listed in prescribing information for each muscle group.
  4. Pediatric lower limb spasticity (ages 2 and older) in accordance with approved dosage listed in the prescribing information.
  Exclusions:
  The use of Dysport for improving the appearance of glabellar lines will not be approved as this is a cosmetic use and benefit exclusion.
  Approval: 1 year.
• **Edecrin (ethacrynic acid)**
  Indications for Approval:
  - The patient must have a documented sulfa allergy
  - Or
  - The patient must have failed a 30-day trial of bumetanide, furosemide, or torsemide*
  
  *Note: torsemide is non-formulary on Centennial Care plans.
  
  Approved by the P&T Committee 07/19/2017.

• **Effient (prasugrel)**
  Indications for Approval (all of the following must be met):
  1. Must be prescribed by a cardiologist.
  2. The patient must have acute coronary syndrome (ACS) and will be managed with percutaneous coronary intervention (PCI) as follows:
     - Patients with unstable angina or NSTEMI
     - OR
     - Patients with STEMI when managed with primary or delayed PCI
  3. Patient must be < 75 year of age unless high risk.
  4. Patient must weigh more than 60 kg
  
  **AND one** of the following must be met:
   a. Documented allergy to clopidogrel (Plavix®), such as a rash.
     - OR
   b. Documented treatment failure with clopidogrel (Plavix®).
     - OR
   c. Patient is considered to be high risk. Examples include:
      - Patient is a diabetic
      - Complex PCI patient with multiple overlapping stents and/or bifurcation stenting
      - Patient has documented severe renal impairment.
  
  Approval Length: To be determined based on the patient’s clinical needs.

References:

2. Effient [package insert]. Indianapolis, IN; Daiichi Sankyo, Inc. and Eli Lilly and Company; July 2009.


Approved by the P&T Committee 11/17/2010.

- **Elidel (pimecrolimus cream)**
  Step Edit Criteria:
  
  The patient must have previous use of at least one formulary topical corticosteroid within the past 90 days.


- **Elmiron (pentosan)**
  Indications for Approval (all of the following must be met):
  1. Documented diagnosis of interstitial cystitis.
  2. Documented trial and failure or intolerance to a 30-day trial of amitriptyline.

  Length of Approval: 6 months.

  **Continuation of Therapy**: Documentation of improvement in pain.

  Quantity Limit: 90 tablets for 30 days.

  Approved by the P&T Committee 01/21/2015.

- **Emcyt (estramustine)**
  Refer to the Oncology criteria located within this document.

  Specialty Pharmacy required.

  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Emend Capsules (aprepitant)**
  Indications for Approval:
  1. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone.

  **AND**

  2. Must meet one of the following criteria:
   - The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential.
   - The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination.
The patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.

Approval Length: Six (6) months.

Quantity Limit:
- 40mg - 1 capsule for a prescription fill
- 80mg – 3 capsules for a prescription fill
- 125mg – 1 capsule for a prescription fill
- 80/125mg pack – 1 package (contains 3 capsules) for a prescription fill.

Alternatives: promethazine, prochlorperazine, ondansetron.

Updated by the P&T Committee 10/19/2016 and 4/19/2017.

**Emend Injection (fosaprepitant)**

Indications for Approval:
1. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone.
   AND
2. Must meet one of the following criteria:
   - The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential.
   - The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination.
   - The patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.

Approval Length: Six (6) months.
Quantity Limit: 4mL (4 vials) for 30 days.

| Code: J1453 | 1mg = 1 billable unit |

Approved by the P&T Committee 05/19/2010. Updated 10/19/2016.

**Emend Oral Suspension (aprepitant)**

Indications for Approval:
1. The patient must be 12 years of age or younger or the patient must be unable to take or swallow Emend capsules.
   AND
2. The patient must be receiving Emend in combination with a 5-HT3 antagonist and dexamethasone.
   AND
3. Must meet one of the following criteria:
   - The patient is being treated with a cancer chemotherapy regimen which has high emetogenic potential
The patient is being treated with a cancer chemotherapy regimen which includes an anthracycline and cyclophosphamide in combination.

The patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.

Quantity Limit: Six (6) kits for 28 days.

Approved by the P&T Committee 10/19/2016.

**Empliciti (elotuzumab)**

Refer to the [Oncology](#) criteria located within this document.

| Code: J9176 | 1 mg = 1 billable unit |

Approved by the P&T Committee 01/17/2019

**Emsam Patch (selegiline patch)**

Indications for Approval:

1. The patient must have a diagnosis of major depressive disorder.
2. The patient is 18 years of age or older.
3. The prescription must be prescribed by a psychiatrist.
4. The patient is symptomatic despite treatment with maximum dose of:
   a. Two different SSRIs (citalopram, fluoxetine, sertraline, paroxetine), and
   b. One SNRI (venlafaxine), and
   c. One miscellaneous antidepressant (bupropion, mirtazapine).

Approval: One year.

Quantity Limit: 30 patches per 30 days.

Alternatives: citalopram, escitalopram, fluoxetine, sertraline, paroxetine, venlafaxine, bupropion, mirtazapine.

**Enbrel (etanercept)**

Criteria dependent on diagnosis

Indications for Approval:

1. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy.
2. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.
3. The appropriate Disease Specific Criteria below has been met.

The patient has a diagnosis of one of the following:
a. Ankylosing Spondylitis
   i. Prescribed by or in consultation with a rheumatologist
   ii. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID), or such treatment is contraindicated or not tolerated.
   iii. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated.
   iv. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Enbrel without a trial of sulfasalazine

b. Polyarticular Juvenile Idiopathic Arthritis
   i. Prescribed by or in consultation with a rheumatologist
   ii. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.
   iii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.
      ▪ Gold Salt
      ▪ Hydroxychloroquine
      ▪ Leflunomide
      ▪ Minocycline
      ▪ Sulfasalazine

c. Psoriatic Arthritis
   i. Prescribed by or in consultation with a dermatologist or rheumatologist
   ii. The has an adequate trial (3 months or more) of one of the following DMARDs:
      ▪ Cyclosporine
      ▪ Leflunomide
      ▪ Methotrexate
      ▪ Sulfasalazine

d. Rheumatoid Arthritis
   AND meets all of the following:
   i. Prescribed by or in consultation with a rheumatologist
   ii. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as: DAS-28 >3.2 or CDAI >10.1.
iii. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.

iv. The patient must have had an adequate trial (3 months or more) of one of the following DMARDs:
   - Azathioprine
   - Gold Salt
   - Hydroxychloroquine
   - Leflunomide
   - Methotrexate
   - Minocycline
   - Sulfasalazine

e. **Plaque Psoriasis**
   
   AND meets all the following:
   
   i. Prescribed by or in consultation with a dermatologist
   
   ii. The patient must have > 10% of their body surface area (BSA) affected by plaque psoriasis (or > 5% of BSA if psoriasis affects hands, feet, face or genitals).
   
   iii. A Psoriasis Area Severity Index (PASI) score ≥ 10 and/or a Dermatology Life Quality Index (DLQI) of ≥ 10.

   The patient has failed to adequately respond to, or is intolerant to a 3-month trial of one of the following:
   - phototherapy or photochemotherapy,
   - methotrexate

4. Medical records or a typed summary documenting all the above criteria must be submitted along with the Pharmacy Exception request.

5. **Continuation Criteria:** Documents showing benefit with treatment

**Quantity Limit:**
   
   - Ankylosing Spondylitis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis, or Pediatric Plaque Psoriasis: 4 auto-injectors, cartridges, syringes, or vials for 28 days.
   
   - Adult Plaque Psoriasis: 8 auto-injectors, cartridges or syringes for 28 days for the first three months, then 4 auto-injectors, cartridges or syringes for 28 days thereafter.

*Specialty Pharmacy required.

Approval Length: One year (for all the above diagnoses).

Updated by the P&T Committee 01/21/2009, 11/06/2013, 07/16/2014, 11/06/2015, 04/19/2017, 07/19/2017 04/18/2018, 01/15/2020.

- **Entresto (sacubitril-valsartan)**

  Indications for Approval:
  
  All of the following must be met:
1. The medication is being initiated by a cardiologist or in consultation with a cardiologist.
2. The patient is 18 years of age or older.
3. The patient has a documented diagnosis of NYHA Class II-III heart failure with a LVEF ≤ 40%.
4. The patient has a systolic blood pressure ≥ 95 mmHg.
5. The patient has an eGFR ≥ 30 mL/min/1.73 m².
6. The patient is receiving therapeutic, or maximally tolerated, doses of standard therapies for heart failure and has recent laboratory documentation of a BNP ≥ 150 pg/mL (or NT-pro-BNP ≥ 600 pg/mL) OR a BNP ≥ 100 pg/mL (or NT-pro-BNP ≥ 400 pg/mL) if the patient has been hospitalized for heart failure in the past 12 months.
7. The patient is receiving a stable dose (i.e., ≥ 4 weeks) of an ACEI or ARB equivalent to at least enalapril 10 mg per day. NOTE: Entresto is meant to replace an ACE inhibitor or ARB and use of an ACE inhibitor or ARB should not be continued along with Entresto.

Quantity Limit: 60 tablets for 30 days.

Approval Length: One year.

Approved by the P&T Committee 10/19/2016.

References:
4. Colucci WS. Pharmacologic therapy in heart failure with reduced ejection fraction. In UpToDate, Gottlieb, SS (Ed), UpToDate, Waltham, MA. (Accessed on September 26, 2016.)

- **Epaned (enalapril maleate oral solution)**
  Indications for Approval:
  The following criteria apply to patients greater than 12 years of age:
  - The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.

  Approved by the P&T Committee: 04/26/2019

- **Erivedge (vismodegib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 30 tablets for 30 days.
Specialty Pharmacy required.
Approved by the P&T Committee 03/21/2012. Updated 11/05/2015.

- **Erleada (apalutamide)**
  Refer to the Oncology criteria located within this document.
  Quantity limit: 120 tablets for 30 days
  Approval: 6 months
  Approved by the P&T Committee 04/18/2018

- **Erwinaze (asparaginase Erwinia chrysanthemi)**
  Refer to the Oncology criteria located within this document.
  | Code: J9019 | 1000 I.U. = 1 billable unit |
  Approved by the P&T Committee 01/18/2012. Updated 11/05/2015.

- **Erythromycin Ethylsuccinate Granules For Oral Suspension (EryPed, E.E.S. granules)**
  **Indications for Approval:**
  The following criteria apply to patients greater than 12 years of age:
  - The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.
  Length of Approval: One course of therapy
  Approved by the P&T Committee 07/18/2018.

- **Erythropoiesis-Stimulating Agents (Aranesp/darbepoetin, Epogen and Procrit/epoetin alfa, Retacrit/epoetin alfa-epbx)**
  *Note: Retacrit (epoetin alpha-epbx) is the formulary preferred epoetin product.*
  *Coverage of Epogen or Procrit will require a documented trial and failure or intolerance to Retacrit.*
  **Indications for Approval:**
  1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.
     a) The maximum dose for the first 4 weeks of treatment is 9 mcg/kg.
     b) Hemoglobin must be <11g/dl.
  2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.
     a) The maximum dose for the first 4 weeks of treatment is 9 mcg/kg.
     b) Hemoglobin must be <11g/dl.
  3. Anemia due to HCV Treatment:
     a) Recent (within 2-3 weeks) hemoglobin <10g/dl AND
     b) Persists for at least 2 weeks after ribavirin dose reduction (may be reduced in 200mg incremental reductions or one-time reduction to 600mg/day) OR
Patient is receiving peginterferon/ribavirin alone with documented evidence that the patient is post-liver transplantation or HIV/HCV co-infected.

The use of these products is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following:

- Aplastic anemia
- B-12 and folate deficiency anemias
- Iron deficiency anemia
- Post-hemorrhagic anemia

Exceptions: Exceptions to the above conditions of coverage are considered through the Medical Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

**Aranesp Billing Code:**

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<td>1mcg (0.001mg) = 1 billable unit</td>
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<tr>
<td>J0882 (ESRD on dialysis)</td>
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**Epogen Billing Codes:**

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<td>Q4081 (ESRD on dialysis)</td>
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**Procrit Billing Codes:**

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Approved by the P&T Committee 07/16/2008. Updated 07/20/2011, 01/15/2014, and 07/18/2018

**Ethylol (amifostine)**

Indications for Approval:

All FDA-approved indications

1. Reduction of renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer.
2. Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancers when the radiation port includes a substantial portion of the parotid glands.

Specialty Pharmacy required.

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Approved by the P&T Committee 07/20/2011.
• **Euflexxa (sodium hyaluronate 1%)**  
  Refer to the Viscosupplementation Criteria located within this document.  
  Quantity Limit: one series of injections.  
  Specialty Pharmacy required.  
| Code: J7323 | 1 injection = 1 billable unit |

Approved by the P&T Committee 01/15/2014. Updated 04/15/2015.

• **Evomela (melphalan)**  
  Refer to the Oncology criteria located within this document.  
  Specialty Pharmacy required.  
  Approved by the P&T Committee 07/20/2016.

• **Exelon (rivastigmine)**  
  Indication for Approval:  
  Member must have a documented trial and failure of formulary preferred cholinesterase inhibitors, donepezil and galantamine.  
  Approval Length: 1 year  
  Quantity Limit: 30 per 30 days  
  Approved by the P&T Committee: 07/17/2019.

• **Extavia (interferon beta-1b)**  
  Indications for Approval:  
  1. The patient must have a documented failure or contraindication to Avonex and Glatopa or is new to Presbyterian and is currently taking Extavia.  
  2. The initial prescription is prescribed by a neurologist.  
  Approval: One year.  
  Alternatives: Avonex, Glatopa

• **Famvir (famciclovir)**  
  Step Edit Criteria:  
  The patient must have a history of TWO claims for acyclovir within the past 120 days.  
  Approved by the P&T Committee 01/17/2019.

• **Fareston (toremifene)**  
  Refer to the Oncology criteria located within this document.  
  Quantity Limit: 30 tablets for 30 days.  
  Specialty Pharmacy required.  
  Approved by the P&T Committee 09/21/2011. Revised 10/15/2014 and 11/05/2015.

• **Farydak (panobinostat)**
Refer to the Oncology criteria located within this document.
Approved by the P&T Committee 04/15/2015. Updated 11/05/2015.

- **Fazaclo (clozapine ODT)**
  Indications for Approval:
  1. A psychiatrist must initiate therapy.
     AND
  2. The patient is unable to take or swallow oral medication. They should not be on other oral medications.
     OR
     The patient is “cheeking” the medication (cheeking is considered not swallowing the medication then spitting it out when the caregiver is not looking).

Quantity Limit:
- 12.5mg – 60 tablets for 30 days
- 25mg – 180 tablets for 30 days
- 100mg – 270 tablets for 30 days

Alternative: clozapine tablets
Approved by the P&T Committee 07/17/2013.

- **Feraheme (ferumoxytol)**
  Refer to the Intravenous Iron criteria located within this document.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Unit</th>
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<tbody>
<tr>
<td>Q0138 (non-ESRD use)</td>
<td>1mg = 1 billable unit</td>
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<tr>
<td>Q0139 (ESRD on dialysis)</td>
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Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- **Ferrlecit (sodium ferric gluconate complex)**
  Refer to the Intravenous Iron criteria located within this document.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Unit</th>
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<tr>
<td>J2916</td>
<td>12.5mg = 1 billable unit</td>
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Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- **Finacea (azelaic acid 15%) gel and foam**
  Step Edit Criteria:
  
  The patient must have a prescription claim history of metronidazole topical within the past 120 days.

Alternative: metronidazole 0.75% topical
Approved by the P&T Committee 04/20/2016

- **Firazyr (icatibant)**
  Note: covered product is the authorized generic for Firazyr
  Indications for Approval (all of the following must be met):
  1. Must be at least 18 years of age

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2. Must meet ALL clinical criteria for hereditary angioedema (HAE).
3. Must be using for ‘on-demand’ treatment
4. Must have a contraindication to Berinert.

Approval: 4 months then re-evaluate for prophylaxis therapy

Specialty Pharmacy: Briova

References:


Approved by the P&T Committee 09/19/2012. Updated: 10/16/2019.

- Firdapse (amifampridine)
  Indications for Approval:
  All of the following must be met:
  1. Prescriber is a neurologist
  2. Patient must be 18 years or older
  3. Documentation of clinical symptoms suggestive of LEMS such as:
     ▪ proximal weakness affecting legs, difficulty standing
     ▪ eyes: dry eyes, delayed pupil reaction to light, ptosis, diplopia
     ▪ face: eyelid elevation
     ▪ throat: difficulty swallowing, difficulty chewing
  4. Documentation of confirmatory diagnostic test results including:
     ▪ Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise
     OR
     ▪ Positive anti-P/Q type voltage-gated calcium channel antibody test
  5. Documentation of a failed trial of pyridostigmine

Continuation of Therapy Criteria:

  1. Documentation of clinical improvement in symptoms

Initial Approval Length: three (3) months
Continuation Approval Length: six (6) months
Quantity Limit: 240 tablets per 30 days.
Specialty Pharmacy required
Approved by the P&T Committee 01/17/2019
References:

- **fluticasone/salmeterol (Advair authorized generic or Wixela)**
  Indications for Approval:
  100mcg and 250mcg Diskus *(only covered for patient under the age of 12)*
  1. Patient must be under the age of 12.
  AND
  2. Must have a prescription claim history of a formulary preferred inhaled corticosteroid (ICS) within the past 150 days or FEV1 less than 50%.
  1. **500mcg Diskus**
  1. Must have a prescription claim history of either mometasone/formoterol MDI (Dulera)* or budesonide/formoterol MDI (Symbicort)* within the past 150 days.
  *Step Edit criteria requirement.
  **OR**
  2. Patient is under the age of 12 and has a documented trial and failure of an orally inhaled corticosteroid or FEV1 of less than 50%.
  Quantity limit: One inhaler for 30 days.
  Approved by the P&T Committee 04/24/2019

- **Focalin (dexmethylphenidate IR tablets)**
  Note: for ages 19 and up, The Cerebral Stimulant/ADHD Treatment criteria also apply.
  **Step Edit Criteria (for patients under the age of 19):**
  The patient must have a prescription claim history for methylphenidate (IR or ER) within the past 180 days.
  **Indications for Approval (for patients age 19 and up):**
  1. Cerebral Stimulant/ADHD Treatment criteria apply.
  2. The patient must have a documented trial and failure of methylphenidate (IR or ER).
  Quantity limit: 60 tablets for 30 days.
  Approved by the P&T Committee 04/19/2017

- **Focalin XR (dexmethylphenidate XR capsules)**
  Note: for ages 19 and up, The Cerebral Stimulant/ADHD Treatment criteria also apply.
  **Step Edit Criteria (for patients under the age of 19):**
The patient must have a prescription claim history for methylphenidate (IR or ER) within the past 180 days.

**Indications for Approval (for patients age 19 and up):**

1. **Cerebral Stimulant/ADHD treatment** criteria apply.
2. The patient must have a documented trial and failure of methylphenidate (IR or ER).

**Quantity Limit:** 30 capsules for 30 days.

Approved by the P&T Committee 04/19/2017

**Forteo (teriparatide)**

**Indications for Approval:**

1. Treatment of postmenopausal women with osteoporosis and at high risk for fracture.
2. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
3. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

**AND all of the following must be met:**

a. Has a T-score of the hip, spine, or radius ≤ -2.5 as evidenced by a bone density scan.

**OR**

Has a 10-year hip fracture probability ≥ 3% or a 10-year major osteoporosis-related fracture probability of ≥ 20% based on the US-adapted WHO absolute fracture risk model, FRAX®, available at [http://www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)

b. Inadequate response to, or is unable to tolerate one oral and an intravenous bisphosphonate or a creatinine clearance (CrCl) of less than 35mL/min.

- Inadequate response is defined as progression of bone loss as determined by DEXA scan or occurrence of an osteoporotic fracture after having been on at least one year of drug therapy.

**Note:** A trial and failure of an intravenous bisphosphonate only will be required if a patient has a relative or absolute contraindication to bisphosphonate therapy such as an increased risk for upper gastrointestinal injury due to a comorbid condition (e.g. esophageal mobility disorder, Barrett’s esophagus), a physical condition (e.g. unable to sit up for the required time period following oral dosing) or a nonfunctional gastrointestinal tract (e.g. enteral feedings via gastric or jejunostomy tube).

Patients with severe systemic reactions (i.e. severe musculoskeletal pain) to one bisphosphonate (IV or oral) will not be required to have an additional bisphosphonate trial.

c. Inadequate response to, or is unable to tolerate Prolia (denosumab).
Note: Patients with severe osteoporosis (T-score ≤ -2.5 with a history of a fragility fracture OR T-score ≤ -3.5) will not be required to have a trial and failure of Prolia.

d. For treatment of postmenopausal women at high risk for fracture patient must also have an inadequate response to, or is unable to tolerate Tymlos (abaloparatide).

Length of Approval: 1 year. Please note parathyroid hormone (PTH) analogs should not be used for more than 2 years. Cumulative use of PTH analogs for greater than 2 years will not be approved.

*Specialty Pharmacy required.

References:
1. Rosen, Harold and Drezner, Marc. Overview of the management of osteoporosis in postmenopausal women. In Up-To-Date, Version 56.0; Waltham, MA. 2018.
2. Rosen, Clifford. Parathyroid hormone/parathyroid hormone-related protein analogs for osteoporosis. In Up-To-Date, Version 21; Waltham, MA. 2018.

Updated by the P&T Committee 07/18/2018.

- **Fortesta (testosterone topical gel)**
  Refer to the Testosterone Products, Non-Preferred Criteria located within this document.
  Approval: 1 year.
  Quantity Limit: two (2) canisters (120 g) for 30 days.
  Approved by the P&T Committee 05/18/2011.
  Revised 07/17/2013 and 10/15/2014.

- **Fragmin (dalteparin)**
  Indications for Approval:
  1. Approved for FDA labeled indications only AND
  2. The patient must have a documented trial and failure of, or clinical reason for avoidance of enoxaparin.
  Quantity Limit: 30ml for 30 days.
  Alternative: enoxaparin
  Approved by the P&T Committee 07/17/2013.

- **Fulphila (pegfilgrastim-jmdb)**
  Refer to the Granulocyte-Colony Stimulating Factors Criteria located within this document.
  Code: Q5108
  0.5 mg = 1 billable unit
  Approved by the P&T Committee 10/17/2018.

- **Gamifant (emapalumab-lzsg)**
Indications for Approval:
All of the following must be met:

1. Primary hemophagocytic lymphohistiocytosis (HLH) based on a molecular diagnosis or family history consistent with primary HLH or 5 out of the 8 criteria fulfilled:
   - Fever
   - Splenomegaly
   - Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin < 9, platelets <100 x 10⁹/L, neutrophils <1 x 10⁹/L
   - Hypertriglyceridemia (fasting triglycerides >3 mmol/L or ≥265 mg/dL) and/or hypofibrinogenemia(≤1.5 g/L)
   - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
   - Low or absent NK-cell activity
   - Ferritin ≥ 500 mcg/L,
   - Soluble CD25 ≥ 2400 U/mL

2. Evidence of active disease as assessed by treating physician

3. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy based on one of the following criteria:
   - Having not responded or not achieved a satisfactory response
   - Having not maintained a satisfactory response to conventional HLH therapy
   - Intolerance to conventional HLH treatments

4. Patients does not have active infections caused by specific pathogens favored by IFNγ neutralization (e.g., mycobacteria and Histoplasma Capsulatum)

5. Gamifant will be administered concomitantly with dexamethasone

Continuation of Therapy Criteria:

1. Documentation of clinical improvement in symptoms.

Initial Approval Length: two (2) months
Continuation Approval Length: three (3) months
Approved by the P&T Committee 01/17/2019.

- **Gazyva (obinutuzumab)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  | Code: J9301 | 10mg = 1 billable unit |

Approved by the P&T Committee 01/15/2014. Updated 11/05/2015.

- **Gel-One (cross-linked hyaluronate)**
  Refer to the Viscosupplementation Criteria located within this document.
  Quantity Limit: 1 dose to knee.
Specialty Pharmacy required.

Code: J7326  
30mg (one dose) = 1 billable unit

Approved by the P&T Committee 12/12/2016.

- Gender Dysphoria Treatment (GNRH Analogs and Cross-Sex Hormones)
  
  Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.

  Indications for Approval:
  
  ▪ As a continuous therapy for Gender Dysphoria in Children and Adolescents.
    1. Treatment with Gonadotropin-Releasing Hormone (GNRH) Analogs (e.g. Lupron, Lupron Depot, Lupron Depot-Ped) - all of the following must be met:
      a. The patient’s insurance benefit includes coverage for the treatment of gender dysphoria.
      b. The drug must be initiated by a pediatric endocrinologist.
      c. The diagnosis of gender dysphoria must be made by a mental health professional with training in child and adolescent developmental psychology and psychopathology and the patient must fulfill DSM-5 criteria.
      d. The patient has experienced puberty to at least Tanner stage 2.
      e. Early pubertal changes have resulted in an increase of the patient’s gender dysphoria.
      f. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
      g. Documentation that the patient will receive psychological and social support during treatment must be provided.
      h. Documentation that the patient has been counseled on the expected outcomes of GNRH analog treatment, the possible side effects of therapy and has provided informed consent before treatment is started.
    2. Cross-Sex Hormone Treatment – all of the following must be met:
      a. The patient’s insurance benefit includes coverage for the treatment of gender dysphoria.
      b. The patient has fulfilled the criteria for GNRH Analog treatment listed above.
      c. The patient is at least 16 years of age or older.
  
  ▪ As a continuous therapy for Gender Dysphoria in Adults (age 18 and over).
    1. Cross-Sex Hormone Treatment - all of the following must be met:
      a. The patient’s insurance benefit includes coverage for the treatment of gender dysphoria.
      b. The patient meets DSM-5 criteria for diagnosis of persistent gender dysphoria documented by a qualified licensed mental health professional experienced in the field;
        ▪ If significant medical or mental health concerns are present, there must be documentation that they are well controlled.
c. One of the following:
   i. Patient has lived as their chosen or reassigned gender full-time for 12 months or more;
   ii. Treatment plan documents that the patient will live as their reassigned gender full-time for a minimum of 12 months while concurrently receiving continuous hormone therapy;
   iii. Patient has completed gender transition and requires continued hormone therapy to maintain physical characteristics more congruent with their gender identity.

Exclusions:
1. Due to a lack of controlled evaluations in females and the potential for virilizing effects, testosterone products will not be approved for use in females who do not meet criteria for gender dysphoria.
2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approved by the P&T Committee 10/15/2014. Revised 07/20/2016.

- **Gilotrif (afatinib)**
  Refer to the **Oncology** criteria located within this document.
  Quantity Limit: 30 tablets for 30 days.
  Approved by the P&T Committee 11/6/2013. Updated 10/15/2014 and 11/05/2015.

- **Gleevec (imatinib)**
  Indications for Approval:
  Refer to the **Oncology** criteria located within this document.
  Continuation Criteria:
  All of the following must be met:
  1. Documentation that the patient does not have evidence of disease progression must be submitted.
  2. Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.
  Approval Length: Six (6) months.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 03/20/2013, 11/05/2015 and 04/18/18.

- **GLP-1 Agonists (Trulicity, Victoza)**
  *Note: Coverage of Victoza (liraglutide) requires a documented trial and failure or intolerance to Trulicity (dulaglutide).*
  Indications for Approval:
  1. Diagnosis of Diabetes Mellitus Type 2.
  2. The patient has a recent (within the past 3 months) documented hemoglobin A1c (A1c) level of < 11 AND one of the following:
a. The patient is concurrently taking a metformin product and has inadequate glycemic control after a trial at a therapeutic dose and requires the addition of another agent, or
b. Is unable to take a metformin product due to one of the following:
   - Documented intolerance to metformin. Examples of intolerance include diarrhea after titration up to a therapeutic dose ≥ 2000mg daily.
   - Documented renal disease or renal dysfunction. For example, serum creatinine levels ≥ 1.5mg/dl (males) or ≥ 1.4mg/dl (females).
   - Documented hepatic disease. For example, cirrhosis or hepatitis.

Continuation of Therapy Criteria:
1. A1c must decrease by 0.5% if initial A1c is ≤ 8%.
2. A1c must decrease by 1% if initial A1c is > 8%.
3. If the A1C value has not decreased according to the protocol listed below, then interventional measures will be taken which may include some or all of the following actions:
   - Referral of the member to the PHP disease management team.
   - Denial of the request with suggested alternative medications.
   - Request for chart notes that describe the treatment plan and/or discussion with the prescribing provider about the treatment plan for the member.

Initial Approval Length: 6 months.
Continuation Approval Length: 1 year.
Approved by the P&T Committee 11/28/2007.
Revised by the P&T Committee 03/24/2010, 07/19/2017 and 04/18/2018.

- **Granix (tbo-filgrastim)**
  Refer to the [Granulocyte-Colony Stimulating Factors](#) Criteria located within this document.

<table>
<thead>
<tr>
<th>Code</th>
<th>1mcg = 1 billable unit</th>
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<tbody>
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<td>J1447</td>
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Approved by the P&T Committee 01/15/2014. Updated 04/15/2015.

- **Granulocyte-Colony Stimulating Factors (Granix/tbo-filgrastim, Fulphila or Neulasta OnPro/pegfilgrastim, Neupogen/filgrastim and Zarxio/filgrastim-sndz)**
  Note: Fulphila injection and Neulasta OnPro are the preferred pegylated G-CSF agents. Neulasta injection is non-formulary on all plans. Zarxio is the formulary preferred non-pegylated G-CSF agent. A documented trial and failure or intolerance to Zarxio will be required for coverage of Granix or Neupogen.

Indications for Approval
1. Cancer patients receiving myelosuppressive therapy.
2. Patients with acute myeloid leukemia receiving induction or consolidation chemotherapy.
3. Cancer patients receiving bone marrow transplant.
4. Patients undergoing peripheral blood progenitor cell collection and therapy.
5. Patients with severe chronic neutropenia (cyclic or idiopathic) that meets the following criteria:
   - Documentation that the patient is symptomatic with at least three clinically significant infections treated with antibiotics or one life-threatening infection treated with IV antibiotic therapy during the previous 12 months.
   - **AND** one of the following:
     - a) Documented diagnosis of severe chronic neutropenia (idiopathic) with an ANC of less than 500/mm³ on three separate occasions over the previous 6 months.
     - **OR**
     - b) Documented diagnosis of severe chronic neutropenia (cyclic) with five consecutive days per cycle with an ANC less than 500/mm³ for each of 3 regularly spaced cycles over a 6-month period.
6. Patients with severe chronic neutropenia (congenital) that have a documented diagnosis of congenital neutropenia.
7. Neulasta OnPro Criteria:
   - a. All FDA-Approved indications
   - b. Billed with one of the following Diagnosis codes: CØØ.Ø- D49.9, Z51.89

**Compendial Uses:** Non-FDA-approved uses that are considered to be “medically-accepted indications” based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment for a compendial use will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

**Exceptions:** Other medical conditions or exceptions to the above conditions of coverage will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

**Approval Length:** For severe chronic neutropenia – one year.

**Billing Code for Granix:**

| Code: J1446 | 5mcg = 1 billable unit |

**Billing Code for Neulasta OnPro:**

| Code: J2505 | 6mg = 1 billable unit |

**Billing Code for Fulphila:**

| Code: Q5108 | 0.5mg = 1 billable unit |

**Billing Code for Neupogen:**

| Code: J1442 | 0.001mg = 1 billable unit |

**Billing Code for Zarxio:**

| Code: J1442 | 0.001mg = 1 billable unit |

Updated by the P&T Committee: 10/17/2018
• **Haegarda (C1 esterase inhibitor, human)**
  Indications for Approval
  All of the following must be met:
  1. One of the following must be met:
     a. At least 12 years of age.
     b. Pregnant
  2. Must meet ALL clinical criteria for hereditary angioedema (HAE).
  3. Must have a documented contraindication or documented failure of Takzyro.
  Approval: 6 months
  Quantity Limit: 8 treatments (according to FDA and weight) for 28 days
  Specialty Pharmacy required: Briova
  Approved by the P&T Committee: 10/16/2019.

• **HepaGam B (Hepatitis B Immune Globulin)**
  Indications for Approval:
  HepaGam will be used for the prevention of hepatitis B recurrence following liver transplantation.
  Approval: One year (for all above diagnoses).

<table>
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<tr>
<th>Code: J1571 (intramuscular)</th>
<th>0.5ml = 1 billable unit</th>
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</thead>
<tbody>
<tr>
<td>Code: J1573 (intravenous)</td>
<td>0.5 ml = 1 billable unit</td>
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</table>

Approved by the P&T Committee 05/21/2008.

• **Hepatitis C Treatment**
  *Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages. Mavyret (glecaprevir and pibrentasvir) is the preferred formulary medication.*
  Indications for Approval:
  1. Patient must be > 17 years of age.
  2. Patient must be diagnosed with Chronic Hepatitis C Infections including laboratory documentation of genotype and subtype³.
     **Date patient diagnosed as having Hepatitis C Infection**
     **Genotype & Subtype _____** (genotype lab result must be submitted with request).
  3. Patient must currently have detectable HCV RNA levels.
     **HCV RNA level_____ Date_____** (current lab result within the past 3 months must be submitted with request).

**Additional Required Information:**
1. Does patient have decompensated cirrhosis Child-Pugh score 7 – 15 (Class B or C)? (COMMENT: patients with severe hepatic impairment should be referred to a
medical practitioner with expertise in that condition [ideally in a liver transplant center].

Required chart note documentation and labs:

b. Recent labs within past 3 months: INR level, albumin, bilirubin.

2. Is member treatment experienced? If yes, answer a, b & c. If no, move to #3.

a. List regimen patient has received including duration of therapy:

b. Did patient complete regimen? _____ If no, reason for discontinuation:

   ______________________________________________________
   ______________________________________________________

c. What the patient’s response to therapy?
   1) Responder (specify which applies to patient below)
      • Relapse
      • Reinfection
   2) Non-responder (specify which applies to patient below)
      • Null responder (HCV RNA levels declined less than 2 log10 IU/ml by week 12)  
      • Partial responders (> 2 log10 IU/ml response whose virus remained detectable by week 24)  

3. Hepatitis A and B screening including HBsAg, anti-HBs, anti-HBc, HAV Ab
   (labs within the past 3 months required)*
   *Hep B tests drawn within the past 3 months not required unless patient is at current risk.

4. Additional required lab results (within the past 3 months):
   a. Aspartate transaminase (AST, including upper and lower limit)
   b. Alanine Transaminase (ALT)
   c. Platelet Count
   d. Bilirubin
   e. Albumin
   f. INR
   g. Absolute Neutrophil Count (ANC)
   h. Hemoglobin (Hgb)
   i. Serum Creatinine (SCr)

Approval Duration:
   ▪ Length of approval will be dependent on multiple factors and must be recommended in either the medication prescribing information or treatment recommendations that are supported by clinical literature including randomized clinical trial(s), meta-analyses, non-randomized studies.

*Specialty Pharmacy required.

References:
1. Mavyret Prescribing Information, Abbvie Inc., 2017


Approved by the P&T Committee 01/21/2015. Updated 01/20/2016, 07/20/2016, 01/01/2017 and 01/01/2018.

- **Hereditary Angioedema**

  **Indications for Approval:**

  **On-Demand Treatment. All of the following must be met:**

  1. The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with a specialist: Allergist, Immunologist.

  2. Diagnosis of Type I/II HAE is documented

     - Recurrent episodes angioedema (without hives), laryngeal edema, abdominal pain and vomiting.
     - Family history
     - Early age of onset (prior to 30 years of age)
     - Confirmation of the following lab values:
       - Low C4 level
       - One of the following:
         - A low C1 inhibitor (C1-INH) antigenic level. –OR-
         - A normal C1-INH antigenic level and a low C1-INH functional level.

     Note: If C4 level is not low, must confirm family history of angioedema (confirmed with laboratory testing) AND must have documented gene mutations such as factor XII, aniopoieten-1 or plasminogen in order to be considered for Hereditary Angioedema treatment. Questionable cases must have documentation of clinically observed episodes and treatment response.

  3. The member has a history of more than one moderate to severe attack per month (ex: swelling of the face, throat, or abdomen).

  4. Baseline frequency of HAE attacks must be documented.

  5. The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy (i.e. must change to progesterone only first).

  6. Age limits. Beinert (≥5 years of age); Cinryze (6-11 years of age); Takzhzyro (≥12 years of age); Haegarda (≥12 years of age); Kalbitor (≥12 years of age); Firazyr (≥18 years of age).
7. If pregnant or lactating: limited to C1 esterase inhibitors (Preferred: Berinert-on-demand, or Haegarda-prophylaxis). Second line is fresh frozen plasma (FFP) when solvent–detergent treated plasma (SDP) isn’t available.

8. Initial therapy should be with on-demand (Berinert or Firazyr preferred).

9. Prophylaxis therapy can be considered when on-demand treatment episodes exceed two per month and/or other factors, such as, life threatening laryngeal attacks or limits emergency access. See prophylaxis requirements.

Notes:
- Treatment of HAE with normal C1-inhibitor (formulary Type III), will be reviewed on a case by case basis.
- Other forms of angioedema (Acquired, Idiopathic etc.) will not meet approval.
- Pre-procedural prophylaxis: Cinryze (short term) can be reviewed case by case basis.

Continuation of therapy for on-demand treatment (Berinert, Kalbitor, Firazyr):
1. Medical records documenting a decrease of at least 50% in the frequency of attacks and significant improvement in severity and duration of attacks must be provided.
2. Evaluate on-demand treatment frequency. If greater than 2 treatment episodes a month, consider prophylaxis therapies; danazol, tranexamic acid, Takhzyro.

**Prophylaxis Treatment Criteria:**
1. Has met all of the above criteria for **on-demand treatment**.
2. Must have documentation showing that greater than 2 on-demand treated episodes per month have been needed or has other life-threatening factors: episode severity and limited emergency services. (note: on-demand therapy should remain available to member after prophylactic treatment).
3. Has trialed and failed or has a contraindication or intolerant to tranexamic acid or attenuated androgens (danazol).
   
   *Note: Danazol is not appropriate for growing children, pregnant women, concomitant liver disease, metabolic or nephrotic syndrome, or mood disorder.*
4. Then the following can be considered:
      - Patients ≥12 years of age
      - Not approved in combination with other prophylactics (Cinryze or Haegarda)
   b. Haegarda: Must have documented trial and failure of Takhzyro.
   c. Cinryze: Must have documented trial and failure of Takhzyro and Haegarda, or age is 6-11.
Approval Length: Discuss all approvals with management
  - Initial, on-demand treatment (Berinert, Kalbitor, Firazyr): 6 months
  - Prophylaxis:
    - First Continuation at 4 months; on-demand treatments must have decreased by >50%.
    - Second Continuation at 8 months: Evaluate on-demand treatment use –AND- if member has been attack free for 6 months, then the dose interval can be decreased to once every 4 weeks.
    - Third continuation at 12 months and beyond: 4 months (if still evaluating dose frequency) –OR- 6 months if stable

Specialty Pharmacy required
Approved by the P&T Committee 10/16/2019.

- **Hexalen (altretamine)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Hizentra (subcutaneous immune globulin)**
  Indications for Approval:
  The patient has a diagnosis of one of the following:
  **Primary immunodeficiencies** including, but not limited to:
  a. Congenital agammaglobulinemia (X-linked agammaglobulinemia)
  b. Hypogammaglobulinemia
  c. Common variable immunodeficiency
  d. X-linked immunodeficiency
  e. Severe combined immunodeficiency
  f. Wiskott-Aldrich syndrome.
     AND
  There is sufficient documentation of infusion reactions with IVIG or inability to obtain IV access.
  Approval: One year (for all above diagnoses).
  Approved by the P&T Committee 07/21/2010.

- **Humira (adalimumab)**
  Criteria dependent on diagnosis
  Indications for Approval:
1. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy. AND
2. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy. AND
3. The appropriate Disease Specific Criteria below has been met.
   The patient has a diagnosis of one of the following:
   a. **Ankylosing Spondylitis**
      i. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated.
      ii. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated.
      iii. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Humira without a trial of sulfasalazine
   b. **Psoriatic Arthritis**
      i. An adequate trial (3 months or more) of methotrexate
      ii. Or if the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following DMARDs:
         ▪ Leflunomide
         ▪ Hydroxychloroquine
         ▪ Sulfasalazine
   c. **Juvenile Idiopathic Arthritis**
      i. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.
      ii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.
         ▪ Leflunomide
         ▪ Hydroxychloroquine
         ▪ Sulfasalazine
         ▪ Minocycline
         ▪ Gold Salt
   d. **Rheumatoid Arthritis**
      AND meets all of the following:
i. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe RA is defined as: DAS-28 >3.2 or CDAI >10.1.

ii. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.

iii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.
   - Leflunomide
   - Hydroxychloroquine
   - Sulfasalazine
   - Minocycline
   - Gold Salt

e. **Crohn’s Disease**

For induction and maintaining clinical remission in patients with moderately to severely active Crohn’s Disease in patients with an inadequate response or intolerance to conventional therapy: Conventional therapy, for the purpose of this policy, includes the use of 3 or more of the following:
   - Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide).
   - Sulfasalazine
   - Immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate).
   - 5-aminosalicylic acid (brand names include Rowasa, Pentasa, and Asacol).
   - Antibiotics (e.g., metronidazole, quinolones).

f. **Ulcerative Colitis**

Moderately to severely active ulcerative colitis in patients who have had an inadequate response to two (2) conventional therapies. Conventional therapy, for the purpose of this policy, includes the use of the following:
   - Topical and oral aminosalicylates.
   - Topical, oral, or IV corticosteroids.
   - Oral or IV immunotherapy (e.g., azathioprine, 6-MP, cyclosporine).
   - Surgery for refractory disease.

g. **Plaque Psoriasis**
Chronic, moderate to severe, Plaque Psoriasis (psoriasis vulgaris) AND meets all the following additional criteria:

i. Involvement of > 10% of the patient’s body surface area (BSA). Exceptions may be considered for extensive recalcitrant facial involvement, pustular involvement of the hands or feet, and/or genital involvement interfering with normal sexual function.

ii. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and/or a Dermatology Life Quality Index (DLQI) of more than 10.

iii. The patient has history of an adequate trial and treatment failure with phototherapy or photochemotherapy.

or

The patient has history of an adequate trial and treatment failure with methotrexate, or such treatment is contraindicated or not tolerated.

h. Hidradenitis Suppurativa (HS)

Documented diagnosis of Hurley Stage III HS or refractory Hurley Stage II hidradenitis suppurativa and the following:

- A trial and failure of antibiotic therapy (i.e. topical 1% clindamycin, doxycycline) or hormonal therapy (finasteride).

i. Uveitis

Documented diagnosis of non-infectious intermediate, posterior and panuveitis in adult patients and meets the following:

- A documented trial and failure, contraindication, or intolerance to conventional therapy such as ophthalmic or systemic corticosteroids AND immunosuppressive drugs (e.g. azathioprine, cyclosporine, methotrexate, or tacrolimus).

4. Medical records or a typed summary documenting all of the above criteria must be submitted along with the Pharmacy Exception request.

Specialty Pharmacy required.

Approval: 1 year (for all above diagnoses).

Updated by the P&T committee 01/21/2009, 11/28/2012, 11/06/2013, 07/16/2014, 11/05/2015, 10/19/2016, 04/19/2017, 07/19/2017 and 10/18/2017.

- **Hycamtin (topotecan)**

  Refer to the Oncology criteria located within this document.

  Specialty Pharmacy required.

  | Code: J9351 | 0.1mg = 1 billable unit |

  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.
• **Ibrance (palbociclib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 21 capsules for 28 days.
  Approved by the P&T Committee 04/15/2015. Updated 11/05/2015.

• **Iclusig (panatinib)**
  Indications for Approval:
  1. Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, accelerated phase, or blast phase.
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).
     - OR
     - Results of mutational testing are positive for T315I
  2. Philadelphia chromosome positive acute lymphoblastic leukemia
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec) AND dasatinib (Sprycel) or nilotinib (Tasigna).
     - OR
     - Results of mutational testing are positive for T315I
  Continuation Criteria:
    All of the following must be met:
    1. Documentation that the patient does not have evidence of disease progression must be submitted.
    2. Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.
  Approval Length: 6 months.
  Quantity Limit: 30 tablets for 30 days.
  Specialty Pharmacy Mandated
  Approved by the P&T Committee 04/18/2018.

• **Imbruvica (ibrutinib)**
  Indications for Approval:
  1. Diagnosis of Chronic Graft Versus Host Disease (cGVHD)
     The patient must have a documented diagnosis of cGVHD and must have a documented trial and failure of prednisone and a calcineurin inhibitor (e.g. cyclosporine and tacrolimus).
  2. All other diagnoses
     There must be a Category 1 or 2 recommendations in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium.
  Quantity Limit: 28 tablets for 28 days
• **Imfinzi (durvalumab)**  
  **Indications for Approval:**
  9. Unresectable Stage III non-small cell lung cancer that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
  10. Locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy AND
     Patient has a documented medical reason for avoiding use of Keytruda (pembrolizumab)*.
     *Keytruda requires a prior authorization for coverage.
  
  Approval Length: Six (6) months.

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<th>10 mg = 1 billable unit</th>
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  **References:**
  1. Imfinzi Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. February 2018.

  Approved by the P&T Committee 04/18/2018.

• **ICS/LABA (Inhaled Corticosteroid/Long-Acting Beta Agonist) Inhalers**  
  **Note:** Covered products are Symbicort (budesonide/fomoterol), Airduo generic (fluticasone/salmeterol), Dulera (mometasone/fomoterol)

  **Step Edit Criteria:**
  - The patient must have a prescription claim history of an orally inhaled corticosteroid or orally inhaled anticholinergic within the past 150 days.
  - OR
  - FEV1 <50%

  Quantity Limit: One inhaler for 30 days.

  Approved by the P&T Committee: 07/19/2019.

• **Increlex (mecasermin)**  
  **Indications for Approval:**
  All FDA-approved indications

  Growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

  - Severe Primary IGFD is defined by all of the following:
    1. Height standard deviation score ≤ -3.0
    2. Basal IGF-1 standard deviation score ≤ -3.0
    3. Normal or elevated growth hormone (GH)
- Severe Primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF-1 gene defects; they are not GH deficient.

Specialty Pharmacy required.
Approved by the P&T Committee 07/20/2011.

- INFeD (iron dextran)
  Refer to the Intravenous Iron criteria located within this document.
  
  | Code: J1750 | 50mg = 1 billable unit |
  
  Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- Injectable Atypical Antipsychotics, Non- preferred
  
  Note: covered products include Perseris (risperidone) and Zyprexa Relprevv (olanzapine)
  
  Indications for Approval:
  All of the following must be met:
  1. All FDA Approved indications
  2. Member must have a documented trial and failure of or medical reason for avoiding use of Aristada and Invega Sustenna or Invega Trinza
  
  Approval Length: one year
  Quantity Limit: 1 vial or syringe per 28 days
  Approved by the P&T Committee 07/17/2019

- Injectafer (ferric carboxymaltose)
  
  Refer to the Intravenous Iron criteria located within this document.
  
  | Code: J1439 | 1mg = 1 billable unit |
  
  Approved by the P&T Committee 11/06/2013.

- Inlyta (axitinib)
  
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 120 tablets for 30 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 03/21/2012. Updated 10/15/2014 and 11/05/2015.

- Intravenous Iron
  
  Covered products are: Dexferrum (iron dextran), Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate), INFeD (iron dextran), Injectafer (ferric carboxymaltose) and Venofer (iron sucrose). These drugs are subject to approved dosage guidelines.
  
  Indications for Approval:
  1. For the treatment of chemotherapy-induced iron deficiency anemia*.
  2. For the treatment of iron deficiency anemia* in chronic kidney disease patients undergoing chronic hemodialysis.
3. For the treatment of documented iron deficiency anemia* in a patient who has a documented disorder of the gastrointestinal tract of which symptoms may be aggravated by oral iron therapy. Example: Inflammatory bowel disease.
4. For the treatment of a documented iron deficiency anemia* in a patient who has had a documented severe intolerance or treatment failure to an oral iron product after an adequate trial and after attempts have been made to identify and treat the underlying cause(s) of the deficiency.

*Iron Deficiency anemia defined as:
- Hemoglobin (Hgb) less than 11gm/dl
- MCV <95 and Ferritin ≤ 45
- MCV <95 and Ferritin 46 to 99 and iron saturation <16%.

Compendial Uses: Non-FDA-approved uses for the injectable iron products that are considered to be “medically-accepted indications” based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with an injectable iron product for compendial uses will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.
Length of approval: One time.
Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- **Iressa (gefitinib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 30 tablets for 30 days.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Isotretinoin products**
  Covered products include: Amnesteem, Claravis, Myorisan, Zenatane, and generic isotretinoin.
  Note: Twenty-four (24) weeks of therapy every 365 days covered without a prior authorization on the Medicaid and Commercial formularies.
  Continuation of Therapy Criteria:
  The following information must be provided:
  - The patient must have a documented diagnosis of persistent or recurring severe recalcitrant nodular acne that is still present and requires additional therapy.
(Note: persistent/recurrent recalcitrant nodular acne is defined as many, greater than 5mm in size, inflammatory nodules unresponsive to conventional therapy)

- At least 8 weeks must have passed since the completion of the previous course of therapy.
- Documentation of the patient’s current weight must be provided.
- Documentation of the cumulative dose reached during the previous course of therapy must be provided.
- Documentation of the expected time needed to reach the cumulative dose goal of 120mg/kg to 220mg/kg must be provided.

**Exclusions:**
- Long-term low doses equal to or less than 0.5mg/kg/day will not be authorized.
- Low dose therapy is only recommended for the first month to prevent initial worsening of acne.

**Quantity Limit:** 60 capsules for 30 days (up to a total of 336 capsules for 365 days).
**Approval Length:** 24 weeks of therapy.

Approved by the P&T Committee 10/19/2016. Updated: 10/17/2018, 10/16/2019.

**References:**

**IVIG (Immune Globulin (human), IV)**

*Note: Preferred products are Flebogamma and Gamunex-C*

**Indications for Approval:**

1. The indications listed below will be considered for approval for treatment with IVIG when use is supported by current treatment guidelines and standard interventions, treatment, and/or therapy has failed or are contraindicated. Dosing,
frequency, and length of therapy must be supported by, and consistent with published medical literature.

2. The patient has a diagnosis of one of the following:
   a) **AIDS**: Children with acquired immunodeficiency syndrome (AIDS).
   b) **Bone marrow and organ transplant recipients** (except corneal) who are at risk for cytomegalovirus (CMV) and pneumonia due to immunosuppressant agents.
   c) **Bone Marrow Transplant**: Post bone marrow transplant setting.
   d) **HIV**: Adults with human immunodeficiency virus (HIV) who are immunosuppressed in association with AIDS or AIDS-related complex (ARC).
   e) **Infection**, prevention in:
      - HIV-infected patients
      - Patients with primary defective antibody synthesis
      - Hypogammaglobulinemia and/or recurrent bacterial infections, with B-cell chronic lymphocytic leukemia
   f) **Kawasaki syndrome** (446.1)
   g) **Primary immunodeficiencies** including, but not limited to:
      - Congenital agammaglobulinemia (X-linked agammaglobulinemia) (279.04)
      - Hypogammaglobulinemia (279.06)
      - Common variable immunodeficiency (279.06)
      - X-linked immunodeficiency (279.05)
      - Severe combined immunodeficiency (279.2)
      - Wiskott-Aldrich syndrome (279.12)
   h) **Thrombocytopenia purpura**: Treatment of idiopathic or immune thrombocytopenia purpura (ITP).

3. **Intravenous Immune Globulin may be considered medically necessary** when standard intervention, treatment, and/or therapy has failed, become intolerable, and/or are contraindicated for any of the following off-label indications:
   a) **Acute inflammatory demyelinating polyneuropathy**, including Guillain-Barré Syndrome, in patients who have one or more of the following:
      - rapid deterioration with acute symptoms for less than two weeks, and/or
      - rapidly deteriorating ability to ambulate, and/or unable to ambulate independently for ten meters, and/or deteriorating pulmonary function tests.
      **NOTE**: IVIG is given as an equivalent alternative to plasma exchange in children and adults. (CAUTION - this is not the same as chronic fatigue syndrome. Refer to the listing of conditions that are considered experimental, investigational, and unproven);
   b) **Autoimmune hemolytic anemia** that does not respond to corticosteroids.
c) **Autoimmune neutropenia** that does not respond to other modalities, or when the later are contraindicated.

d) **Chronic inflammatory demyelinating polyneuropathy (CIDP)** - used either alone or following therapeutic plasma exchange to prolong its effect.

e) **Hyperimmunoglobulin E (HIE) syndrome** (Job’s Syndrome, Hyper IgE Syndrome)

f) **Infections** in high-risk, preterm, low-birth-weight neonates, as prophylaxis and/or treatment adjunct.

g) **Inflammatory myopathies**: Refractory inflammatory myopathies (e.g., polymyositis, dermatomyositis) for corticosteroid-resistant patients, or patients in whom corticosteroids are contraindicated.

h) **Lambert-Eaton myasthenic syndrome (LEMS)**, not controlled by anticholinesterases and diaminopyridine.

i) **Malignancies of various types**, especially leukemic illnesses that are vulnerable to recurrent infections secondary to an immunosuppressed system, including multiple myeloma with stable plateau phase disease and at high risk of recurrent infections. CAUTION - this is not the same as multiple myeloma in any other phase. Refer to the list of conditions that are considered investigational.

j) **Multifocal motor neuropathy** in patients with anti-GM1 antibodies and conduction block who have tried and/or failed conventional therapy, such as corticosteroids and/or immunosuppressive (e.g., cyclophosphamide) therapy.

k) **Multiple Sclerosis (MS)**, severe manifestations of relapsing-remitting type only, when other therapy has failed, become intolerable, and/or are contraindicated. CAUTION - this is not the same as chronic- (primary- or secondary-) progressive multiple sclerosis. Refer to the listing of conditions that are considered experimental, investigational, and unproven.

l) **Myasthenia gravis**, with the following conditions:
   - Acute severe decompensation when other treatments have been unsuccessful or are contraindicated, or
   - Myasthenia crisis (i.e., an acute episode of respiratory muscle weakness) in patients with contraindications to plasma exchange, or
   - chronic debilitating disease in spite of treatment with cholinesterase inhibitors, and/or complications from or failure of steroids and/or azathioprine.

m) **Neonatal alloimmune thrombocytopenia**, severe: When other interventions have failed or are contraindicated. CAUTION - this is not the same as non-immune thrombocytopenia. Refer to the listing of conditions that are considered experimental, investigational, and unproven.

n) **Post transfusion purpura** (severe).
o) **Pure red cell aplasia** with documented parvovirus B19 infection and with severe, refractory anemia.

p) **Solid organ transplant**, prior to transplant for treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ.

q) **Solid-organ transplant**, following transplant for treatment of antibody-mediated rejection.

r) **Stiff Person Syndrome** (Moersch-Woltman Syndrome) when:
   - Anti-GAD antibody is present, and
   - Other therapy has failed (i.e., benzodiazepines and/or baclofen, phenytoin, clonidine, tizanidine).
   - **Systemic Lupus Erythematosus (SLE)** in patients with severe active illness for whom other interventions have been unsuccessful or intolerable.

s) **Toxic Shock Syndrome** or Toxic Necrotizing Fasciitis due to streptococcal or staphylococcal organisms, when:
   - Infection is refractory to several hours of aggressive therapy, and/or
   - An undrainable focus is present, and/or
   - The patient has persistent oliguria with pulmonary edema.

t) **Vasculitis Syndrome** in patients with severe active illness for whom other interventions have been unsuccessful or intolerable.

**Exclusions:**
The use of intravenous and/or subcutaneous immunoglobulin is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following:
- Acquired Factor VIII inhibition
- Acquired von Willebrand's Syndrome
- Acute lymphoblastic leukemia
- Acute renal failure
- Adrenoleukodystrophy
- Amyotrophic lateral sclerosis (ALS or Lou Gehrig disease)
- Antiphospholipid Ab Syndrome
- Aplastic anemia
- Asthma and inflammatory chest disease
- Behçet's Syndrome
- Burns
- Chronic (primary or secondary) progressive multiple sclerosis
- Chronic Fatigue Syndrome
- Congenital heart block
- Cystic fibrosis
- Demyelinating optic neuritis
- Diabetes mellitus
- Diamond-Blackfan anemia
- Endotoxemia
- Epilepsy
- Euthyroid ophthalmopathy
- Factor VIII inhibitors, acquired
- Hemolytic transfusion reaction (except post-transfusion purpura)
- Hemolytic Uremic Syndrome
- Hemophagocytic Syndrome
- Inclusion-body myositis
- Membranous nephropathy
- Motor neuron syndromes
- Multiple myeloma (except multiple myeloma with stable plateau phase disease who are at high risk of recurrent infections—see Off-Label Indications above)
- Myelopathy, HTLV-1 associated
- Neonatal hemolytic disease
- Nephrotic Syndrome
- Non-immune thrombocytopenia
- Paraproteinemic neuropathy
- Post-infectious sequelae
- Progressive lumbosacral plexopathy
- Recent-onset dilated cardiomyopathy
- Recurrent otitis media
- Recurrent, spontaneous fetal loss with previous pregnancies.
- Refractory rheumatoid arthritis, adult and juvenile
- Thrombotic thrombocytopenic purpura
- Uveitis

**EXCEPTIONS:** Exceptions to these conditions of coverage are considered through the Prior Authorization process. Clinical, peer reviewed, published evidence will be required for any diagnosis not otherwise listed.

Approval: Up to one year

| Codes: J Code varies by product | 500mg = 1 billable unit |

Approved by the P&T Committee 05/21/2008. Updated 07/19/2017.

- **Jakafi (ruxolitinib)**

  Indications for Approval:
  1. Oncology/Hematology Indications
     - There must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class 1 or II recommendation in the Thomson Micromedex DrugDex compendium.
2. Graft Versus Host Disease
   • All of the following must be met:
     a. Diagnosis of steroid resistant acute GVHD following an allogeneic hematopoietic stem cell transplantation (allo-HSCT)
     b. Grade 2 to 4 acute GVHD
     c. Patient has progressive or unchanged GVHD, or development of GVHD in another organ despite treatment with corticosteroid therapy
     d. Two of the following treatments have been trialed at therapeutic doses: cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil
   • Exclusions
     a. Has received more than 1 allogenic-HSCT
     b. Evidence of relapsed primary disease or have been treated for relapse after the allo-HSCT was performed

Quantity Limit: 60 tablets for 30 days.
Specialty pharmacy required.
Approved by the P&T Committee 01/18/2012. Updated 10/15/2014, 01/21/2015 and 11/05/2015, 10/16/19.

• **Kadcyla (ado-trastuzumab emtansine)**
  Refer to the **Oncology** criteria located within this document.

| Code: J9354 | 1mg = 1 billable unit |

Approved by the P&T Committee 07/17/2013. Updated 11/05/2015.

• **Kadian (morphine extended release capsules)**
  Refer to the **Morphine Sulfate ER Capsules, Tablets (Avinza, Kadian)** Criteria located within this document.

Approved by the P&T Committee 09/19/2007.

• **Kalbitor (ecallantide)**
  **Indications for Approval**
  All of the following must be met:
  1. Must meet ALL clinical criteria for hereditary angioedema (HAE).
  2. Must be at least 12 years of age.
  3. Must only be used for on-demand treatment and be administered in-office.
  4. Must have a contraindication to Berinert and Firazyr.

Approval Length: 6 months
Quantity Limit: Two Episodes for 28 days
Specialty Pharmacy: Briova

References:


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<th>1mg = 1 billable unit</th>
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Approved by the P&T Committee 09/19/2012. Updated: 10/16/2019.

- **Kalydeco (ivacaftor)**
  
  **Indications for Approval:**

  All of the following must be met:

  1. Documentation that patient has a diagnosis of cystic fibrosis.
  2. Patient is ≥ 6 months of age.
  3. Patient is **not** homozygous for the F508del mutation in the CFTR gene and has one of the CFTR gene mutations as indicated in the FDA label.
  4. Documentation of all of the following:
     i. Pretreatment ppFEV₁ (within the past 30 days). For patients ≤ 6 years of age, submission of appropriate baseline pulmonary monitoring/testing is required.
     ii. Patient has had two negative respiratory cultures for any of the following: *Burkholderia cenocepacia*, *Burkholderia dolasa*, or *Mycobacterium abscessus* in the past 12 months.
     iii. Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter.
     iv. Baseline ophthalmic exam for pediatric patients.
     v. No dual therapy with another CFTR potentiator is planned.

  **Continuation Criteria:**

  All of the following must be met:

  1. Patients response to therapy is documented (e.g. stable or improvement of ppFEV₁ from baseline, weight gain, decreased exacerbations, etc.).
  2. Patient has had two negative respiratory cultures for any of the following: *Burkholderia cenocepacia*, *Burkholderia dolasa*, or *Mycobacterium abscessus* in the past 12 months.
  3. Documentation of annual testing of ALT, AST, and bilirubin levels after the first year of therapy.
  4. No dual therapy with another CFTR potentiator is planned.
Quantity limit: 60 tablets or unit-dose packets for 30 days
Initial Approval Length: 6 months.
Continuation Approval Length: 1 year.
Specialty Pharmacy required.
Approved by the P&T Committee 04/18/2018. Updated: 10/16/19.

- **Kazano (alogliptin/metformin)**
  Refer to the DPP-4 Inhibitors criteria located within this document.
  Quantity Limit: 60 tablets for 30 days.
  Alternative: metformin
  Approved by the P&T Committee 07/19/2017

- **Keytruda (pembrolizumab)**
  Refer to the Oncology criteria located within this document.
  Code: J9271
  1mg = 1 billable unit
  Approved by the P&T Committee 10/15/2014. Updated 11/05/2015.

- **Kisqali (ribociclib)**
  Refer to the Oncology criteria located within this document.
  Quantity limit:
  - 200mg/day dose pack - 21 tablets for 28 days
  - 400mg/day dose pack - 42 tablets for 28 days
  - 600mg/day dose pack - 63 tablets for 28 days.
  Approved by the P&T Committee 04/19/2017.

- **Kisqali Femara Co-Pack (ribociclib/letrozole)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit:
  - 200 Co-Pack – 49 tablets for 28 days
  - 400 Co-Pack – 70 tablets for 28 days
  - 600 Co-Pack – 91 tablets for 28 days
  Approved by the P&T Committee 10/18/2017.

- **Kuvan (sapropterin dihydrochloride)**
  Indications for Approval:
  All of the following must be met:
  1. The patient has a documented diagnosis of phenylketonuria.
  2. Kuvan is being prescribed by a metabolic disease specialist.
  3. Tetrahydrobiopterin (BH4) deficiency has been ruled out.
  4. The patient has a baseline phenylalanine level ≥ 600 µmol/L.
  5. The patient has failed a phenylalanine-restricted diet alone despite strict compliance.
  6. The patient is seeing a dietician that specializes in phenylketonuria/metabolic disease.
Initial Length of Approval: 1 month
Quantity limit:
Quantity will be limited to an amount sufficient to allow for up to the FDA approved maximum recommended dosage.

Continuation of Therapy Criteria:
All of the following must be met:
1. Kuvan is being prescribed by a metabolic disease specialist.
2. The patient is following a phenylalanine restricted diet.
3. Laboratory reassessment has been conducted after the initial one month trial of Kuvan. Based on the laboratory reassessment one of the following will apply:
   a) Patients responding to therapy (≥ 30% reduction in blood phenylalanine levels from baseline) and have maintained phenylalanine levels below baseline levels will be approved for an additional 1 year of therapy.
   b) Patients receiving a dose of 10 mg/kg/day whose blood phenylalanine levels have not decreased from baseline by ≥ 30% after 1 month of therapy should increase to 20 mg/kg/day. These patients will be approved for an additional 1 month of therapy at the higher dose.
   c) Patients receiving a dose of 20 mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline by ≥ 30% after one month of therapy at this dose are considered non-responders and no further treatment with Kuvan will be authorized.

Continuation of Therapy Length of Approval: Up to 1 year (based on response to therapy).

References:
2. Bodamer OA. Overview of phenylketonuria. In UpToDate, Hahn S (Ed), Waltham, MA. 2018.

Approved by the P&T Committee 07/18/2018.

- **Kyprosil (carfilzomib)**
  Refer to the Oncology criteria located within this document.

  Code:  J9047

  1mg = 1 billable unit

  Approved by the P&T Committee 09/19/2012. Updated 11/05/2015.

- **Kytril (granisetron) Tablets**
  Step Edit Criteria:
  The patient must have a prescription claim history of at least a 5-day trial of generic ondansetron oral tablets within the past 120 days.

  Quantity Limit: 20 tablets for 30 days.

  Alternative: ondansetron tablets.

  Approved by the P&T Committee 05/19/2010.

  References:


- **Lartruvo (olaratumab)**
  Refer to the Oncology criteria located within this document.

| Code: J9285 | 10mg = 1 billable unit |

Approved by the P&T Committee 01/18/2017.

- **Latuda (lurasidone)**
  Indications for Approval:
  - The medication requested must be used for the treatment of a medical condition approved by the U.S. Food and Drug Administration (FDA). If it is not approved by the FDA, its use must be supported in the medical compendia.
  - Must be initiated by a behavioral health practitioner or in consultation with a behavioral health practitioner for all indications:
    1. Schizophrenia
      - The patient must have a trial and failure of three (3) formulary atypical antipsychotics. Medication trials that fail due to lack of efficacy must be attempted at a maximal approved dose for a minimum of 4 weeks if no response, and a minimum of 12 weeks if partial response.
      OR
      - The patient has a current diagnosis of Metabolic Syndrome, Pre-Metabolic Syndrome, or Diabetes Mellitus and has failed ziprasidone and aripiprazole or there is clinical documentation why they are not clinically appropriate.
    2. Bipolar 1 Disorder, Depression (Bipolar 1 disorder with depressed phase)
      - The patient must have an adequate trial of quetiapine or medical reason for avoiding use.
    3. Major Depressive Disorder
      - Medication is being used in combination with an antidepressant medication.
      AND
      - The patient has a trial and failure of at least one of each of the following:
        - Selective serotonin reuptake inhibitor.
        - Serotonin norepinephrine reuptake inhibitor (SNRI), mirtazapine, or bupropion.
        - Formulary preferred atypical antipsychotic used for the adjunctive treatment of major depressive disorder with an antidepressant.

Length of approval: 1 year
Approved by the P&T Committee 04/24/19.

- **Lenvima (lenvatinib)**
  Refer to the [Oncology](#) criteria located within this document.
  Approved by the P&T Committee 04/15/2015. Updated 11/05/2015.

- **Letairis (ambrisentan)**
  Refer to the [Pulmonary Arterial Hypertension](#) Criteria located within this document.
  Quantity Limit: 30 tablets for 30 days
  Specialty Pharmacy required
  Approved by the P&T Committee 05/16/2012. Revised 07/16/2014, 11/05/2015 and 04/19/2017.

- **Leukeran (chlorambucil)**
  Refer to the [Oncology](#) criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Lialda (mesalamine delayed release)**
  **Step Edit Criteria:**
  The patient must have a claim history within the past 545 days of a 30-day trial of balsalazide or sulfasalazine.
  Quantity limit: 120 tablets for 30 days
  Approved by the P&T Committee 01/17/2019.

- **Libtayo (cemiplimab-rwlc)**
  Refer to the [Oncology](#) criteria located within this document.
  Approval: 6 months
  Approved by the P&T Committee 01/17/2019

- **Lonsurf (trifluridine/tipiracil)**
  Refer to the [Oncology](#) criteria located within this document.
  Quantity limit: 40 tablets for 28 days.
  Approved by the P&T Committee 11/05/2015.

- **Lorbrena (lorlatinib)**
  Refer to the [Oncology](#) criteria located within this document.
  Quantity limit:
  - 100 mg tablets: 30 tablets for 30 days
  - 25 mg tablets: 90 tablets for 30 days
  Approval: 6 months
  Approved by the P&T Committee 01/17/2019
• **Lotemax and Lotemax SM (loteprednol etabonate)**

  Step Edit Criteria:
  
  The member must have a claim history within the past 120 days of a formulary ophthalmic corticosteroid.

  Alternatives: dexamethasone ophthalmic, fluorometholone ophthalmic, prednisolone acetate ophthalmic, prednisolone sodium phosphate ophthalmic.

  Approved by the P&T Committee 03/24/2010. Updated 04/24/2019.

• **Lovenox (enoxaparin)**

  *Note: Quantities of enoxaparin that do not exceed 30 syringes in a 90 day period will not require a prior authorization for coverage.*

  **Indications for Approval:**
  
  One of the following must be met:
  
  1. The patient has an active cancer diagnosis.
  2. The patient is currently pregnant and has a condition associated with a high risk of developing thrombosis (e.g., personal or family history of venous thromboembolism, current deep vein thromboembolism or pulmonary embolism, factor V Leiden mutation, mechanical prosthetic heart valve, atrial fibrillation, antiphospholipid antibody syndrome).
  
  *Pregnancy must be confirmed by positive lab results or imaging.*

  3. Other indications – medical records must be submitted documenting a medical reason for avoiding the use of formulary agents and the requested duration of therapy must be supported in by the medical compendia.

  Length of Approval:
  
  ▪ Active cancer diagnosis: 6 months
  ▪ Pregnancy: Up to 6 weeks after delivery date
  ▪ Other indications: Up to 6 months

  Approved by the P&T Committee 04/18/2018.

• **Lumigan (bimatoprost 0.01% ophthalmic solution)**

  Step Edit Criteria:

  The patient must have a prescription claim history for latanoprost 0.005% ophthalmic solution within the past 180 days.

  Approved by the P&T Committee 04/19/2017.

• **Lumoxiti (moxetumomab pasudotox-tdfk)**

  Refer to the *Oncology* criteria located within this document.

  Approved by the P&T Committee: 04/24/2019

• **Lunesta (eszopiclone)**

  Step Edit Criteria:

  The patient must have a claim history of two of the following:
- Zolpidem
- A benzodiazepine
- Trazodone

Quantity Limit: 30 tablets for 30 days.
Approved by the P&T Committee 07/15/2009. Updated 04/20/2016 and 04/19/2017.

- **Luvox CR (fluvoxamine)**
  Step Edit Criteria:
  The patient must have a 30-day trial of two of the following:
  clomipramine, fluoxetine, paroxetine, sertraline.

  Alternatives: clomipramine, fluoxetine, paroxetine, sertraline.

  Approved by the P&T Committee 07/17/2013.

- **Lynparza (olaparib)**
  Refer to the Oncology criteria located within this document.

  Quantity limit:
  - 50mg capsules - 480 capsules for 30 days.
  - 100mg tablets – 120 tablets for 30 days.
  - 150mg tablets – 120 tablets for 30 days.

  Approved by the P&T Committee 01/21/2015. Updated 11/05/2015 and 10/18/2017.

- **Lyrica (pregabalin)**
  Indications for Approval:
  1. **Partial seizures:**
     The patient must have a documented failure at therapeutic doses on at least two preferred anticonvulsants.
  2. **Neuropathic pain (caused by diabetic neuropathy or spinal cord injury) and post-herpetic neuralgia:**
     The patient must have a documented trial and failure at therapeutic doses of all of the following:
     a) Gabapentin (1,200 to 2,400 mg/day).
     b) One of the following: a tricyclic antidepressant (TCA) or a formulary SNRI (i.e. venlafaxine).
  3. **Fibromyalgia:**
     The patient must have a documented failure of the following:
     a) A daily low-impact exercise program.
     b) A tricyclic antidepressant at therapeutic doses such as amitriptyline, desipramine, or nortriptyline.
     c) Gabapentin at a therapeutic dose (1,200 to 2,400 mg/day).

  Approval: 1 year.

  Quantity Limit: 90 capsules for 30 days. Maximum dose of 600mg daily.
  225mg – 60 capsules for 30 days.
300mg – 60 capsules for 30 days.
Alternatives: gabapentin, amitriptyline, desipramine, nortriptyline, citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, carbamazepine, lamotrigine, or divalproex.
The above Criteria will not apply to patients established on pregabalin therapy.
Sampling does not qualify as established therapy.
Approved by the P&T Committee 01/16/2008.

- **Marqibo (vincristine sulfate liposome)**
  Refer to the Oncology criteria located within this document.
  Code: J9371
  1mg = 1 billable unit
  Approved by the P&T Committee 11/06/2013. Updated 11/05/2015.

- **Matulane (procarbazine)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Mavyret (glecaprevir/pibrentasvir)**
  Refer to the Hepatitis C treatment criteria located within this document.
  Quantity Limit: 3 tablets a day.
  Duration of Therapy:
  Limited to the recommended duration of therapy in the manufacturer’s prescribing information or Class I or II recommendations by the AASLD/IDSA guidelines.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/06/2017.

- **Maxalt (rizatriptan)/ Maxalt ODT (rizatriptan orally disintegrating)**
  Refer to the Triptans, Preferred Criteria located within this document.
  Quantity Limit: 18 tablets for 30 days.

- **Megace ES (megestrol)**
  Indications for Approval:
  The patient must have a documented failure, or contraindication to megestrol suspension.
  AND
  The patient has a diagnosis of cancer-related cachexia.
  OR
  The patient has a diagnosis of AIDS Wasting Syndrome.
Approval: One year.
Alternative: megestrol immediate release tablets or suspension.

- **Mekinist (trametinib)**
  - Refer to the Oncology criteria located within this document.
  - Quantity Limit:
    - 0.5mg – 90 tablets for 30 days.
    - 1mg, 2mg – 30 tablets for 30 days.
  - Specialty Pharmacy required.
  - Approved by the P&T Committee 07/17/2013. Updated 04/16/2014, 10/15/2014 and 11/05/2015.

- **Mektovi (benimetinib)**
  - Indications for Approval:
    - Refer to the Oncology criteria located within this document.
  - Length of Approval: 6 months
  - Quantity limit: 180 tablets per 30 days
  - References:
    - Approved by the P&T Committee 07/18/2018.

- **Methylin (methylphenidate) oral solution**
  - Indications for Approval:
    - The following criteria apply to patients greater than 12 years of age:
      1. The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.
      2. For patients age 19 and up to treat ADHD, Cerebral Stimulant criteria also apply.
  - Length of Approval: One (1) year.
  - Quantity Limit: 5mg/mL solution: 180mL for 30 days, 10mg/mL: 450 mL for 30 days
  - Approved by the P&T Committee 10/16/2019.

- **Morphine Sulfate ER Capsules, Tablets (Avinza, Kadian)**
  - Step Edit Criteria:
    - The patient must have claim history of fentanyl transdermal patches and oxymorphone ER within the past 90 days.
  - Approved by the P&T Committee 09/19/2007.

- **Mulpleta (lusutrombopag)**
Indications for Approval:
All of the following must be met:
1. Patient is aged ≥ 18 years
2. Request submitted by gastroenterologist, hematologist, or hepatologist
3. Procedure date must be at least 8-14 days from request date.
4. Must have documentation of baseline platelets less than 50x109/L.
5. Must be undergoing a procedure that carries an intermediate to high risk of bleeding:
   ▪ Spinal surgery
   ▪ Cardiac surgery
   ▪ Large polypectomy
   ▪ Liver biopsy

Exclusions: Patients undergoing low-risk procedures, such as: paracentesis, routine endoscopy, or central line placement

Approval Length: 7 days
Continuation Approval Length: not allowed, only one course will be approved
Quantity Limit: 7 tablets per 7 days.
Specialty Pharmacy required
Approved by the P&T Committee 01/16/2019.

• **Multaq (dronedarone)**
  Indications for Approval:
  1. Atrial Fibrillation
  2. Paroxysmal Atrial Fibrillation
  3. Atrial Flutter
  AND
  Must meet all of the following criteria:
  ▪ Must not have NYHA Class IV heart failure or NYHA Class II-III heart failure with a recent decompensation.
  ▪ A documented trial and failure of:
    a) Two generic antiarrhythmics such as flecainide, sotalol, or propafenone.
    OR
    b) amiodarone with unacceptable side effects.

Quantity Limit: 60 tablets for 30 days.
Alternatives: amiodarone, flecainide, propafenone, sotalol.
Approved by the P&T Committee 11/16/2009.
Criteria based on the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation.

• **Myleran (busulfan)**
Refer to the Oncology criteria located within this document.
Specialty Pharmacy required.
Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Myorisan (isotretinoin capsules)**
  Refer to the Isotretinoin criteria located within this document.
  Approved by the P&T Committee 10/19/2016. Updated: 10/17/2018, 10/16/2019.

- **Namenda XR (memantine SR)**
  Step Edit Criteria:
  The patient must have a claim history of donepezil or Namenda immediate release tablets within the past 545 days.
  Quantity limit: 30 tablets for 30 days.
  Alternatives: donepezil, Namenda IR tablets
  Approved by the P&T Committee 04/16/2014.

- **Nesina (alogliptin)**
  Refer to the DPP-4 Inhibitors criteria located within this document.
  Quantity Limit: 30 tablets for 30 days.
  Alternative: metformin
  Approved by the P&T Committee 07/19/2017

- **Neulasta OnPro(pegfilgrastim)**
  Refer to the Granulocyte-Colony Stimulating Factors Criteria located within this document.
  Code: J2505
  6mg = 1 billable unit
  Approved by the P&T Committee 05/19/2010.

- **Neumega (oprelvekin)**
  Indications for Approval:
  All FDA-approved indications
  Prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions in adult patients with non-myeloid malignancies who are at high risk for severe thrombocytopenia following myelosuppressive chemotherapy.
  Approval: Initial length of approval up to 21 days per course, reauthorization up to 6 months.
  Specialty Pharmacy required.
  Code: J2355
  5mg = 1 billable unit
  Approved by the P&T Committee 07/20/2011.

- **Neupogen (filgrastim)**
Refer to the [Granulocyte-Colony Stimulating Factors](#) Criteria located within this document.

| Code: J1442 | 0.001mg = 1 billable unit |

Approved by the P&T Committee 05/19/2010.

- **Nexavar (sorafenib)**
  - Refer to the [Oncology](#) criteria located within this document.
  - Quantity Limit: 120 tablets for 30 days.
  - Specialty Pharmacy required.
  - Approved by the P&T Committee 09/21/2011. Updated 10/15/2014 and 11/05/2015.

- **Nubeqa (darolutamide)**
  - Refer to the Oncology criteria located within this document.
  - Quantity Limit: 120 tablets for 30 days
  - Specialty Pharmacy Required Approval: 6 months
  - Approved by the P&T Committee: 10/16/2019.

- **Nuedexta (dextroamphetamine/quinidine)**
  - **Indications for Approval** (all of the following must be met):
    1. Documented diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).
    
    *Note: The safety and efficacy to treat emotional lability caused by other conditions, such as stroke, Alzheimer’s disease, Parkinson’s disease, or traumatic brain injury have not been established by well controlled clinical trials.*

    2. Must be prescribed by or in consultation with a neurologist.

    3. Member must have a documented baseline score ≥ 13 on the Center for Neurologic Study - Lability Scale (CNS-LS).

    4. Documents showing the number of daily episodes must be submitted.

  - **Continuation of Treatment Criteria** (all of the following must be met):
    1. Documentation showing the CNS-LS score has decreased and the decrease is maintained.

    2. Documented decrease in the number of daily episodes.

  - Initial Approval: One month
  - Approval for Continuation of Therapy: 6 months
  - Quantity Limit: 60 tablets for 30 days.
  - Approved by the P&T Committee 04/19/2017

- **Nutritional Supplementation**
  - **Indications for Approval:**
1. For patients who must be tube fed oral nutritional supplements and products, requests should be submitted directly to Presbyterian Health Plan’s enteral nutrition provider.

2. Oral nutritional support:
   a. On the basis of a specific medical indication for a patient who has a defined need for which nutritional support is considered therapeutic, and for which regular food, blenderized food, or commercially available retail consumer nutritional supplements would not meet his or her medical needs. A current dietary or nutritional consult will be required for evaluation.
   b. When medically necessary due to inborn errors of metabolism. A current dietary or nutritional consult will be required for evaluation.
   c. When medically necessary to correct or ameliorate physical illnesses or conditions in a patient under 21 years of age. A current dietary or nutritional consult will be required for evaluation.

Examples of medical necessity:
   i. Diagnosis or clinical condition that relates to the need for restoration of a pathological loss of tissue and attempts at regular food intake have failed to increase the protein and caloric absorption.
   ii. Conditions related to swallowing disorders, malabsorption syndromes, and/or chronic conditions with persistent weight loss, or debilitated skin integrity contribution or poor healing of tissues, i.e. decubitus ulcers, etc.

Exclusions:
- Coverage does not include commercially available food alternatives, such as low or sodium-free foods, low or fat-free foods, low or cholesterol-free foods, low or sugar-free foods, low or high calorie foods for weight loss or weight gain, or alternative foods due to food allergies or intolerance.
- Enteral nutrition for non-tube fed patients or patients who DO NOT have inborn errors of metabolism or other medical conditions under the age of 5 years is not a covered benefit. Patient should be referred to Women, Infants, and Children (WIC) Food and Nutrition Services. Participation or eligibility for WIC is not a requirement for coverage by Presbyterian Health Plan.

Approved by the P&T Committee 04/16/2014. Updated: 04/16/2019, 07/17/2019.

References:

- **NuvaRing (etonogestrel/ethinyl estradiol)**
Step Edit Criteria:
A prescription claim history of an 84-day supply of a formulary oral contraceptive or medroxyprogesterone acetate injection within the past 120 days is required.
Quantity Limit: One (1) ring for 28 days.
Age Limit: Maximum of 55 years of age.
Approved by the P&T Committee 01/21/2015. Updated 04/18/2018.

• **Nuvigil (armodafinil)**
Indications for Approval:
The medication must be prescribed by a sleep specialist or neurologist and must meet one of the following:
1. A documented diagnosis of narcolepsy
   - The member must have a treatment failure, inability to tolerate, or other medical contraindication (including but not limited to: cardiovascular disease) to one or more formulary alternative medications.
2. A documented diagnosis of Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)
   - Documentation that the member has been on CPAP for at least two months and is using it four or more hours a night is required.
3. A documented diagnosis of Shift Work Sleep Disorder (SWSD)
   - A letter from the employer is required stating the member is working a variable, alternating, or third shift.
4. A documented diagnosis of Multiple Sclerosis Fatigue.
Quantity Limit:
- All strengths: 30 tablets per 30 days
Alternatives: methylphenidate, methylphenidate extended release (Metadate CD, methylphenidate ER tablets 10mg, 20mg) dextroamphetamine, amphetamine/dextroamphetamine
Approved by the P&T Committee 04/16/2014. Updated 01/17/2018, 07/17/2019.

• **Ocrevus (ocrelizumab)**
Indications for Approval:
1. Must be prescribed by a neurologist.
2. A diagnosis of multiple sclerosis:
   - Relapsing -remitting multiple sclerosis and a documented trial and failure of a preferred interferon or glatiramer.
   - Primary progressive multiple sclerosis.
Note: Patients diagnosed with primary progressive multiple sclerosis will not require a trial and failure of other medications.
Specialty Pharmacy required.

| Code: J2350 | 1mg = 1 billable unit |

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Approved by the P&T Committee 07/19/2017. Updated 01/17/2018.

- **Odomzo (sonidegib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 30 capsules for 30 days.
  Approved by the P&T Committee 11/05/2015.

- **Ofev (nintedanib)**
  **Indications for Approval:**
  All of the following must be met:
  1. Patient is aged ≥ 40 years
  2. Ofev is prescribed by, or in consultation with, a pulmonologist
  3. Patient has a baseline FVC ≥ 50%
  4. The diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed by one of the following:
     a) Finding on high-resolution computed tomography indicates usual interstitial pneumonia (UIP)
     b) A surgical lung biopsy demonstrates UIP
     c) Exclusions from other known causes of interstitial lung disease must be documented (i.e. occupational or environmental exposure, drug toxicity, or connective tissue disease)
  5. The patient is a nonsmoker or has been abstinent from smoking for at least 6 weeks
  6. Ofev will not be used in combination with Esbriet
  **Continuation of Therapy Criteria:**
  1. Predicted FVC has not declined ≥10% or >200mL decrease
  2. Patient continues to be smoke free
  Quantity limit: 60 capsules for 30 days
  Specialty Pharmacy required.
  Approval: One (1) year.
  Approved by the P&T Committee 10/17/2018.

- **Omnitrope (somatotropin)**
  **Indications for approval in CHILDREN (up to age 18):**
  All of the following must be met.
  1. Documented growth hormone deficiency that meets the following criteria:
     a. Patient must be evaluated by a pediatric endocrinologist.
     b. Epiphyses are not closed.
     c. Must meet **TWO** of the following criteria:
        1. Subnormal response (≤10ng/ml) to at least two GH provocative stimulation tests or subnormal response to one GH provocative
stimulation test and IGF-1 and IGFBP-3 more than 2 SD below the mean for age and gender.

- In a neonate with hypoglycemia, but not metabolic disorder, a peak GH level less than 20 ng/ml is usually diagnostic of GHD.

Note: Provocative stimulation tests include arginine, clonidine, glucagon, insulin, and levodopa. Two tests can be performed simultaneously.

2. Baseline height ≤ 2.25 SD below mean (or below the 3rd percentile) for age or gender.

3. Growth failure defined by the following rates:
   a. Age two to four years: height velocity (HV) less than 5.5 cm/year (<2.2 inches/year)
   b. Age four to six years: HV less than 5 cm/year (<2 inches/year)
   c. Age six years to puberty:
      i. HV less than 4 cm/year for boys (<1.6 inches/year)
      ii. HV less than 4.5 cm/year for girls (<1.8 inches/year)

4. Documentation of bone age is more than 2 SD below the mean for chronological age.

2. Turner Syndrome in females
   a. Diagnosis of Turner Syndrome confirmed by appropriate genetic testing.
   b. Patient has a growth rate below 7 cm per year if less than 3 years of age, and below 4 cm per year if greater than 3 years of age.
   c. Bone age less than 14 years.
   d. Documentation provided that epiphyses are not closed.

3. Chronic Renal Insufficiency
   a. Documented clinical diagnosis of chronic renal insufficiency.
   b. Patient has a growth rate below 7 cm per year if less than 3 years of age and below 4 cm per year if greater than 3 years of age.
   c. Existing metabolic derangements (such as acidosis, secondary hyperparathyroidism, malnutrition) have been corrected.
   d. Documentation provided that epiphyses are not closed.
   e. Patient is not post renal transplant.

4. Small for gestational age
   a. Documented birth weight of less than 2,500 g at a gestational age of more than 37 weeks or a birth weight or length below the 3rd percentile for gestational age.
   b. Documented lack of sufficient catch-up growth by age 2 and a height of less than 2 SD for chronological age.

5. Noonan Syndrome and Prader-Willi Syndrome
   a. Diagnosis confirmed by appropriate genetic testing.
   b. Documentation provided that epiphyses are not closed.

Continuation of Therapy Criteria and Approval Length for Children:
1. Epiphyses must not be closed.
2. First year of therapy: Height velocity must double the pretreatment rate.
3. After first year of therapy: Height velocity must be ≥ 2.5cm/yr.

**Indications for approval in ADULTS:**
All of the following must be met.

1. **Adult onset GHD** - Multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma.
   a. Patient has ≥ 2 of the following pituitary hormone deficiencies: thyroid stimulating hormone deficiency, adrenocorticotropin hormone deficiency, gonadotropin deficiency, and arginine vasopressin (aka vasopressin or antidiuretic hormone (ADH)) deficiency.
   b. Low serum IGF-I.
   c. Patient must exhibit clinical features of adult GHD including: increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors (high LDL, low HDL).
   d. Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request.

2. **Childhood onset GHD** - Adults who were GH deficient as children or adolescents.
   a. Patient has subnormal response to at least 2 provocative stimulation tests (≤ 5 ng/ml) following a GH washout period (1-3 months).
   b. Patient must exhibit clinical features of adult GHD including: increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors.
   c. Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request.

**Continuation of Therapy Criteria and Approval Length for Adults:** Authorization for all of the above indications will be for 1 year, after which documentation will be required to support therapy benefit.

**Compendial Uses:** Non-FDA-approved uses for the growth hormone products that are considered to be “medically-accepted indications” based on the drug information sources that CMS has recognized to be authoritative compendia will be considered for approval for treatment with if the diagnosis, dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature. Continuation of treatment or retreatment with a growth hormone product for a compendial use will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

**Exceptions:** Any other medical conditions or exceptions to the above conditions of coverage for a growth hormone product will be considered through the Pharmacy Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed. Specialty Pharmacy required.

*Note:* Vials only will be covered on Medicaid plans.

Approved by the P&T Committee 07/2004.
Revised 07/21/2010, 09/19/12, 11/06/2013, and 04/2/2019.

**References:**
• **Oncology**

*Note: Preferred formulary medications must be utilized before consideration of non-formulary agents and all medications are subject to formulary quantity limits and approved dosages.*

**Indications for Approval:**

There must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium.

Updated by the P&T Committee 01/17/2018.

• **Onpattro (patisiran lipid complex injection)**

**Indications for Approval:**

All of the following must be met

1. Member is 18 years of age or older.
2. Member has a documented diagnosis of peripheral nerve disease caused by hereditary transthyretin-mediated amyloidosis (hATTR)
3. Documentation that the member has a pathogenic transthyretin (TTR) mutation (e.g., V30M).
4. Documentation of one of the following:
   a. Baseline polyneuropathy disability (PND) score ≤ IIIb
   b. Baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2
5. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction)
6. Member is not currently taking diflunisal, tafamidis, doxycycline or tauroursodeoxycholic acid.
7. Documentation that the member does not have severe renal impairment, end-stage renal disease, moderate or severe hepatic impairment, or prior liver transplant.
8. Requested dose is within accordance with the U.S. Food and Drug administration prescribing information.

**Continuation of Therapy Criteria:**

1. Documentation of one of the following:
   a. Patient continues to have PND score ≤ IIIb
   b. Patient continues to have a FAP Stage 1 or 2
2. Documentation that the member has experienced a positive clinical response to Onpattro
3. Member is not currently taking diflunisal, tafamidis, doxycycline or tauroursodeoxycholic acid.
4. Requested dose is within accordance with the U.S. Food and Drug administration prescribing information.

Length of Approval: 1 year.

<table>
<thead>
<tr>
<th>Code: C9036</th>
<th>0.1 mg = 1 billable unit</th>
</tr>
</thead>
</table>

Approved by the P&T Committee 10/17/2018.

- **Opana ER (oxymorphone HCl ER)**
  
  *Criteria apply to oxymorphone ER only. Opana ER Crush Resistant is not covered.*

  **Step Edit Criteria:**
  
  The patient must have a claim history of morphine sulfate extended release tablets (MS Contin) within the past 90 days.

  **Quantity Limit:** 60 tablets for 30 days

  Approved by the P&T Committee 09/10/2007.

- **Opioid Cumulative Doses Exceeding 90 MME per day**

  All of the following must be met:

  1. The member is NOT being treated for cancer pain, receiving hospice care or palliative care, or a resident of a long-term care facility (excluded from this criteria)
  2. Thorough pain history has been performed that includes all other opioid and non-opioid therapies trialed
  3. Pain intensity evaluation with numeric rating scale (0-10 scale) for
     a. Current pain
     b. Average pain level in last week
  4. What is the total daily morphine milligram equivalent?
  5. Cumulative opiate doses totaling >90 mg Morphine milligram equivalent (MME) must provide a clear treatment plan including goals for pain and function.
  6. If this request is for >200mg of morphine sulfate equivalent per day, state timeframe for tapering down to less than 200mg MME
  7. Is the current addition (leading to >90 mg MME) for treatment of acute pain?
     a. Has this patient already completed 15 days of opioid medication treatment for acute pain in the last 12 months?
     b. If the patient has already received three refills beyond the first 15 days this PA will be denied
  8. Signed controlled substance agreement and a clear action plan when the agreement is broken
  9. Regular follow-up visits ≤ 3 months from last visit
  10. Provider must provide a current Urine Drug Screen (UDS)
      a. Identification of other non-prescribed substances must be addressed
b. Absence of prescribed drug in urine drug screen must be addressed
   i. Two negative urine drug screens will result in denial of requests

11. The requesting provider must pull the New Mexico Board of Pharmacy
    Prescription Monitoring Program (PMP) report and certify that the patient is not
    receiving pain medications from multiple sources (doctor shopping or receiving
    controlled substances from multiple pharmacies)
   a. Any aberrant activity must be addressed

12. Documentation that a prescription for naloxone has been issued to the member
    must be provided.

13. For continuation- documentation supporting efficacy of current regimen is
    required (pain scores, clinical/functional response)

14. If the patient does not experience improvement in pain and function and needs
    increasing dosages, documentation that a pain management specialist was
    consulted is required

Approval Length: up to 6 months
Approved by the P&T Committee 10/16/2019

- **Opdivo (nivolumumab)**
  Refer to the Oncology criteria located within this document.
  
  | Code: J9299 | 1mg = 1 billable unit |

Approved by the P&T Committee 01/21/2015. Updated 04/15/2015 and 11/05/2015.

- **Orap (pimozide)**
  Indications for Approval:
  All of the following must be met:
  1. Member must have a documented diagnosis of Tourette disorder or delusional
     infestation.
  2. Member has a documented trial and failure of at least 2 preferred formulary
     antipsychotic medications used to treat the medical conditions noted above.

Approval Length: 1 year
Quantity Limit: 30 tablets per 30 days
Approved by the P&T Committee: 07/17/2019.

- **Orencia (abatacept)**
  Indications for Approval:
  1. The patient must have a current PPD (tuberculosis) negative skin test, negative
     QuantiFERON-TB Gold test, or documented treatment for latent tuberculosis
     prior to initiation of therapy. AND
2. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23, or Prevnar) prior to initiation of therapy. AND
3. The patient must have had a documented trial and failure of both Humira (adalimumab) and one other formulary TNF-inhibitor. AND
4. The appropriate disease specific criteria below have been met:

   a. **Adult Psoriatic Arthritis**
      i. The patient must have an adequate trial (3 months or more) of methotrexate. If methotrexate is contraindicated, a 3 month or more trial of one for the following other disease modifying anti-rheumatic drugs (DMARDs) is required:
         - Leflunomide
         - Sulfasalazine
      ii. The patient must have a documented trial and failure of both and Humira (adalimumab) and one other formulary TNF-inhibitor.

   b. **Juvenile Idiopathic Arthritis**
      i. The patient must have had an adequate trial (three months or more) of methotrexate at a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (three months or more) of one of the following other disease modifying anti-rheumatic drugs (DMARDs) is required:
         - Leflunomide
         - Hydroxychloroquine
         - Sulfasalazine
         - Minocycline
         - Gold Salt
      ii. The patient must have a documented trial and failure of both Humira (adalimumab) and one other formulary TNF-inhibitor.

   c. **Rheumatoid Arthritis (RA)**
      i. Documented presence of moderate to severe RA. Moderate to severe RA is defined as: DAS28 > 3.2 or CDAI > 10.1.
      ii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted dose for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other disease modifying anti-rheumatic drugs (DMARDs) must have been tried:
         - Leflunomide
         - Hydroxychloroquine
▪ Sulfasalazine
▪ Minocycline
▪ Gold Salt

Subcutaneous Administration for Adult RA
▪ After a single intravenous infusion as a loading dose, a 125mg subcutaneous injection should be given within 24 hours, followed by 125mg subcutaneously once a week
▪ Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Ocrecia without an intravenous loading dose.
▪ Patients transitioning from Ocrecia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

5. Medical records or a typed summary documenting all of the above must be submitted with the Prior Authorization request.

Approval: 1 year
Specialty Pharmacy required.
Quantity Limit: Autoinjector/Syringe – 4 autoinjectors/syringes every 28 days.

| Code: J0129 | 10mg = 1 billable unit |

Approved by the P&T Committee 01/21/2009. Updated 05/20/2009, 11/06/2013, 07/16/2014 and 10/18/2017.

• Orilissa (elagolix)

Indications for Approval:
Must meet all of the following:
1. Documentation that patient has moderate to severe pain associated with endometriosis
2. Documentation that patient does not have one of the following contraindications to use:
   • Pregnancy
   • Osteoporosis
   • Severe hepatic impairment
   • Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil).
3. Documented trial and failure of at least two of the following:
   • Nonsteroidal anti-inflammatory medication
   • Hormonal contraceptive
   • GnRH agonist

Continuation of Therapy Criteria:
1. Documentation that patient has decrease in endometriosis related pain.
2. Documented decrease in analgesic medications used

**Quantity limit:**
- 150 mg tablet: 30 tablets for 30 days
- 200 mg tablet: 60 tablets for 30 days

**Initial Approval Length:** Three (3) months.

**Reauthorization**:  
- 150 mg tablet: One (1) year
- 200 mg: Three (3) months

*NOTE: A maximum of 24 months of therapy with Orilissa 150 mg will be authorized and a maximum of 6 months of therapy with Orilissa 200 mg will be authorized.

Specialty Pharmacy required.

Approved by the P&T Committee 10/17/2018.

Reference:


- **Orkambi (lumacaftor-ivacaftor)**

  **Indications for Approval:**

  **All of the following must be met:**

  1. Documentation that patient has a diagnosis of cystic fibrosis.
  2. Patient is ≥ 6 years of age.
  3. Patient is homozygous for the F508del mutation in the CFTR gene.
  4. Documentation of all of the following:
     i. Pretreatment ppFEV₁ (within the past 30 days).
     ii. Patient has had two negative respiratory cultures for any of the following: *Burkholderia cenocepacia*, *Burkholderia dolasa*, or *Mycobacterium abscessus* in the past 12 months.
     iii. Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter.
     iv. Baseline ophthalmic exam for pediatric patients.
     v. No dual therapy with another CFTR potentiator is planned.

  **Continuation Criteria:**

  **All of the following must be met:**

  1. Patients response to therapy is documented (e.g. stable or improvement of ppFEV₁ from baseline, weight gain, decreased exacerbations, etc.).
  2. Patient has had two negative respiratory cultures for any of the following: *Burkholderia cenocepacia*, *Burkholderia dolasa*, or *Mycobacterium abscessus* in the past 12 months.
  3. Documentation of annual testing of ALT, AST, and bilirubin levels after the first year of therapy.
  4. No dual therapy with another CFTR potentiator is planned.

**Quantity limit:** 120 tablets for 30 days

**Initial Approval Length:** 6 months.
Continuation Approval Length: 1 year.
*Specialty Pharmacy required.
Approved by the P&T Committee 04/18/2018.

- **Oseni (alogliptin and pioglitazone)**
  Step Edit Criteria:
  The patient must have a prescription claim history for metformin or alogliptin within the past 545 days.
  Quantity limit: 30 tablets for 30 days
  Approved by the P&T Committee 04/18/2018.

- **Paxil CR (paroxetine CR)**
  Step Edit Criteria:
  The patient must have a 30-day trial and failure on 3 formulary generic selective serotonin reuptake inhibitors (SSRIs) within the past 545 days.
  Alternatives: citalopram, escitalopram, fluoxetine, paroxetine, and sertraline.

- **Paxil (paroxetine) oral suspension**
  Indications for approval:
  Documentation that the patient is unable to swallow oral tablets or capsules AND
  The patient is not currently taking other medications in an oral tablet or capsule form.
  Quantity Limit: 900 mL for 30 days
  Approval Length: Up to 1 year
  Approved by the P&T Committee 04/18/2018.

- **Pegasys (peginterferon alfa-2A)**
  Indications for Approval:
  Please refer to the [Hepatitis C Treatment criteria](#) for approval criteria located within this document.
  Approval Length: 12 weeks.
  Specialty Pharmacy required.
  Approved by the P&T Committee 07/17/2013. Updated 01/21/2015.

- **Perjeta (pertuzumab)**
  Refer to the [Oncology criteria](#) located within this document.
  Code: J9306
  1mg = 1 billable unit
  Approved by the P&T Committee 07/18/2012. Updated 11/05/2015.
• **Piqray (alpelisib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 60 tablets for 30 days
  Specialty Pharmacy Required
  Approval: 6 months
  Approved by the P&T Committee: 10/16/2019.

• **Polivy (polatuzumab vedotin-piiq)**
  Refer to the Oncology criteria located within this document.
  Approval: 6 months
  Approved by the P&T Committee: 10/16/2019.

• **Pomalyst (pomalidomide)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 21 capsules for 28 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 03/20/2013. Updated 07/15/2015 and 11/05/2015.

• **Poteligeo (mogamulizumab-kpkc)**
  Refer to the Oncology criteria located within this document.
  Code: C9038  1 mg = 1 billable unit
  Approved by the P&T Committee 10/17/2018.

• **Potiga (ezogabine)**
  Indications for approval:
    1. Documented diagnosis of partial-onset seizures.
       AND
    2. A trial and failure of two medications indicated for partial-onset seizures.
  Quantity Limit: 90 tablets for 30 days.
  Approval: One year
  Approved by the P&T Committee 05/16/2012

• **PrandiMet (repaglinide/metformin)**
  Step Edit Criteria:
    The patient must have previous use of at least one of the medications (Prandin or metformin) that make up the combination medication within past 120 days.
  Alternatives: Prandin, metformin.
  Approved by the P&T Committee 05/20/2009.

• **Prandin (repaglinide)**
  Step Edit Criteria:
The patient must have a 30-day prescription fill of metformin in the past 545 days.
Alternative: metformin
Approved by the P&T Committee 07/18/2018.

**Prevacid (lansoprazole capsules)**
Step Edit Criteria:
The patient must have a claim history of a 30-day trial of omeprazole and pantoprazole within the past 545 days.
Quantity Limit: 60 capsules for 30 days.
Alternatives: omeprazole capsules, pantoprazole
Approved by P&T Committee 01/20/2016.

**Prevacid SoluTabs (lansoprazole orally disintegrating tablet)**
Indications for Approval:
1. Patients with a feeding tube.
   **OR**
2. Patients under one year of age.
Approved by the P&T Committee 05/19/2010

**Prolia (denosumab)**
Indications for Approval:
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture.
2. Treatment to increase bone mass in men with osteoporosis at high risk for fracture.
3. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy* for non-metastatic prostate cancer.
4. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy† for breast cancer.
5. Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture.

**AND all of the following must be met:**
   a. T-score of ≤ -2.5 at the femoral neck, total hip or lumbar spine by DXA.
      **OR**
      Low bone mass (T-score between -1.0 and -2.5 at the femoral neck, total hip, or lumbar spine by DXA) **and** a 10-year hip fracture probability ≥ 3% or a 10-year major osteoporosis-related fracture probability ≥ 20% based on the USA-adapted WHO absolute fracture risk model (Fracture Risk Algorithm (FRAX®)). The FRAX tool may be accessed using the following link: [www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)
      **OR**
Personal history of hip or vertebral fracture occurring during adulthood in the absence of major trauma (i.e. fracture that occurs following a fall from standing height or less).

b. The patient has an inadequate response to or is intolerant to one oral bisphosphonate and one intravenous bisphosphonate or a creatinine clearance (CrCl) of < 35 mL/minute.

- Inadequate response is defined as one of the following:
  - Progression of bone loss as determined by DEXA after one year of therapy.
  - Occurrence of osteoporotic fracture after having been on at least one year of drug therapy.

- A trial and failure of an intravenous bisphosphonate only will be required if a patient has a relative or absolute contraindication to oral bisphosphonate therapy such as an increased risk for upper GI injury due to a co-morbid condition (e.g., esophageal motility disorder or Barret’s esophagus), physical condition (e.g., cannot sit-up for the required time period following oral dosing), a nonfunctional GI tract (e.g., enteral feedings via gastric or jejunostomy tube).

- Patients with severe systemic reactions (i.e., severe musculoskeletal pain) to one bisphosphonate (IV or oral) will not be required to have an additional bisphosphonate trial.

c. Documentation that any pre-existing hypocalcemia is corrected prior to the start of Prolia therapy and patient will be taking calcium 1000mg daily and at least 400 IU vitamin D daily while on Prolia therapy is required.

Continuation of Therapy Criteria:
1. Documentation of the most recent BMD testing (DXA spine and hip) must be provided.
2. BMD must be stable or improving based on repeat DXA results one to two years after initiating therapy and on periodic repeat BMD assessments thereafter.

Approval Length: One year.
Specialty Pharmacy required.

| Code:  J0897 | 1mg = 1 billable unit |

* Androgen Deprivation Therapy: orchiectomy, gonadotropin-releasing hormone antagonists (degarelix, goserelin, histrelin, leuprolide, triptorelin), or anti-androgen therapy (bicalutamide, flutamide, nilutamide)
† Aromatase Inhibitor Therapy: anastrozole, letrozole, exemestane.

References:

Approved by the P&T committee 01/19/2011. Revised 11/16/2011, 11/28/2012, 04/15/2015, 04/19/2017 and 07/18/2018

- **Protein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors**

  *Note: The preferred formulary medication (Repatha) must be utilized before consideration of non-formulary agents in this class, and all medications are subject to formulary quantity limits and approved dosages.*

  Indications for Approval (all must be met):

  1. Must be prescribed by, or in consultation with one of the following:
     a. Cardiologist
     b. Endocrinologist
     c. Lipid specialist
  2. Submission of medical records (e.g. chart notes, laboratory values) documenting one of the following diagnoses:
     a. Atherosclerotic Cardiovascular Disease (ASCVD) as confirmed by one of the following:
        i. Acute coronary syndromes
        ii. History of myocardial infarction
        iii. Stable or unstable angina
iv. Coronary or other arterial revascularization
v. Stroke
vi. Transient ischemic attack
vii. Peripheral arterial disease presumed to be of atherosclerotic origin

b. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by Dutch Lipid Clinic diagnostic criteria score greater than or equal to 9 (i.e. definite FH)
c. Homozygous Familial Hypercholesterolemia (HoFH)
   i. Genetic analysis (note that evolocumab is not covered for members with two LDL receptor negative alleles), or
   ii. An untreated LDL level over 500mg/dl, and
       1) The presence of xanthomas before the age of 10, or
       2) Evidence of heterozygous familial hypercholesterolemia in both parents.

3. Submission of medical records (e.g. chart notes, laboratory values) documenting ONE of the following:
   a. Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy and will continue to receive a high-intensity statin (Table 1) at maximally tolerated dose.
   b. Both of the following:
      i. Patient is unable to tolerate* high-intensity statins.
      ii. Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin therapy and will continue to receive a moderate-intensity statin (Table 1) at maximally tolerated dose.
   c. Both of the following:
      i. Patient is unable to tolerate* moderate- and high-intensity statins.
      ii. Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin (Table 1) at maximally tolerated dose.
   d. Patient is unable to tolerate* low-, moderate-, and high-intensity statins, and
      i. Has undergone a trial of a statin re-challenge with another low intensity statin with documented reappearance of muscle symptoms, or
      ii. Has a labeled contraindication to all statins as documented in medical records, or
iii. Has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times the upper limit of normal (ULN).

4. Submission of medical records (e.g. chart notes, laboratory values) documenting one of the following:
   a. If the patient is within 25% of goal LDL-C, patient must have received at least 12 consecutive weeks of ezetimibe therapy as adjunct to maximally tolerated statin therapy and will continue to receive ezetimibe.
   b. Patient has a history of failure, contraindication, or intolerance to ezetimibe.

5. Submission of medical records (e.g. chart notes, laboratory values) documenting the following within the past 30 days: LDL-C equal to or greater than 70mg/dl less than 50% LDL-C reduction from baseline while on maximally tolerated lipid lowering regimen.

6. Medication is used as adjunct to a low-fat diet and exercise.

7. Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

*Statin Intolerance for the purpose of this criteria is defined as intolerable and persistent (i.e. >2 weeks) symptoms: 1) Myalgia (muscle symptoms without CK elevations), or 2) Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]).

Table 1

<table>
<thead>
<tr>
<th>HIGH-INTENSITY statin</th>
<th>atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODERATE-INTENSITY statin</td>
<td>atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, fluvastatin XL 80 mg, fluvastatin 40 mg twice daily, or pitavastatin ≥2 mg</td>
</tr>
<tr>
<td>LOW-INTENSITY statin</td>
<td>simvastatin 10 mg, pravastatin 10-20 mg,Lovastatin 20 mg, fluvastatin 20-40 mg, pitavastatin 1 mg</td>
</tr>
</tbody>
</table>

Criteria for Continuation of Therapy:
1. Submission of medical records (e.g. chart notes, laboratory values) documenting all of the following:
   a. Adherence to complete lipid lowering regimen as evidenced by consistent prescription fills including statin, PCSK9 and other Lipid Lowering Therapy (LLT) such as ezetimibe and/or lipid apheresis. AND
   b. Greater than 50% LDL-C reduction after initiation of PCSK9 therapy. Or
   c. Patients with HoFH: Greater than 20% LDL-C reduction after initiation of PCSK9 therapy.

Quantity Limit:
- HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD – two (2) injections monthly
- HoFH – three (3) injections monthly

Length of Approval:
- Initial approval – three (3) months
- Continuation – six (6) months

Specialty Pharmacy Required.

Approved by the P&T Committee 11/05/2015. Updated 04/20/2016 and 01/17/2018.

References:
• **Protopic (tacrolimus ointment)**
  Step Edit Criteria:
  The patient must have previous use of at least one formulary topical corticosteroid within the past 90 days.

• **Provenge (sipuleucel-T)**
  Refer to the Oncology criteria located within this document.
  Approved by the P&T Committee 03/21/2012. Updated 11/05/2015.

• **Provigil (modafinil)**
  Indications for Approval:
  The medication must be prescribed by a sleep specialist or neurologist and must meet one of the following:
  1. A documented diagnosis of narcolepsy
     • The member must have a documented treatment failure, inability to tolerate, or other medical contraindication (including but not limited to: cardiovascular disease) to one or more formulary alternative medications.
  2. A documented diagnosis of Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)
     • Documentation that the member has been on CPAP for at least two months and is using it four or more hours a night is required.
  3. A documented diagnosis of Shift Work Sleep Disorder (SWSD)
     • A letter from the employer is required stating the member is working a variable, alternating, or third shift.
  4. A documented diagnosis of Multiple Sclerosis Fatigue.

  Quantity Limit: 30 tablets for 30 days.
  Alternatives: methylphenidate, methylphenidate extended release (Metadate CD, methylphenidate ER tablets 10mg, 20mg) dextroamphetamine, amphetamine/dextroamphetamine.
  Approved by the P&T Committee 09/15/2010.

• **Psychotropic Drugs and Medications, Non-Preferred**
  Covered products are: Pristiq (desvenlafaxine), Fetzima (levomilnacipran), nefazodone, protriptyline, trimipramine, Trintellix (vortioxetine), Marplan (isocarboxazid)
  Indications for Approval:
  All of the following must be met:
  1. Member has a documented diagnosis of depression.
2. Member has an adequate trial and failure of each of the following (Note: An adequate trial for the purposes of these criteria will be a trial at a therapeutic dose for at least 4 weeks of therapy without improvement in symptoms or documentation of intolerable side effects to the medication.):
   a. A formulary preferred SSRI
   b. A formulary preferred SNRI
   c. A formulary preferred atypical antidepressant (bupropion, mirtazapine)

Approval Length: 1 year
Approved by the P&T Committee: 07/17/2019.

- **Pulmonary Arterial Hypertension Criteria**
  Indications for Approval:
  1. Must be prescribed by a cardiologist or pulmonologist.
  2. Meets diagnostic criteria for Pulmonary Arterial Hypertension as determined by a right heart catheterization.
     a. mPAP >25mmHg at rest.
     b. Normal pulmonary arterial wedge pressure ≤15mmHg
     c. Pulmonary Vascular Resistance (PVR) >3 Wood units.
  3. If the patient has a positive vasoreactive test, documents must show a trial of maximally tolerated calcium channel blocker (long-acting nifedipine, diltiazem, or amiodipine)
     - Positive vasoreactive test is defined as a fall in mPAP ≥10mmHg to an mPAP ≤ 40mmHg, AND cardiac output must be unchanged or increased.
  4. Documentation of the following additional information must be provided
     a. WHO/NYHA modified functional class ≥ 2 (see table 1)
        i. Treatment for functional class 1 is not recommended at this time.
     b. NT-proBNP at time of diagnosis
     c. Cardiac Index
     d. Sv,02 (mixed venous oxygen saturation)
     e. 6 minute walk distance

Continuation Criteria:
Documents showing 3 of the following must be provided for continued approval
  1. Improvement in WHO functional class from baseline (lower number is better)
  2. Decrease in NT-proBNP from baseline
  3. Cardiac Index increased from baseline
  4. Sv,02 increased from baseline
  5. Symptoms progression has decreased or stopped

Initial Approval Length: 3 months.
Continuation Approval Length: 1 year.

**Table 1 Definition of WHO Functional Class**

<table>
<thead>
<tr>
<th>Functional Class</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>Symptoms do not limit physical activity. Ordinary physical activity does not cause undue discomfort</td>
</tr>
<tr>
<td>Class 2</td>
<td>Slight limitation of physical activity. The patient is comfortable at rest, but experiences symptoms with ordinary physical activity</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Class 3</td>
<td>Marked limitation of activity. Patient is comfortable at rest, but experiences symptoms with minimal physical activity</td>
</tr>
<tr>
<td>Class 4</td>
<td>Inability to carry out any physical activity. The patient may experience symptoms even at rest. Discomfort is increased by any physical activity. Manifest signs of right-sided heart failure</td>
</tr>
</tbody>
</table>

Approved by the P&T Committee 04/19/2017.

- **Qbrelis (lisinopril oral solution)**
  
  **Indications for Approval:**
  
  The following criteria apply to patients greater than 12 years of age:
  
  The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.

  Approved by the P&T Committee: 04/26/2019

- **Ranexa (ranolazine)**
  
  **Step Edit Criteria:**
  
  The member must have a claim history within the past 120 days of all of the following agents:
  
  a) Beta Blocker
  b) Calcium Channel Blocker
  c) Nitrate

  Alternatives: atenolol, carvedilol, diltiazem, isosorbide dinitrate, isosorbide mononitrate, metoprolol, nadolol, nifedipine, nitroglycerin, propranolol, verapamil.

  Prior Authorization Criteria approved by the P&T Committee 09/20/2006.
  
  Revised to Step Edit Criteria by the P&T Committee 03/24/2010.

- **Rebetol (ribavirin)**
  
  **Indications for Approval:**
  
  Please refer to the [Hepatitis C Treatment](#) criteria for approval criteria located within this document.

  Approval Length: Up to 24 weeks.

  Specialty Pharmacy required.

  Approved by the P&T Committee 07/17/2013. Updated 01/21/2015.

- **Remeron Sol Tab (mirtazapine ODT)**
  
  **Indications for Approval:**
  
  1. A psychiatrist must initiate therapy.
     
       AND
     
  2. The patient is unable to take or swallow oral medication. They should not be on other oral medications.
OR

The patient is “cheeking” the medication (cheeking is considered not swallowing the medication then spitting it out when the caregiver is not looking).

Quantity Limit: 30 tablets for 30 days.
Alternative: mirtazapine tablets
Approved by the P&T Committee 07/17/2013.

- **Remicade (infliximab)**
  Note: Renflexis (infliximab-ABDA) is the preferred formulary infliximab product on all formularies. Remicade will only be covered for indications for which Renflexis does not have FDA Approval.

  **Indications for Approval:**
  1. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.
     AND
  2. The patient should have documentation of having received pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.
     AND
  3. The appropriate Disease Specific Criteria below has been met.

    The patient has a diagnosis of one of the following:
    a. **Juvenile Rheumatoid Arthritis**
       i. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.
       ii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.
          ▪ Leflunomide
          ▪ Hydroxychloroquine
          ▪ Sulfasalazine
          ▪ Minocycline
          ▪ Gold Salt

    4. Medical records or a typed summary documenting all of the above criteria must be submitted along with the Pharmacy Exception request.

Specialty Pharmacy required.

Approval Length: One year (for all above diagnoses).

| Code: J1745 | 10mg = 1 billable unit |
• **Renflexis (infliximab-ABDA)**  
  Criteria is dependent on diagnosis  
  Indications for Approval:  
  1. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.  
     **AND**  
  2. The patient should have documentation of having received pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.  
     **AND**  
  3. The appropriate Disease Specific Criteria below has been met.  
     The patient has a diagnosis of one of the following:  
     a. **Ankylosing Spondylitis**  
        i. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated.  
        ii. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated.  
        iii. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Remicade without a trial of sulfasalazine  
     b. **Psoriatic Arthritis**  
        i. An adequate trial (3 months or more) of methotrexate  
        ii. Or if the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following DMARDs:  
           ▪ Leflunomide  
           ▪ Hydroxychloroquine  
           ▪ Sulfasalazine  
     c. **Rheumatoid Arthritis**  
        AND meets all of the following:  
        i. Documented presence of moderate to severe rheumatoid arthritis (RA). Moderate to severe rheumatoid arthritis is defined as: DAS-28 >3.2 or CDAI >10.1.  
        ii. The patient has received at least 3 months of current and continuous (at a minimum quarterly) follow-up.
iii. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted dose for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.

- Leflunomide
- Hydroxychloroquine
- Sulfasalazine
- Minocycline
- Gold Salt

d. **Crohn’s Disease**
   i. Fistulizing Crohn’s Disease
   or
   Induction and maintenance of clinical remission in moderately to severely active Crohn’s Disease in patients with an inadequate response or intolerance to conventional therapy.
   
   Conventional therapy, for the purpose of this policy, includes the use of three or more of the following:
   - Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
   - Sulfasalazine
   - Immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate)
   - 5-aminosalicylic acid (brand names include Rowasa®, Pentasa® and Asacol®)
   - Antibiotics (e.g., metronidazole, quinolones).

e. **Plaque Psoriasis**
   Chronic, moderate to severe, Plaque Psoriasis (psoriasis vulgaris) AND meeting all the following additional criteria:
   
   i. Involvement of $\geq 10\%$ of the patient’s body surface area (BSA). Exceptions may be considered for extensive recalcitrant facial involvement, pustular involvement of the hands or feet, and/or genital involvement interfering with normal sexual function.
   
   ii. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and/or a Dermatology Life Quality Index (DLQI) of more than 10.
   
   iii. History of an adequate trial and treatment failure with phototherapy or photochemotherapy or such treatment is contraindicated, not tolerated, or unavailable.
   or
History of an adequate trial and treatment failure with methotrexate or such treatment is contraindicated or not tolerated.

f. **Adult Ulcerative Colitis**
   Moderately to severely active Ulcerative Colitis in patients who have had an inadequate response to conventional therapy. Conventional therapy, for the purpose of this policy, includes the use of the following:
   - Topical and oral aminosalicylates
   - Topical, oral or IV corticosteroids
   - Oral or IV immunotherapy (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
   - Surgery for refractory disease.

g. **Pediatric Ulcerative Colitis**
   Moderately to severely active Ulcerative Colitis in patients who have had an inadequate response to conventional therapy. Conventional therapy, for the purpose of this policy, includes the use of the following:
   - Topical and oral aminosalicylates
   - Topical, oral or IV corticosteroids
   - Oral or IV immunotherapy (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
   - Surgery for refractory disease.

4. Medical records or a typed summary documenting all of the above criteria must be submitted along with the Pharmacy Exception request.

*Specialty Pharmacy required.

Approval: One year (for all above diagnoses).

| Code: Q5104 | 10mg = 1 billable unit |

Approved by the P&T Committee 04/18/2018. Updated 01/17/2019, 10/16/2019.

- **Repatha (evolucumab)**
  Refer to the [Protein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors](#) criteria located within this document.

  **Quantity Limit:**
  - HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD – two (2) injections monthly
  - HoFH – three (3) injections monthly, Repatha Pushtronex System – 3.5ml for 28 days.

  **Length of Approval:**
  - Initial approval – three (3) months
  - Continuation – six (6) months
  - Specialty Pharmacy Required.
• **Restasis (cyclosporine ophthalmic emulsion)**
  Indications for Approval:
  1. It is prescribed by an optometrist or ophthalmologist.
     AND
  2. The patient has a diagnosis of keratoconjunctivitis sicca.
     or
     The patient has a diagnosis of Sjogren’s disease.
     AND
  3. The patient has failed at least two separate 30-day trials of different over-the-counter (OTC) ocular lubricants/artificial tear solutions (one of which must be from the high viscosity class, unless clinically contraindicated).

Initial Approval Length: 6 months.

Quantity Limit:
- Restasis – 60 vials for 30 days
- Restasis Multidose bottle – 5.5mL for 30 days.

Alternatives: Artificial Tears solution 0.4%, Artificial Tears solution 1.4%, Moisture Eyes 1-0.3%, Systane ointment.

Initial Length of Approval: 6 months

References:

Approved by the P&T committee 03/17/2004. Revised 07/16/2014 and 01/21/2015.

• **Retacrit (epoetin alpha-epbx)**
  Indications for Approval:
  1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.
     a) The maximum dose for the first 4 weeks of treatment is 9 mcg/kg.
     b) Hemoglobin must be <11g/dl.
  2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.
     a) The maximum dose for the first 4 weeks of treatment is 9 mcg/kg.
     b) Hemoglobin must be <11g/dl.
  3. Anemia due to HCV Treatment:
     a) Recent (within 2-3 weeks) hemoglobin <10g/dl
     AND
     b) Persists for at least 2 weeks after ribavirin dose reduction (may be reduced in 200mg incremental reductions or one-time reduction to 600mg/day)

OR
Patient is receiving peginterferon/ribavirin alone with documented evidence that the patient is post-liver transplantation or HIV/HCV co-infected.

The use of Retacrit is considered experimental, investigational, and unproven for any indication not listed above, including but not limited to the following:
- Aplastic anemia
- B-12 and folate deficiency anemias
- Iron deficiency anemia
- Post-hemorrhagic anemia

Exceptions: Exceptions to the above conditions of coverage are considered through the Medical Exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Quantity Limits:
- 2000 U/mL, 3000 U/mL, 4000 U/mL, 10000 U/mL: 12 vials (12 mL) per 28 days.
- 40000 U/mL: 4 vials (4 mL) per 28 days.

Length of Approval: Up to 6 months.

<table>
<thead>
<tr>
<th>Code: Q5106 (non-ESRD use)</th>
<th>1000 units = 1 billable unit</th>
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<tr>
<td>Code: Q5105 (ESRD on dialysis)</td>
<td>100 units = 1 billable unit</td>
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References:

Approved by the P&T Committee 07/18/2018.

- **Retin-A (tretinoin)**
  Refer to the Retinoids, Topical Criteria located within this document.

- **Retinoids, Topical (Differin 0.1%, Retin-A)**
  Note: Covered products are Differin (adapalene 0.1%) and Retin-A (tretinoin)
  Indications for Approval: (for patients age 40 and up)
  - The patient has a diagnosis of actinic keratosis.
    OR
  - The patient has a diagnosis of adult acne.
  Approval: 6 months
  Rationale: This drug is on the formulary primarily for the treatment of acne. The drug is not covered for cosmetic purposes, such as to decrease fine facial lines associated with aging.

- **Revatio (sildenafil)**
  Refer to the Pulmonary Arterial Hypertension Criteria located within this document.
  Quantity Limit: 90 tablets per month for Primary Pulmonary Hypertension.
Note: maximum FDA dosage is 60mg/day.
Updated by the P&T Committee 04/19/2017

- **Revlimid (lenalidomide)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/06/2013, 01/15/2014, 04/15/2015 and 11/05/2015.

- **Rhopressa (netarsudil)**
  **Step Edit Criteria:**
  The patient must have a claim history of one preferred ophthalmic prostaglandin within the past 120 days.
  Approval: One (1) year.
  Approved by the P&T Committee 10/17/2018.

- **Risperdal M-Tab (risperidone orally disintegrating tablet)**
  **Indications for Approval:**
  1. A psychiatrist must initiate therapy.
  2. The patient is unable to take or swallow oral medication. They should not be on other oral medications.
  **OR**
  The patient is “cheeking” the medication (cheeking is considered not swallowing the medication then spitting it out when the caregiver is not looking).
  **Quantity Limit:**
  0.25mg, 0.5mg, 1mg, 2mg, 3mg – 60 tablets for 30 days
  4mg – 120 tablets for 30 days
  **Alternatives:** risperidone tablets.
  **Approval:** One year.

- **Rituxan (rituximab)**
  **Indications for Approval:**
  Due to a black box warning regarding the risk of reactivation of the hepatitis B virus (HBV) and recommendations by the FDA, all patients must be screened for HBV infection within a year prior to initiation of Rituxan.
  1. Non-Hodgkin’s Lymphoma (NHL)
  2. CD20-positive CLL – in conjunction with fludarabine and cyclophosphamide.
  3. Rheumatoid Arthritis (RA) – must meet all of the following:
     a. The patient is 18 years or older.
     b. This must be prescribed by or in conjunction with a rheumatologist
c. Documented presence of moderate to severe rheumatoid arthritis. Moderate to severe RA is defined as: DAS-28 >3.2 or CDAI >10.1.
d. The patient must have had a documented trial and failure of TWO preferred targeted immunomodulators for this indication
e. Must be given in conjunction with methotrexate or leflunomide if the patient is intolerant to methotrexate.
f. Will not be approved for use in combination with targeted immunomodulators

**Dosing criteria for RA** - The recommended dose is two 500 -1000mg IV infusions separated by 14 days.

**Retreatment criteria for RA** – Continued use will require Prior Authorization and will only be approved if the course is to be administered six (6) months from the last course of treatment and there is documentation of improvement in disease activity after previous infusions. For retreatment earlier than 6 months since completion of the last course of therapy, there must be a documented increase in disease activity (i.e. increase of ≥ 1 point on CDAI or increase of ≥ 1 on DAS-28). Requests for retreatment sooner than 16 weeks since completion of the last course of treatment will not be approved.

Initial length of approval:  6 months
Subsequent length of approval: 1 year, QL: Two 1000mg infusions separated by 2 weeks every 6 months.

4. Wegener’s granulomatosis (WG) in combination with glucocorticoids.
5. Microscopic polyangiitis (MPA) in combination with glucocorticoids.
6. Pemphigus Vulgaris (PV) in adult patients – must meet all of the following:
   a. Patient has documented moderate to severe PV.
   b. Patient will be receiving Rituxan in combination with a tapering course of glucocorticoids.

The following indications listed below will be considered for approval for treatment with Rituxan if standard interventions, treatment, and/or therapy has failed, become intolerable, and/or are contraindicated. Dosing, frequency, and length of therapy must be supported by, and consistent with published medical literature.

Continuation of treatment or retreatment with Rituxan for the following indications listed below will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical literature.

- Graft versus host disease
- Multicentric Castleman’s disease (angiofollicular lymph node hyperplasia)
- Multiple Sclerosis (MS)
- Myasthenia Gravis
- Neuromyelitis optica
- Post-transplant lymphoproliferative disorder (PTLD)
▪ Prophylaxis of rejection in sensitized kidney transplant recipients with donor specific antibodies
▪ Refractory autoimmune hemolytic anemia (AIHA)
▪ Refractory immune or idiopathic thrombocytopenic purpura (ITP)
▪ Relapsed or refractory hairy cell leukemia (HCL) in persons who have failed at multiple (two or more) courses of cladribine
▪ Second-line treatment of persons with relapsed or refractory CD20 positive chronic lymphocytic leukemia (CLL)
▪ Symptomatic persons with stage III-IV nodular lymphocyte-predominate Hodgkin’s disease (LPHD) who are refractory or intolerant to standard chemotherapy
▪ Systemic lupus erythematosus (SLE)
▪ Waldenstrom’s macroglobulinemia (WM)

Exceptions: Any other medical conditions or exceptions to the above conditions of coverage for Rituxan will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Approval: For NHL and CD20-positive CLL – 1 year.
For RA and all other diagnoses – a single round of therapy. Subsequent doses based on the patient’s clinical evaluation prior to the next dose.
For PV – 1 year. Two 1000 mg doses two weeks apart initially, 500 mg at month 12, then 500 mg every 6 months thereafter.

| Code: J9312 | 10mg = 1 billable unit |

Approved by the P&T Committee 09/17/2008.

• **Rocklatan (netarsudil and latanoprost)**
  Indications for approval:
  Has intolerance to or has not reached IOP-lowering goals following treatment with at least two agents with different mechanisms of action used in combination, such as prostaglandins, beta blockers, or cholinergic agonists.

Approval Length: one year
Approved by the P&T Committee 07/26/2019

• **Rozerem (ramelteon)**
  Indications for Approval:
  Insomnia - Patient must have a documented treatment failure of all of the following:
  ▪ Zolpidem oral tablets
  ▪ A formulary benzodiazepine used for the treatment of insomnia.
  ▪ Trazodone
Quantity Limit: 30 tablets per 30 days.
Alternatives: lorazepam, temazepam, trazodone, triazolam, zolpidem.
Approved by the P&T Committee 07/15/2009.

- **Rubraca (rucarparib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 120 tablets for 30 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 01/18/2017.

- **Rydapt (midostaurin)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit:
  - Acute myeloid leukemia (AML) – 120 tablets for 30 days.
  - Aggressive systemic mastocytosis (ASM), Systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL) – 240 tablets for 30 days.
  Approved by the P&T Committee 07/19/2017.

- **Sanctura (trospium)**
  Step Edit Criteria:
  The patient must have a claim history of generic oxybutynin XL within the past 545 days.
  Alternatives: oxybutynin XL, oxybutynin transdermal (Oxytrol® for Women).
  Approved by the P&T Committee 09/15/2010.

- **Sanctura XR (trospium ER)**
  Step Edit Criteria:
  The patient must have a claim history of generic oxybutynin XL within the past 545 days.
  Alternatives: oxybutynin XL, oxybutynin transdermal (Oxytrol® for Women).
  Approved by the P&T Committee 09/15/2010.

- **Sarafem (fluoxetine HCl tablets)**
  Indications for Approval:
  All of the following must be met:
  1. Member must have a documented diagnosis of pre-menstrual dysphoric disorder (PMDD)
  2. Member must have a documented trial and failure of fluoxetine capsules (generic for Prozac) and at least one additional formulary preferred selective-serotonin reuptake inhibitors (e.g., citalopram, escitalopram, sertraline).
Approval Length: 1 year
Quantity Limit: 30 tablets per 30 days
Approved by the P&T Committee: 07/17/2019.

- **Sensipar (cinacalcet)**
  Indications for Approval:
  1. The patient has a diagnosis of secondary hyperparathyroidism with chronic kidney disease on chronic dialysis and all of the following:
     a. Intact parathyroid hormone (iPTH) >300 pg/ml.
     b. Serum calcium level > 8.4 mg/dl (corrected for serum albumin).
     c. The patient has continued hyperparathyroidism despite management with standard therapy (i.e. dietary phosphate restriction, phosphate binders, and vitamin D).
  2. The patient has a diagnosis of hypercalcemia with Parathyroid Carcinoma and all of the following:
     a. Serum calcium level > 12.5 mg/dl (corrected for serum albumin).
     b. Medication is being given to the patient to control hypercalcemia prior to surgical intervention; in a patient who is not a surgical candidate; or recurrence despite surgical intervention.
  3. Severe hypercalcemia (serum calcium level > 12.5 mg/dl corrected for serum albumin) in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy.
Approval: One year.
Revised by the P&T Committee 11/05/2015.

- **Sklise Lotion (ivermectin)**
  Step Edit Criteria:
  The patient must have a trial and failure of permethrin within the past 60 days.
Approved by the P&T Committee 11/06/2013.

- **Soliris (eculizumab)**
  Indications for Approval:
  1. Paroxysmal Nocturnal Hemoglobinuria (PNH)
     The patient is being treated for paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. A record of the Hematocrit/Hemoglobin lab tests for the past one year and lab evidence for hemolysis must be submitted.
     AND
     a. The following diagnostic tests performed (documentation must accompany the request):
        - Flow Cytometric Immunophenotyping (FCMI)
        - PNH Gel Card Test (GAT)
- Ham Test
- Sucrose Lysis Test (SLT)

AND

b. The prescribing physician is a hematology/oncology specialist.

OR
c. The patient has prior history of blood transfusions (please provide number of blood transfusions administered per year).

OR
d. The patient has prior use of erythropoietin (please provide number of doses administered per year).

OR
e. The patient has history of failure of at least two standard therapies for PNH.

These therapies could include prednisone, danazol, azathioprine, and/or cyclosporine. The definition of “failure” could include intolerable side effects that would preclude use or ongoing hemolysis resulting in symptomatic anemia requiring treatment. With regard to prednisone, the definition of failure will include stopping prednisone if the dose cannot be reduced to less than 20mg daily within a few months of starting therapy.

• Approval Length: The approval will be for a total of 3 months, chart notes and laboratory results must document patient response for an extension of Prior Authorization.

2. Atypical hemolytic Uremic Syndrome (aHUS).
   ▪ A documented diagnosis of Atypical hemolytic Uremic Syndrome (aHUS).
   ▪ Approval Length: The approval will be for a total of 3 months, chart notes and laboratory results must document patient response for an extension of Prior Authorization.

3. Generalized Myasthenia Gravis (gMG)
   a. Positive serologic test for anti-acetylcholine receptor (anti-A ChR) antibodies.
   b. Myasthenia Gravis Foundation (MGFA) Clinical Classification Class* II to IV.
   c. MG-Activities of Daily Living (MG-ADL)* total score ≥ 6.
   d. A documented trial and failure of pyridostigmine.
   e. A documented trial and failure of at least a year with 2 or more immunosuppressant therapies (e.g. glucocorticoids, azathioprine, mycophenolate, cyclosporine, or tacrolimus).
   f. Patient has required chronic plasmapheresis/plasma exchange or IVIG.
      ▪ Length of Approval – 6 months
Continuation of Therapy Criteria: Documented improvement in the MG-ADL score of at least 3 points.

*The MG-ADL assessment and MGFA Clinical classifications can be found at [http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx](http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx)

4. Neuromyelitis optica spectrum disorder
   a. Must be prescribed by or in consultation with a neurologist
   b. Must have a diagnosis of neuromyelitis optica spectrum disorder
   c. Must be anti-aquaporin-4 (AQP4) antibody positive
   d. Must provide documentation that a meningococcal vaccine was given at least two weeks prior to the administration of the first dose of Soliris
   e. Approval length will be 6 months

**Restrictions:** As part a risk management program, providers and patients must enroll with Soliris™ OneSource Safety Registry prior to treatment initiation (1-888-765-4747).

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<tr>
<th>Code: J9310</th>
<th>10mg = 1 billable unit</th>
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Specialty Pharmacy required.


- **Soriatane (acitretin)**

  **Indications for Approval:**
  The patient must have documented chronic severe plaque psoriasis and meet all of the following:
  1. Involvement in greater than or equal to 10% of the patient’s body surface area.
     AND
  2. Psoriasis Area Severity Index of 10 or more and/or Dermatology Life Quality Index of more than 10.
     AND
  3. History of an adequate trial and treatment failure with phototherapy or photochemotherapy, or such treatment is contraindicated, not tolerated, or is unavailable.
     AND
  4. History of an adequate trial and treatment failure with methotrexate, or such treatment is contraindicated or not tolerated.

  **Quantity Limit:** 60 capsules for 30 days

  Specialty Pharmacy required.

  Approved by the P&T Committee 07/17/2013. Updated 04/18/2018

- **Sporanox (itraconazole)**

  **Step Edit Criteria:**

PPC061309 Page 134 of 170 Effective 01/01/2020
The patient must have a claim history of terbinafine tablets or fluconazole tablets within the past 90 days.

Quantity Limit: 168 capsules for 365 days.

Alternative: terbinafine, fluconazole

Approved by the P&T Committee 07/17/2013. Updated 07/19/2017.

**Sporanox (itraconazole)**

Step Edit Criteria:

The patient must have a claim history of terbinafine tablets or fluconazole tablets within the past 90 days.

Quantity Limit: 168 capsules for 365 days.

Alternative: terbinafine, fluconazole

Approved by the P&T Committee 07/17/2013. Updated 07/19/2017.

**Spravato (esketamine)**

Indications for Approval:

All of the following must be met:

1. Documentation of failure of ALL of the following:
   - Three formulary antidepressants at an optimized dose for at least 8 weeks of treatment for each agent with adherence confirmed by prescription claims data.
   - Two adjunct agents such as: atypical antipsychotics, lithium, thyroid hormone, or electroconvulsive therapy for at least 8 weeks of treatment for each agent with adherence confirmed by prescription claims or medical claims data.

2. Documentation of the antidepressant that will be used concurrently with Spravato.

3. Patient must be 18 years of age or older.

4. Documentation that the patient is not pregnant.

5. Patient does not have any of the following contraindications
   - Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels)
   - History of intracerebral hemorrhage
   - Hypersensitivity to esketamine, ketamine, or any of the excipients

6. Documentation that the provider requesting medication is certified in the Spravato REMS program

7. Documentation that the member patient is enrolled in the Spravato REMS program and that the Spravato Medication Guide has been reviewed with the patient.
8. Documentation of the patient’s baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D).

Continuation of Therapy Criteria:
1. Documentation of maintenance of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurements).
   Approval Length: four weeks
Continuation Approval Length: 6 months
Specialty Pharmacy required
Approved by the P&T Committee: 07/17/2019.
References:

- **Sprycel (dasatinib)**
  Indications for Approval:
  1. Philadelphia chromosome positive chronic myeloid leukemia in chronic phase
     - Patient has a low-risk score and has intolerance, disease progression, or resistance to prior therapy with imatinib (Gleevec)
     OR
     - Patient has an intermediate- or high – risk score.
  2. Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec)
  3. Philadelphia chromosome positive acute lymphoblastic leukemia
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec).

Continuation Criteria:
All of the following must be met:
1. Documentation that the patient does not have evidence of disease progression must be submitted.
2. Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.
Quantity Limit: 30 tablets for 30 days.
Specialty Pharmacy required.
• **Steglatro (ertugliflozin)**  
  **Indications for Approval:**  
  1. Diagnosis of Diabetes Mellitus Type 2.  
  2. The patient has a recent (within the past 3 months) documented hemoglobin A1c (A1c) level of < 11 AND one of the following:  
      a. The patient is concurrently taking a metformin product and has inadequate glycemic control after a trial at a therapeutic dose and requires the addition of another agent, or  
      b. Is unable to take a metformin product due to one of the following:  
         • Documented intolerance to metformin. Examples of intolerance include diarrhea after titration up to a therapeutic dose ≥ 2000mg daily.  
         • Documented renal disease or renal dysfunction. For example, serum creatinine levels ≥ 1.5mg/dl (males) or ≥ 1.4mg/dl (females).  
         • Documented hepatic disease. For example, cirrhosis or hepatitis.  

  **Continuation of Therapy Criteria:**  
  1. A1c must decrease by 0.5% if initial A1c is ≤ 8%.  
  2. A1c must decrease by 1% if initial A1c is > 8%.  
  3. If the A1C value has not decreased according to the protocol listed below, then interventional measures will be taken which may include some or all of the following actions:  
      • Referral of the member to the PHP disease management team.  
      • Denial of the request with suggested alternative medications.  
      • Request for chart notes that describe the treatment plan and/or discussion with the prescribing provider about the treatment plan for the member.  

Initial Approval Length: 6 months.  
Continuation Approval Length: 1 year.  
Quantity Limit: 30 tablets for 30 days.  
Approved by the P&T Committee 10/17/2018.

• **Stiolto Respimat (tiotropium and olodaterol)**  
  **Step Edit Criteria:**  
  The patient must have a claim history of a formulary long-acting anticholinergic or a long-acting beta agonist (LABA) product within the past 180 days.  
  OR
The patient is diagnosed with COPD and in Group D. Group D defined as: \( \geq 2 \) exacerbations a year or \( \geq 1 \) hospitalization for exacerbation; and a CAT \( \geq 10 \) or mMRC grade \( \geq 2 \).

Approved by the P&T Committee 04/20/2016. Updated 04/19/2017.

- **Stivarga (regorafenib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 84 tablets for 28 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 11/28/2012. Updated 07/17/2013, 11/05/2015 and 07/19/2017.

- **Strattera (atomoxetine)**
  Note: For patients age 19 and up to treat ADHD, the Cerebral Stimulant/ADHD Treatment criteria also apply.
  Step Edit Criteria (for patients under the age of 19):
    - The patient must have a prescription claim history for a methylphenidate compound and amphetamine compound within the past 180 days.
  Indications for Approval (for patients age 19 and up):
    1. The patient has a history of a substance abuse disorder and meets the DSM-5 diagnostic criteria for ADHD. Refer to the Cerebral Stimulant/ADHD criteria. OR
    2. The patient has a trial and failure of a methylphenidate compound and amphetamine compound and meets the DSM-5 diagnostic criteria for ADHD. Note: Refer to the Cerebral Stimulant/ADHD criteria.
  Quantity limit: 30 capsules for 30 days.
  Approved by the P&T Committee 04/19/2017

- **Strensiq (asfostase alfa)**
  Indications for Approval:
    1. The patient has a diagnosis of either perinatal/infantile or juvenile-onset hypophosphatasia (HPP) and documentation of all of the following:
      a. Patient is \( \leq 18 \) years of age or was \( \leq 18 \) years of age at onset.
      b. Patient has/had clinical manifestations consistent with HPP at the age of onset prior to age 18 such as:
        i. Vitamin B6-dependent seizures
        ii. Skeletal abnormalities (rachitic chest deformity leading to respiratory problems or bowed arms/legs).
        iii. “Failure to thrive”
      c. Patient has radiographic imaging to support the diagnosis of HPP at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis).
d. Genetic testing has been completed confirming ALPL mutations.
e. Laboratory documentation of low serum alkaline phosphatase (ALP) in the absence of bisphosphonate use.
f. Laboratory documentation of one of the following: elevated phosphoethanolamine (PEA), elevated pyridoxal-5’-phosphate (PLP) in the absence of vitamin supplements or elevated inorganic pyrophosphate (PPi).

2. The prescriber is a specialist in the area of patient’s disease (e.g., endocrinologist).
3. The requested dose is within the FDA approved dosing range. A current weight for the patient must be documented.

Initial Approval Length: 6 months.

Continuation of Therapy:
1. Documentation that the patient has responded to treatment must be provided.
2. There must be evidence of improvement and/or stabilization in respiratory status, growth, or radiographic findings.

Continuation of therapy length of approval: 12 months

Exclusions: Strensiq will not be approved for use in patients with evidence of odontohypophosphatasia only, or for patients greater than 18 years without medical records to support diagnosis and onset of HPP prior to 18 years of age.

Specialty Pharmacy required.

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Approved by the P&T committee 07/19/2017.

- **Sutent (sunitinib)**
  Refer to the [Oncology criteria](#) located within this document.

Specialty Pharmacy required.

Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Sylatron (peginterferon alfa-2b)**
  Refer to the [Oncology criteria](#) located within this document.

Specialty Pharmacy required.

Approved by the P&T Committee 05/18/2011. Updated 11/05/2015.

- **Symbyax (olanzapine/fluoxetine)**

  Indications for Approval:
  All of the following must be met for their respective diagnosis:
  1. For Bipolar Depression:
     a. Must have prescription claim history for olanzapine (Zyprexa)
     b. For members without prescription claim history for olanzapine (Zyprexa), all of the following criteria must be met:
        i. Must have a diagnosis of Bipolar depression
        ii. Must be prescribed by a behavioral healthcare provider
iii. Must have a trial of olanzapine (Zyprexa) in the past year

2. For Major Depressive Disorder:
   a. Must have a diagnosis of treatment resistant Major Depressive Disorder
   b. Must have failure of both monotherapy and combination antidepressant therapy which includes both of the following:
      i. An adequate trial and failure (duration of at least 4 weeks) of, or intolerance to monotherapy with 2 different antidepressant therapies
      ii. A trial and failure, an inadequate response (duration of at least 4 weeks), or intolerance to one of the following:
         a. A single trial of combination antidepressant therapy such as a Selective Serotonin Reuptake Inhibitor (SSRI) and bupropion or a Selective Norepinephrine Reuptake Inhibitor (SNRI) and bupropion
         b. A single trial of an antidepressant with augmentation therapy (such as lithium)

Approval Length: 1 year
Quantity Limit: 30 tablets per 30 days
Approved by the P&T Committee: 07/17/2019.

• Symdeko (tezacaftor/ivacaftor)
  Indications for Approval:
  All of the following must be met:
  1. Documentation that patient has a diagnosis of cystic fibrosis.
  2. Patient is 6 years of age or older.
  3. Documentation of one of the following:
     i. Patient is homozygous for the F508del mutation in the CFTR gene.
     OR
     ii. Patient has at least one of the CFTR gene mutations as indicated in the FDA label.
  4. Documentation of all of the following:
     i. Pretreatment ppFEV₁ (within the past 30 days).
     ii. Patient has had two negative respiratory cultures for any of the following: *Burkholderia cenocepacia*, *Burkholderia dolasa*, or *Mycobacterium abscessus* in the past 12 months.
     iii. Baseline ALT, AST, and bilirubin that are less than three times upper limit of normal. ALT and AST should be assessed every 3 months during the first year of treatment, and annually thereafter.
     iv. Baseline ophthalmic exam for pediatric patients.
     v. No dual therapy with another CFTR potentiator is planned.

Continuation Criteria:
All of the following must be met:
1. Patients response to therapy is documented (e.g. stable or improvement of 
ppFEV₁ from baseline, weight gain, decreased exacerbations, etc.).
2. Patient has had two negative respiratory cultures for any of the following:  
   *Burkholderia cenocepacia, Burkholderia dolasa,* or *Mycobacterium abscessus*  
in the past 12 months.
3. Documentation of annual testing of ALT, AST, and bilirubin levels after the  
   first year of therapy.
4. No dual therapy with another CFTR potentiator is planned.

Quantity limit: 60 tablets for 30 days
Initial Approval Length: 6 months.
Continuation Approval Length: 1 year.
Specialty Pharmacy required.
Approved by the P&T Committee 04/18/2018. Updated 10/16/2019.

- **Symlin (pramlintide)**
  Prior Authorization Criteria:
  Initial requests must be prescribed by endocrinologist.
  Indications for Approval:
    A Prior Authorization may be requested for refills only after therapy initiation by  
    an endocrinologist, due to the stringent blood glucose monitoring requirements.
  Approval: One year.
  Approved by the P&T Committee 09/21/2005.

- **Synagis (palivizumab)**
  Indications for Approval:
    One of the following must be met:
    1. The patient is less than 12 months old (as of November 15) and with  
       hemodynamically significant congenital heart disease (CHD).
    2. The patient is less than 12 months old (as of November 15), born at less than 32  
       weeks, zero days and with chronic lung disease (CLD) of prematurity requiring  
       oxygen of FiO2 greater than 21% for greater than 28 days after birth.  
       Or  
       The patient is less than 24 months old (as of November 15) with chronic lung  
       disease (CLD) and continues on supplemental oxygen, diuretic or corticosteroid.
    3. The patient is less than 24 months old (as of November 15) and with severe  
       immunodeficiency.
    4. The patient is less than 12 months old (as of November 15) and with severe  
       neuromuscular disease with inability to clear secretions.
    5. The patient is less than 12 months old (as of November 15) and with congenital  
       abnormality of the airway with inability to clear secretions.
6. The patient is less than 12 months old (as of November 15) and born at 28 weeks, six days gestation or less.

7. The patient is less than 24 months old (as of November 15) and who undergo cardiac transplantation during the RSV season.

Approval: Synagis will only be approved and administered during the local Synagis season.
All Synagis injections will be administered through Presbyterian Home Healthcare Statewide Network contracted home care agencies.
Approved by the P&T Committee 10/15/2014.

- **Tabloid (thioguanine)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Tafinlar (dabrafenib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 120 capsules for 30 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 07/17/2013. Updated 04/16/2014 and 11/05/2015.

- **Tagrisso (osimertinib)**
  Refer to the Oncology criteria located within this document.
  Length of Approval: 6 months
  Quantity limit: 30 tablets per 30 days
  References:
  1. Tagrisso Prescribing Information. AstraZeneca Pharmaceuticals, LP. Wilmington, DE. April 2018.
  Approved by the P&T Committee 07/18/2018.

- **Takhzyro (lanadelumab-flyo)**
  Indications for Approval
  All of the following must be met:
  1. Must meet ALL criteria for HAE –AND- On-demand treatment (see below HAE criteria)
  2. Must meet ALL of the following prophylactic treatment criteria.
     a. Must have documentation showing that greater than 2 on-demand treated episodes per month have been needed or has other life-threatening factors: episode severity and limited emergency services. (note: On-Demand therapy should remain available to member after prophylactic treatment).
b. Has trialed and failed or has a contraindication or intolerant to tranexamic acid or attenuated androgens (danazol). *Danazol is not appropriate for growing children, pregnant women, concomitant liver disease, metabolic or nephrotic syndrome, or mood disorder.
c. Patients ≥12 years of age
d. Not approved in combination with other prophylactics (Cinryze or Haegarda)

Criteria for Continuation:
1. First Continuation at 4 months, on-demand therapy:
   a. Treatments must have decreased by >50%.
2. Second Continuation at 8 months:
   a. Evaluate on-demand treatment use, if member has been attack free for 6 months, then the dose interval can be decreased to once every 4 weeks.
3. Third continuation at 12 months and beyond:
   a. 4 months (if still evaluating dose frequency)
   b. 6 months if stable

Approval Length:
- First year: every 4 months
- Second year: every 6 months

Quantity Limit: Max 2 vials per 28 days (at 8 months review for dose interval reduction (to once monthly)
Specialty Pharmacy Required: BriovaRx
Approved by the P&T Committee 10/16/2019.

• **Talzenna (talazoparib)**
  Refer to the Oncology criteria located within this document.
  Quantity limit:
  - 1 mg capsules: 30 capsules for 30 days
  - 0.75 mg capsules: 90 capsules for 30 days
  Approval: 6 months
  Approved by the P&T Committee 01/17/2019

• **Tarceva (erlotinib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 60 tablets for 30 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 07/17/2013, 10/15/2014 and 11/05/2015.

• **Targretin (bexarotene)**
  Refer to the Oncology criteria located within this document.
Specialty Pharmacy required.
Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Tasigna (nilotinib)**
  Indications for Approval:
  1. Philadelphia chromosome positive chronic myeloid leukemia in chronic phase
     - Patient has a low-risk score and has intolerance, disease progression, or resistance to prior therapy with imatinib (Gleevec)
     OR
     - Patient has an intermediate- or high – risk score.
  2. Philadelphia chromosome positive chronic myeloid leukemia in accelerated or blast phase.
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec)
  3. Philadelphia chromosome positive acute lymphoblastic leukemia
     - Patient has intolerance, disease progression, or resistance to therapy with imatinib (Gleevec).

  Continuation Criteria:
  All of the following must be met:
  1. Documentation that the patient does not have evidence of disease progression must be submitted.
  2. Documentation that the patient does not have unacceptable toxicity from therapy must be submitted.

  Quantity Limit: 120 capsules for 30 days.
Specialty Pharmacy required.
Approved by the P&T Committee 09/21/2011. Updated 11/05/2015 and 04/18/2018.

- **Tecentriq (atezolizumab)**
  Refer to the Oncology criteria located within this document.

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<th>Code: J9022</th>
<th>10mg = 1 billable unit</th>
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  Approved by the P&T Committee 07/20/2016.

- **Temodar (temozolomide)**
  Refer to the Oncology criteria located within this document.
Specialty Pharmacy required.
Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Testopel Pellets (testosterone pellets)**
Indications for Approval:

Refer to the [Testosterone Products, Non-Preferred](#) Criteria located within this document.

Approval: One year.
Quantity Limit: 6 pellets for 90 days.
Approved by the P&T Committee 05/16/2012.
Revised 09/19/12 and 10/15/2014.

- **Testosterone Products, Non-Preferred**
  
  *Note: Covered products are Androderm, Fortesta and Testopel.*

Indications for Approval:

Patient must be over the age of 18 and meet one of the following:

1. **Primary hypogonadism in men (congenital or acquired)**
   Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.
   **AND**
   Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH.

2. **Hypogonadotrophic hypogonadism in men (congenital or acquired)**
   Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation.
   **AND**
   Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH†.
   † If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider.

3. **As a continuous therapy for Gender Dysphoria (age 16 and up)**
   Specific criteria apply. Refer to the [Gender Dysphoria Treatment Criteria](#) within this document.

**AND**

Must have a documented trial and failure of AndroGel.

Exclusions:

1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criteria for gender dysphoria.
2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approved by the P&T Committee 05/16/2012.
Revised 09/19/12 and 10/15/2014.
• **Testosterone Products, Preferred**

*Note: Covered products are testosterone 1% gel, testosterone cypionate and testosterone enanthate.*

Patient must be over the age of 18 and meet one of the following:

1. **Primary hypogonadism in men (congenital or acquired)**
   
   Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

   **AND**

   Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with an elevated LH and FSH.

2. **Hypogonadotropic hypogonadism in men (congenital or acquired)**

   Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation.

   **AND**

   Lab results required are two low TOTAL testosterone levels (drawn on separate days) and one lab with a low or low-normal LH and FSH†.

   † If your patient has low LH and FSH levels, please follow-up on these low levels or consider a referral to an endocrinology provider.

3. **As a continuous therapy for Gender Dysphoria (age 16 and up)**

   Specific criteria apply. Refer to the [Gender Dysphoria Treatment Criteria](#) within this document.

**Exclusions:**

1. Due to a lack of controlled evaluations in women and the potential for virilizing effects, testosterone products will not be approved for use in women who do not meet criteria for gender dysphoria.

2. Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Approved by the P&T Committee 09/16/2009. Revised 05/18/2011 and 10/15/2014.

• **Thalomid (thalidomide)**

   Refer to the [Oncology Criteria](#) located within this document.

   Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

• **Thiola (tiopronin)**

   **Indications for Approval:**

   All of the following must be met:

   1. Patient has a documented diagnosis of cystinuria.
2. Patient has tried and failed conservative therapy including the following: high fluid intake, sodium and protein restriction, and urinary alkalinization (e.g. use of potassium citrate).

Continuation of Therapy Criteria:
Documentation of decrease stone formation must be provided.
Length of Approval: 6 months.
Quantity limit: 300 tablets per 30 days.
References:
1. Thiola (tiopronin) [prescribing information]. San Antonio, TX: Mission Pharmacal Company; REV 010060.

Approved by the P&T Committee 07/18/2018.

- **Tibsovo (ivosidenib)**
  Refer to the [Oncology criteria](#) located within this document.
  Approved by the P&T Committee 10/17/2018.

- **Trelstar (triptorelin pamoate)**
  Refer to the [Oncology criteria](#) located within this document.
  Approval: 6 months
  Approved by the P&T Committee 10/16/2019

- **Tresiba (insulin degludec)**
  Step Edit Criteria:
  The patient must have a prescription claim history of Basaglar (insulin glargine) within the past 545 days.
  Alternative: Basaglar
  Approved by the P&T Committee 05/15/2019.

- **Triptans, Preferred**
  *Note: Covered products are Amerge (naratriptan), Maxalt (rizatriptan), Maxalt ODT (rizatriptan ODT) and Zomig (zolmitriptan).*
  Step Edit Criteria:
  The patient must have a claim history of a sumatriptan product (tablets, nasal spray, or injection) in the past 120 days.
  Alternative: sumatriptan
  Quantity Limit: 18 tablets for 30 days.
  Approved by the P&T Committee 10/19/2016.

- **Trulicity (dulaglutide)**
  Refer to the [GLP-1 Agonists (Trulicity and Victoza)](#) criteria for Medicaid Plans located within this document.
  Quantity Limit: 2mL (4 pens) for 28 days.
Approved by the P&T Committee 07/19/2017).

- **Tykerb (lapatinib)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit:  180 tablets for 30 days.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 01/15/2014, 10/15/2014 and 11/05/2015.

- **Tymlos (abaloparatide)**
  Indications for Approval:
  1. Treatment of postmenopausal women with osteoporosis and at high risk for fracture.
  AND all of the following must be met:
     a. Has a T-score of the hip, spine, or radius ≤ -2.5 as evidenced by a bone density scan.
     OR
     Has a 10-year hip fracture probability ≥ 3% or a 10-year major osteoporosis-related fracture probability of ≥ 20% based on the US-adapted WHO absolute fracture risk model, FRAX®, available at [http://www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)
     OR
     Personal history of hip or vertebral fracture occurring during adulthood in the absence of major trauma (i.e. fracture that occurs following a fall from standing height or less).
     b. Inadequate response to, or is unable to tolerate one oral and one intravenous bisphosphonate or a creatinine clearance (CrCl) of less than 35mL/min.
        ▪ Inadequate response is defined as progression of bone loss as determined by DEXA scan or occurrence of an osteoporotic fracture after having been on at least one year of drug therapy.
  Note: A trial and failure of an intravenous bisphosphonate only will be required if a patient has a relative or absolute contraindication to bisphosphonate therapy such as an increased risk for upper gastrointestinal injury due to a comorbid condition (e.g. esophageal mobility disorder, Barrett’s esophagus), a physical condition (e.g. unable to sit up for the required time period following oral dosing) or a nonfunctional gastrointestinal tract (e.g. enteral feedings via gastric or jejunostomy tube).
  Patients with severe systemic reactions (i.e. severe musculoskeletal pain) to one bisphosphonate (IV or oral) will not be required to have an additional bisphosphonate trial.
  c. Inadequate response to, or is unable to tolerate Prolia (denosumab).
**Note:** Patients with severe osteoporosis ($T$-score $\leq -2.5$ with a history of a fragility fracture OR $T$-score $\leq -3.5$) will not be required to have a trial and failure of Prolia.

Length of Approval: 1 year. Please note parathyroid hormone (PTH) analogs should not be used for more than 2 years. Cumulative use of PTH analogs for greater than 2 years will not be approved.

*Specialty Pharmacy required.

References:

1. Tymlos (abaloparatide) [prescribing information]. Waltham, MA: Radius Health; April 2017.
2. Rosen, Harold and Drezner, Marc. Overview of the management of osteoporosis in postmenopausal women. In Up-To-Date, Version 56.0; Waltham, MA. 2018.
3. Rosen, Clifford. Parathyroid hormone/parathyroid hormone-related protein analogs for osteoporosis. In Up-To-Date, Version 21; Waltham, MA. 2018.

Updated by the P&T Committee 07/18/2018.

- **Tysabri (natalizumab)**
  
  Indications for Approval (all of the following must be met):
  
  1. Must be prescribed by a neurologist.
  2. Patient must have relapsing form of multiple sclerosis.
  3. Must be used as monotherapy.
  4. Patient must have a documented trial and failure or inability to tolerate
     a) Glatopa
     AND
     b) An interferon beta 1A or 1B product such as Avonex, Rebif, Extavia.
  
  Approval: One year.

  References:
  

  | Code: J2323 | 1mg = 1 billable unit |

Approved by the P&T Committee 07/18/2012.
• **Uloric (febuxostat)**
  Indications for approval:
  1. Gout Prophylaxis
     AND
  2. One of the following criteria must be met:
     a. Documented failure at maximal therapeutic doses (600mg/day) of allopurinol.
        A documented failure is considered as non-resolution of tophi or at least 4 gout attacks (joint flares) per year with demonstrated medication compliance.
        OR
     b. Documented intolerance to allopurinol. Examples of intolerance include skin reactions or cytopenias.
        OR
     c. Treatment failure of allopurinol due to documented renal insufficiency.
        Example: CrCl ≤ 30ml/min.

Quantity Limit: 30 tablets for 30 days.
Alternatives: allopurinol, colchicine.
Approved by the P&T Committee 03/19/2009.

• **Ultomiris (ravulizumab-cwyz)**
  Indications for Approval:
  1. The patient is being treated for paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. A record of the Hematocrit/Hemoglobin lab tests for the past one year and lab evidence for hemolysis must be submitted.
     AND
     a. Has received a meningococcal vaccine at least 2 weeks prior to planned receipt of the first dose of Ultomiris.
     b. The following diagnostic tests performed (documentation must accompany the request):
        - Must have a laboratory confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as evidenced by having detectable GPI-deficient hematopoietic clones (Type III PNH RBC) via Flow Cytometry.
        - Laboratory report of flow cytometry testing must include at least 2 different reagents tested on at least 2 cell lineages.
        - Documentation of greater than 50 % of glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs);
         AND
     c. The patient must have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage).
         AND
     d. Must have an LDH level of 1.5 times the upper limit of the normal range.
AND
e. One of the following:
   i. Hemoglobin ≤ 7g/dL
   ii. Both of the following
      1) Hemoglobin ≤ 9g/dL
      2) Patient is experiencing symptoms of anemia

AND
f. The prescribing physician is a hematology/oncology specialist.
 OR
g. The patient has prior history of blood transfusions (please provide number of blood transfusions administered per year).

Approval Length: The approval will be for a total of 3 months.

Continuation of Therapy Criteria:
1. Documentation of a meningococcal vaccination at least every 5 years while on Ultomiris.
2. Patient has experienced an improvement in fatigue and quality of life.
3. Documentation demonstrating a positive clinical response from baseline:
   i. Increased or stabilization of hemoglobin levels
   ii. Reduction in transfusions
4. Continuation approval length: 6 months

Specialty Pharmacy required.
Updated by the P&T Committee 04/24/2019.

- **Unituxin (dinutuximab)**
  Refer to the Oncology criteria located within this document.
  Approved by the P&T Committee 11/05/2015.

- **Valcyte (valganciclovir)**
  Indications for Approval:
  1. Treatment of cytomegalovirus (CMV) retinitis in adult patients with acquired immunodeficiency syndrome (AIDS).
  2. Prevention of CMV disease in adult patients at high-risk with kidney, heart, and kidney-pancreas transplants.
  3. Prevention of CMV disease in pediatric patients at high risk with kidney or heart transplants.

Quantity Limit:
- 450mg tablet - 60 tablets for 30 days.
- 50mg/mL solution – 18mL/day.

Approved by the P&T Committee 1/20/2010. Updated 01/17/2018.
• **Valtrex (valacyclovir)**
  Step Edit Criteria:
  The patient must have a history of **TWO** claims for acyclovir within the past 120 days.
  Approved by the P&T Committee 01/17/2019.

• **Vancocin (vancomycin) 250 mg capsules**
  Indications for Approval:
  1. A microbial culture or toxin is positive for Clostridium difficile.
  2. Documentation that the patient has an initial episode of severe or fulminant Clostridium difficile.

  **Note:** Clostridium difficile overgrowth generally occurs in patients recently treated with antibiotics, which may be referred to as antibiotic-associated colitis.

  Approval: One time, no refills.

  Rationale: This Prior Authorization is based on a recommendation of the Centers for Disease Control (CDC) to limit the use of this drug. The use of this drug orally has been suggested to promote the emergence of resistant organisms, especially multi-drug resistant Enterococcus.

  Oral vancomycin is not absorbed systemically and will not effectively treat infections outside the gastrointestinal tract.

  Quantity Limit: 80 capsules per 30 day period.

  Approved by the P&T Committee 4/18/2018.

• **Varizig (varicella zoster immune globulin, human injection)**
  Indications for Approval:
  1. Immunocompromised patients without evidence of immunity.
  2. Newborn infants whose mothers have signs and symptoms of varicella around the time of delivery (i.e. 5 days before to 2 days after).
  3. Hospitalized premature infants born at ≥ 28 weeks gestation whose mothers do not have evidence of immunity to varicella.
  4. Hospitalized premature infants born at <28 weeks gestation or who weigh ≤1,000 grams at birth, regardless of their mothers’ evidence of immunity to varicella.
  5. Pregnant women without evidence of immunity.

  **Administration:**
  Varizig should be administered as soon as possible within 10 days of varicella-zoster virus exposure.

  Approved by the P&T Committee 07/15/2015.

• **Venclexta (venetoclax)**
  Refer to the Oncology criteria located within this document.

  Length of Approval: 6 months

  Quantity limit:
- 10 mg tablets: 2 tablets per day.
- 50 mg tablets: 1 tablet per day.
- 100 mg tablets: 4 tablets per day.
- Starter Pack: One pack per 28 days.

References:

Approved by the P&T Committee 07/18/2018.

- **Venofer (iron sucrose)**
  Refer to the Intravenous Iron criteria located within this document.

| Code: J1756 | 1mg = 1 billable unit |

Approved by the P&T Committee 05/19/2010. Revised 03/20/2013.

- **Verzenio (abemaciclib)**
  Refer to the Oncology criteria located within this document.

  Quantity limit: 60 tablets for 30 days
  Approval: 6 months

References:
1. Verzenio Prescribing Information. Lilly USA, LLC. Indianapolis, IN. February 2018.

Approved by the P&T Committee 04/18/2018

- **Vfend (voriconazole)**
  Indications for approval:
  The patient has a documented diagnosis of one of the following:
  1. Invasive aspergillosis.
  2. *Candida Krusei*.
  3. An organism known to be resistant to high dose fluconazole and susceptible to voriconazole.

*Documentation must include a culture report or susceptibility report if applicable.

Quantity Limit: 60 tablets for 30 days.

**Continuation of Therapy Criteria:** To ensure that therapeutic blood levels have been reached, voriconazole trough levels (see below) must be provided with each subsequent request for continuation of therapy.

**Notes:** Voriconazole levels may have up to a 100-fold inter-patient and intra-patient variance depending on age, concurrent illness, liver function, drug interactions or genetic polymorphisms. The therapeutic trough interval for voriconazole is 1mg to 5.5mg/L. Below 1mg/L the dose is too low and the patient may not receive any clinical benefit and levels above 5.5mg/L may lead to associated toxicities. Levels should be
taken 5 to 7 days after initiation or change of voriconazole therapy. The procedure for collecting levels can be found at: http://www.tricore.org/Healthcare-Professionals/Directory-of-Services.aspx?keyword=voricon
Approved by the P&T Committee 11/16/2009.

References:

- **Victoza (liraglutide)**
  
  *Note: Coverage of Victoza will require a documented trial and failure or intolerance to Trulicity (dulaglutide).*

  Refer to the GLP-1 Agonists (Trulicity and Victoza) criteria located within this document.

  Initial Approval Length: 6 months.
  Continuation Approval Length: 1 year.
  Quantity Limit: 3 pens (9mL) for 30 days.
  Approved by the P&T Committee 11/28/2007.
  Revised by the P&T Committee 03/24/2010, 07/19/2017 and 04/18/2018.

- **Viibryd (vilazodone)**
  
  Indications for Approval:
  1. Diagnosis of major depressive disorder
     AND
  2. A documented trial and failure of all of the following:
     - Selective serotonin reuptake inhibitor (SSRI)
     - Serotonin-norepinephrine reuptake inhibitor (SNRI)
  Quantity Limit: 30 tablets for 30 days.
  Alternatives: citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine IR, venlafaxine ER capsules.
  Approved by the P&T Committee 07/20/2011.

- **Vimpat (lacosamide)**
  
  Indications for Approval (all of the following are required):
  1. Must be prescribed by a neurologist.
  2. Must have a confirmed diagnosis of partial onset seizures
  3. Must be 4 years of age or older
  4. Must have a documented trial and failure or intolerance to at least two formulary anticonvulsants.
Approval: 1 year.

Quantity Limits:
- Tablets – 60 tablets for 30 days
- Oral solution – 1200 mL for 30 days

Approved by the P&T Committee 04/19/2017. Updated 04/18/2018.

- **Viscosupplementation**

  *Note: Formulary products are Gel-One (cross-linked hyaluronate) and Euflexxa (sodium hyaluronate 1%).*

  **Indications for Approval** (all must be met):

  1. Clinical diagnosis of osteoarthritis of the knee supported by radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to the knee or joint space narrowing
     OR
     Documented symptomatic arthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria which requires knee pain and at least five (5) of the following:
     - Age older than 50 years
     - Bony enlargement on exam
     - Bony tenderness on exam
     - Crepitus on exam on exam
     - No palpable warmth on exam
     - Morning stiffness that improves within 30 minutes of activity
     - Erythrocyte sedimentation rate less than 40mm/hour
     - Rheumatoid factor less than 1:40
     - Synovial fluid analysis: clear viscous, white blood cell count less than 2,000 µL (2.00 x 10⁹/L)
  2. The pain cannot be attributed to other forms of joint disease (e.g. acute knee injuries, rheumatoid arthritis, patella-femoral syndrome, chondromalacia of the knee).
  3. The pain interferes with functional activities.
  4. Documented lack of functional improvement following of a 3 month trial of at least two of the following:
     - Non-pharmacological interventions (e.g. exercise, weight loss, physical therapy)
     - Non-narcotic analgesics (e.g. acetaminophen, topical capsaicin, tramadol)
     - Non-steroidal anti-inflammatory drugs (NSAIDs)
     - Intra-articular corticosteroids
  5. Bilateral injections may be allowed if both knees meet the criteria for coverage.

  **Criteria for Continuation of Therapy:**

  1. Documentation of significant reduction in pain and improvement in function must be provided.
  2. Pain has recurred.
  3. At least 6 months have passed since the prior series of injections.

  **Quantity Limits:**
- **Euflexxa** - 1 series of injections to knee.
- **Gel-One** - 1 dose to knee.

Specialty Pharmacy required.

**Billing Code for Euflexxa**

| Code: J7323 | 1 injection = 1 billable unit |

**Billing Code for Gel-One**

| Code: J7326 | 30mg (one dose) = 1 billable unit |

Approved by the P&T Committee 01/15/2014. Updated 04/15/2015.

- **Vizimpro (dacomitinib)**
  
  Refer to the Oncology criteria located within this document.

  Quantity limit:
  
  30 tablets for 30 days

  Approval: 6 months

  Approved by the P&T Committee 01/17/2019

- **Votrient (pazopanib)**
  
  Refer to the Oncology criteria located within this document.

  Quantity Limit: 120 tablets for 30 days.

  Specialty Pharmacy required.

  Approved by the P&T Committee 09/21/2011. Updated 05/16/2012, 10/15/14 and 11/05/2015.

- **Vytorin (ezetimibe/simvastatin)**

  **Step Edit Criteria:**

  The patient must have a trial and failure on at least one of the following statins within the past 180 days: lovastatin, pravastatin, or simvastatin.

  Alternatives: lovastatin, pravastatin, and simvastatin.

- **Vyvanse (lisdexamfetamine)**

  **Indications for Approval:**

  1. **Attention Deficit Hyperactivity Disorder (ADHD)** –

     **Note:** For patients age 19 and up to treat ADHD, *Cerebral Stimulant/ADHD treatment* criteria also apply.

     - The patient must have a trial and failure of a formulary generic methylphenidate based CNS stimulant AND a formulary generic amphetamine CNS based stimulant.

  2. **Binge Eating Disorder (BED)** – all of the following are required:

     - A documented diagnosis of moderate to severe BED.
The patient has not responded to, or does not have access to cognitive behavioral therapy (CBT), guided self-help based on CBT, or interpersonal psychotherapy.

- Failure of one of the following: A selective serotonin reuptake inhibitor (SSRI), topiramate, or zonisamide.

Quantity Limit: 30 capsules for 30 days.

Approved by the P&T Committee 01/21/2009. Updated 07/15/2015, 11/5/2015 and 10/19/2016.

- **Vyxeos (daunorubicin/cytarabine)**
  
  **Indications for Approval:**

  Newly diagnosed therapy-related Acute Myeloid Leukemia (t-AML) or Acute Myeloid Leukemia with myelodysplasia-related changes (AML-MRC). and all of the following:

  - Patient is 18 years of age or older.
  - ECOG is ≤ 2.
  - Baseline LVEF is within normal limits.
  - Total cumulative doses of non-liposomal daunorubicin ≤ 550 mg/m2 or ≤ 400mg/m2 in patients who received radiation therapy to the mediastinum.
  - Will not be used in combination with other chemotherapy.

  Length of approval: 6 months.

  Dosing limits: Up to 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) will be authorized.

  Approved by the P&T Committee 01/17/2018.

- **Xalkori (crizotinib)**

  Refer to the Oncology criteria located within this document.

  Quantity Limit: 60 capsules for 30 days.

  Specialty Pharmacy required.

  Approved by the P&T Committee 09/21/2011. Updated 10/15/2014 and 11/05/2015.

- **Xanax XR (alprazolam extended-release tablets)**

  **Step Edit Criteria:**

  The patient must have a prescription claim history for a preferred formulary benzodiazepine within the past 90 days.

  Quantity limit:

  - 0.5 mg, 1 mg, and 2 mg extended-release tablets: 30 tablets for 30 days.
  - 3 mg extended-release tablets: 60 tablets for 30 days.

  Approved by the P&T Committee 04/18/2018.

- **Xarelto (rivaroxaban)**

  **Indications for Approval of 10mg, 15mg, and 20 mg strengths:**

  1. All FDA-approved indications
AND
2. The patient must have tried and failed warfarin or have a medical reason for not taking warfarin (poor INR control despite good adherence, allergy, intolerance, contraindication to use, or significant barrier to warfarin monitoring).
   a. If the patient is diagnosed with non-valvular atrial fibrillation (AF), warfarin will not be required.
      i. Non-valvular atrial fibrillation is defined as atrial fibrillation in a person without a mechanical heart valve OR AF in the absence of moderate to severe mitral stenosis
   b. If the patient is being treated for cancer-associated venous thromboembolism, warfarin will not be required

Indications for Approval of 2.5 mg strength:
1. Receiving concurrent aspirin therapy of at least 81 mg daily
   AND
2. One of the following diagnoses:
   A. Coronary Artery Disease:
      1. Over age 65 with any of the following conditions:
         • MI within the previous 20 years OR
         • Multi-vessel coronary disease with history of stable or unstable angina OR
         • Multi-vessel percutaneous coronary intervention OR
         • Multi-vessel CABG surgery
      2. ≤ 65 years old with one of the above conditions AND meets either of the following:
         a. Documented atherosclerosis or revascularization involving at least two of the following vascular beds:
            • Coronary vasculature
            • Aorta
            • Arterial supply to the brain
            • Gastro-intestinal tract
            • Lower limbs
            • Upper limbs
            • Kidneys
         b. Two additional risk factors from the list below:
            • Smoker within the previous year
            • Diabetes
            • eGFR <60 ml/min
            • Heart failure (ejection fraction must be >30%)
            • Non-lacunar ischemic stroke at least one month prior to start of therapy
B. **Diagnosis of peripheral arterial disease:**
   1. Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac, or infra-inguinal arteries, OR
   2. Previous limb or foot amputation for arterial vascular disease, OR
   3. History of intermittent claudication and one or more of the following:
      a. An ankle/arm blood pressure (BP) ratio < 0.90, OR
      b. Significant peripheral artery stenosis (≥50%) documented by angiography, or by duplex ultrasound, OR
      c. Previous carotid revascularization or asymptomatic carotid artery stenosis ≥50% as diagnosed by duplex ultrasound or angiography.

**Quantity Limit:**
- Starter Pack – 51 tablets for 90 days.
- 10mg and 20mg tablets - 30 tablets for 30 days.
- 2.5 mg tablets - 60 tablets for 30 days


**Reference:**

- **Xatmep (methotrexate oral solution)**
  *Indications for Approval:*
  The following criteria apply to patients greater than 12 years of age:
  - The patient is unable to take or swallow oral medications and should not be on other oral tablets or capsules.

Approved by the P&T Committee: 04/26/2019

- **Xeljanz/Xeljanz XR (tofacitinib)**
  *Indications for Approval:*
  1. The patient must have a current PPD (tuberculosis) negative skin test, negative QuantiFERON-TB Gold test, or documented treatment for latent tuberculosis prior to initiation of therapy.
     AND
  2. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23, or Prevnar) prior to initiation of therapy.
     AND
  3. The appropriate Disease Specific Criteria below has been met.
     a. **Rheumatoid Arthritis (RA)**
All of the following must be met:

i. Documented presence of moderate to severe rheumatoid arthritis defined as: DAS-28 >3.2 or CDAI >10.1.

ii. The patient must have had an adequate trial (three months or more) of methotrexate to a maximum tolerated dose (weight adjusted for children). If the patient has a contraindication to methotrexate, then an adequate trial (three months or more) of one of the following other disease modifying anti-rheumatic drugs (DMARDs) is required:
   - Leflunomide
   - Hydroxychloroquine
   - Sulfasalazine
   - Minocycline
   - Gold Salt

iii. The patient must have had a documented trial and failure of Humira (adalimumab) and one other preferred formulary biologic DMARD.

iv. Medical records or a typed summary documenting all of the above must be submitted with the prior authorization request.

b. Psoriatic Arthritis (PsA)

All of the following must be met:

i. The patient must have an adequate trial (three months or more) of methotrexate to a maximum tolerated dosage. If the patient has a contraindication to methotrexate then the patient must have an adequate trial of leflunomide.

ii. The patient must have had a documented trial and failure of Humira (adalimumab) and one other preferred formulary biologic DMARD.

c. Ulcerative Colitis (UC) (Immediate Release ONLY)

All of the following must be met:

i. The patient has documented moderately to severely active UC.

ii. The medication must be prescribed by or in consultation with a gastroenterologist

iii. The patient must have an adequate trial (3 months or more) or intolerance to at least two (2) of the following:
   - Thiopurines (azathioprine, 6-MP)
   - 5-Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
   - Cyclosporine
   - Steroids
iv. The patient must have had a documented trial and failure of Humira (adalimumab) and one other preferred formulary biologic DMARD.

Continuation of Therapy:
   Documentation of clinical benefit is required.

Quantity Limit:
   ▪ Xeljanz 5mg and 10 mg tablets - 60 tablets for 30 days.
   ▪ Xeljanz XR 11mg – 30 tablets for 30 days.

Initial Approval Length: Six (6) months.
Reauthorization: One (1) year.
Specialty Pharmacy required.

References:

Approved by the P&T Committee 07/16/2014. Updated 01/17/2018 and 07/18/18.

- **Xeloda (capecitabine)**
  Refer to the Oncology criteria located within this document.
  Specialty Pharmacy required.
  Approved by the P&T Committee 09/21/2011. Updated 11/05/2015.

- **Xenazine (tetrabenazine)**
  **Indications for Approval:**
  1. The patient does not have untreated or inadequately treated depression.
  2. The patient is not actively suicidal.
  3. The patient does not have hepatic impairment.
  4. The patient is not taking monoamine oxidase inhibitors (MAOIs) or reserpine.
  5. The appropriate Disease Specific Criteria below have been met.

  a. **Chorea associated with Huntington disease**
     i. The medication is being prescribed by or in consultation with a neurologist.
     ii. The patient is ambulatory.
     iii. Documentation of a baseline a of a baseline total maximal chorea score from the Unified Huntington Disease Rating Scale (UHDRS) must be provided.
     iv. The member has a documented trial and failure, or intolerance to, or a medical reason for avoiding the use of one of the following: amantadine or riluzole.
b. Tardive Dyskinesia
   i. The medication is prescribed by or in consultation with a neurologist or psychiatrist.
   ii. The patient has documented diagnosis of tardive dyskinesia.
   iii. Trial and failure of one of the following: amantadine, anticholinergic medication (e.g. trihexyphenidyl, benztropine), or a benzodiazepine (e.g. clonazepam).
   iv. Documentation of a baseline Abnormal Involuntary Movement Scale (AIMS) must be provided.

c. Tics associated with Tourette syndrome
   i. The medication is prescribed by or in consultation with a neurologist.
   ii. Documentation that tics are interfering with social interactions, school or job performance, activities of daily living, or are causing discomfort, pain, or injury.
   iii. There has been an inadequate response to or a medical reason for avoiding the use of the following treatment modalities:
      • For tics due to Tourette syndrome: risperidone or fluphenazine.
      • For tics due to Tourette syndrome with concurrent ADHD: clonidine or guanfacine.

Continuation of Therapy:
1. For all indications: Documentation showing the patient continues to be monitored for depression, suicidal ideation, and hepatic impairment.
2. Chorea associated with Huntington disease: Documented improvement in the total maximal chorea score from the UHDRS compared to baseline.
3. Tardive Dyskinesia: Documented improvement in AIMS compared to baseline.
4. Tics associated with Tourette syndrome: Documented reduction in frequency and intensity of tics.

Initial Approval: 6 months
Renewal: 1 year
Quantity Limits:
- 12.5mg - 90 tablets for 30 days
- 25mg – 120 tablets for 30 days.

Approved by the P&T Committee 10/18/2017. Updated 07/17/2019.

- **Xermelo (telotristat)**
  Indications for Approval:
  Initial Approval Criteria
  1. The patient is 18 years for age or older.
  2. The patient is being treated for carcinoid syndrome diarrhea.
3. Xermelo is being prescribed by, or in consultation with, an oncologist or gastroenterologist.
4. The patient has been on a maximum tolerated dose of somatostatin analog (SSA) for at 3 months and continues to have 4 or more bowel movements a day.
5. The patient has tried and failed other antidiarrheal therapies (e.g. loperamide, ondansetron, bile acid sequestrants).
6. Xermelo will be used in combination with a SSA.

**Continuation of Therapy Criteria:**

Documentation showing a decrease in the number of bowel movements a day is required.

**Approval Length:**

- Initial Approval - 12 weeks.
- Continuation of Therapy – Up to one year.

**Quantity Limit:** 90 tablets for 30 days.

Specialty Pharmacy required.

Approved by the P&T Committee 07/19/2017

- **Xgeva (denosumab)**

Indications for Approval (ALL of the following are required):

1. Documented diagnosis for the prevention of skeletal related events with bone metastases from solid tumors or multiple myeloma with failure or intolerance, or clinical rationale for the avoidance of Zometa or Aredia.
   - Example of failure would be a pathologic fracture while receiving Zometa or Aredia with compliance for at least 3 continuous months.
   - Example of clinical rationale for avoidance of Zometa or Aredia with compliance for at least 3 continuous months.

   OR

   Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

   OR

   Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

2. Documented serum calcium.

3. Evidence of concurrent treatment with calcium and vitamin D or rationale for avoidance.

*The National Cancer Institute defines a solid tumor as an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign or malignant. Examples of solid tumors are sarcomas, carcinomas, and lymphomas.*

Specialty Pharmacy required.

<table>
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<th>Code:</th>
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<th>1mg = 1 billable unit</th>
</tr>
</thead>
</table>

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References:

Approved by the P&T Committee 03/16/2011. Updated 11/06/2013, 10/15/2014, and 04/18/2018.

• **Xifaxan (rifaximin)**

  Indications for Approval
  1. Traveler’s diarrhea (200mg strength only) – Patient must meet all of the following criteria:
     ▪ Documented diagnosis of traveler’s diarrhea due to a noninvasive strain of *E.Coli*.
     ▪ Documented treatment failure with an oral antibiotic such as azithromycin or ciprofloxacin.
  2. Hepatic encephalopathy (200mg and 550mg strengths) – Patient must meet all of the following criteria:
     ▪ Documented diagnosis of hepatic encephalopathy.
     ▪ Documented treatment failure or documented intolerance or contraindication to lactulose.
  3. Irritable Bowel Syndrome, Diarrhea Predominant (IBS-D) – Patient must meet all of the following criteria:
     ▪ Documented diagnosis of Irritable Bowel Syndrome with diarrhea as the predominant symptom.
     ▪ Documented trial and failure of dietary modification (e.g. low FODMAP diet, lactose avoidance, gluten avoidance).
     ▪ Documented trial and failure of at least two of the following: antidiarrheals (i.e. loperamide), antispasmodics, or tricyclic antidepressants.
  4. Small Bacterial Overgrowth (SIBO) - Patient must meet all of the following criteria:
     ▪ Documentation of a recent positive lactulose/glucose breath test must be submitted and one of the following are met:
       a. An absolute increase in hydrogen by ≥20 ppm above baseline within 90 minutes.
       b. A methane level ≥ 10 ppm
     ▪ The patient must have documented trial and failure of one other antibiotic treatment (e.g., amoxicillin/clavulanate, metronidazole plus cephalaxin, metronidazole plus sulfamethoxazole/trimethoprim double strength).

Quantity Limits:
  Travelers’ Diarrhea – 9 tablets (200mg) for 3 days for any one 30-day period.
  Hepatic Encephalopathy –
▪ 200mg tablets - up to 180 tablets for 30 days.
▪ 550mg tablets – 60 tablets for 30 days.

**IBS-D**
▪ 42 tablets (550mg) for 14 days for any one 30-day period.
▪ Patients who experience a recurrence of symptoms can be retreated up to two times with the same dosage regimen.

**SIBO** – 42 tablets (550 mg tablets) for 14 days.

Approved by the P&T Committee 07/15/2009. Updated 05/19/2010, 07/15/2015 and 04/18/2018.

**Xolair (omalizumab)**

**Indications for Approval:**

**Treatment of Chronic Idiopathic Urticaria**

All of the following must be met:

1. The patient must have a documented diagnosis of chronic idiopathic urticaria.
2. Must be prescribed by Allergist/Immunologist.
3. Documentation of all the following is required:
   a. Minimum 30 day trial of scheduled, high dose non-sedating anti-histamines in combination with montelukast.
   b. Minimum of one short course of corticosteroids.
   c. Minimum 30 day trial of immunosuppressant, immunomodulatory or anti-inflammatory agent (i.e. cyclosporine, mycophenolate, tacrolimus, dapsone, hydroxychloroquine, sulfasalazine or methotrexate).

**Continuation of treatment for Chronic Idiopathic Urticaria**

Documentation of ALL the following is required:

1. Reduction in exacerbation frequency.
2. Reduction in exacerbation intensity.
3. Decrease in oral corticosteroid use.

Initial approval length: 3 months.

Subsequent approvals: Up to 6 months.

**Treatment of Moderate to severe persistent asthma**

All of the following must be met:

1. The requesting physician is an allergist or pulmonologist.
2. The patient’s age is 6 years or greater.
3. The patient has a documented IgE level > 30 IU/ml.
4. The specific evidence of “allergic asthma,” is supported by clinical and lab findings such as positive skin tests, symptom patterns, etc.
5. The patient has a documented failure on a minimum 6-month trial of inhaled steroid and long-acting beta-2 agonist combination therapy at maximum doses.
6. There is sufficient evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, or emergency room visits.

Initial Approval Length: 6 months, then evaluate for effectiveness and discontinue if not useful.

Dosing: Dosing of Xolair is considered medically necessary according to the FDA-approved labeling of Xolair (see Tables 1 and 2).

**Xolair FDA-approved Dosing Recommendations**:  
Table 1. Subcutaneous Xolair Doses Every 4 weeks for patients 12 years of age and Older with Asthma

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE</th>
<th>Body Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥30-100 IU/mL</td>
<td>30-60 kg</td>
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<tr>
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<td>&gt;400-500 IU/mL</td>
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<tr>
<td>&gt;600-700 IU/mL</td>
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Table 2. Subcutaneous Xolair Doses Every 2 weeks for patients 12 years of age and Older with Asthma

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<tr>
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<td>SEE TABLE 2</td>
</tr>
<tr>
<td>&gt;600-700 IU/mL</td>
<td>SEE TABLE 2</td>
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</tbody>
</table>

**DO NOT DOSE**

Dosing for Chronic Idiopathic Urticaria: 150 mg or 300 mg by subcutaneous route every 4 weeks

*Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. September 2014

| Code: J2357 | 5mg = 1 billable unit
---|---

Approved by the P&T Committee 11/16/2005. Revised 04/16/2014, 10/15/2014 and 10/19/2016.

- **Xospata (gliteritinib)**  
  Refer to the [Oncology](#) criteria located within this document.

Quantity limit:
- 90 tablets for 30 days

Approval: 6 months
• **Xtandi (enzalutamide)**
  Refer to the Oncology criteria located within this document.
  Quantity Limit: 120 capsules for 30 days.

• **Xulane (norelgestromin/ethinyl estradiol)**
  Step Edit Criteria:
    A prescription claim history of an 84-day supply of a formulary oral contraceptive or medroxyprogesterone acetate injection within the past 120 days is required.
  Quantity Limit: Three (3) patches for 28 days.
  Age Limit: Maximum age of 55 years.
  Approved by the P&T Committee 01/21/2015. Updated 04/18/2018.

• **Xyrem (sodium oxybate)**
  Indications for Approval:
  The medication must be prescribed by a neurologist or sleep specialist and must meet one of the following:
     All of the following are required:
     ■ The patient must be over the age of 7
     ■ The prescriber must participate in the “Xyrem Success Program”
     ■ The patient has a documented trial and failure of, or intolerance to an antidepressant (tricyclic antidepressant, formulary selective serotonin receptor inhibitor (SSRI), venlafaxine).
  2. Excessive daytime sleepiness (EDS) in narcolepsy.
     All of the following are required:
     ■ The patient must be over the age of 7
     ■ The prescriber must participate in the “Xyrem Success Program”
     ■ The patient has a documented trial and failure of, or intolerance to an adequate trial of a preferred formulary cerebral stimulant (methylphenidate or dextroamphetamine) and Nuvigil (armodafinil)*
       *Armodafinil requires a prior authorization.

Exclusions:
  1. Xyrem will not be approved if patient is being treated with sedative hypnotics or other CNS depressants.
  2. Patients with succinic semialdehyde dehydrogenase deficiency.
  3. Patients with a history of drug abuse.
  Quantity Limit: 540mL for 30 days.
Approved by the P&T Committee 07/17/2013. Updated 04/15/2015, 01/17/2019.

References:

- **Yervoy (ipilimumab)**
  - Refer to the [Oncology criteria](#) located within this document.
  - Code: J9228  
    | 1mg = 1 billable unit |
  - Approved by the P&T Committee 05/18/2011. Updated 04/15/2015 and 11/05/2015.

- **Zaltrap (ziv-aflibercept)**
  - Refer to the [Oncology criteria](#) located within this document.
  - Code: J9400  
    | 1mg = 1 billable unit |
  - Approved by the P&T Committee 07/19/2012. Updated 11/05/2015.

- **Zarxio (filgrastim-sndz)**
  - Refer to the [Granulocyte-Colony Stimulating Factors criteria](#) located within this document.
  - Code: Q5101  
    | 0.001mg = 1 billable unit |
  - Approved by the P&T Committee 11/05/2015.

- **Zejula (niraparib)**
  - Refer to the [Oncology criteria](#) located within this document.
  - Quantity Limit: 90 capsules for 30 days.
  - Approved by the P&T Committee 07/19/2017

- **Zelboraf (vemurafenib)**
  - Refer to the [Oncology criteria](#) located within this document.
  - Quantity Limit: 240 tablets for 30 days.
  - Specialty Pharmacy required.
  - Approved by the P&T Committee 09/21/2011. Updated 10/15/2014 and 11/05/2015.

- **Zenatane (isotretinoin capsules)**
  - Refer to the [Isotretinoin criteria](#) located within this document.
  - Approved by the P&T Committee 10/19/2016. Updated: 10/17/2018, 10/16/2019.

- **Zolinza (vorinostat)**
  - Refer to the [Oncology criteria](#) located within this document.
  - Quantity Limit: 120 capsules for 30 days.
  - Specialty Pharmacy required.
• **Zortress (everolimus)**  
Indications for Approval:  
Criteria is dependent upon diagnosis  
1. Kidney transplant  
   ▪ Zortress is being administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids.  
2. Liver Transplant  
   ▪ Zortress is being administered no earlier than 30 days post-transplant with low dose tacrolimus and corticosteroids.  
Approved by the P&T Committee 07/17/2013.

• **Zostavax (zoster vaccine, live)**  
Indications for Approval (all must be met):  
1. Minimum age of 60.  
2. Contraindication to Shingrix (zoster vaccine, recombinant).  
Quantity limit: One vial for a lifetime.  
Approval: one dose.  

• **Zydelig (idelalisib)**  
Refer to the [Oncology](#) criteria located within this document.  
Quantity Limit: 60 tablets for 30 days.  
Approved by the P&T Committee 10/15/2014. Updated 11/05/2015.

• **Zyflo CR (zileuton ER)**  
Indications for Approval:  
The patient must have an adequate trial (at least two months) of an inhaled corticosteroid and a preferred formulary leukotriene receptor antagonist (montelukast or zafirlukast).  
Quantity Limit: 120 tablets for 30 days.  
Approved by the P&T Committee 07/19/2017.

• **Zykadia (ceritinib)**  
Refer to the [Oncology](#) criteria located within this document.  
Quantity Limit: 150 capsules for 30 days.  
Specialty Pharmacy required.  
Updated 11/05/2015.
• **Zytiga (abiraterone)**
  Indications for Approval:
  
  All FDA approved indications.
  
  Required Medical Information:
  
  For Non-FDA approved indications, there must be a Category 1 or 2 recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class 1 or II recommendation in the Thomson Micromedex DrugDex compendium.
  
  Quantity Limit:
  
  - 250 mg tablets: 120 tablets for 30 days.
  
  Specialty Pharmacy required.
  
  References:
  

Approved by the P&T Committee 07/20/2011. Updated 01/16/2013, 10/15/2014, 11/05/2015, 04/18/2018, and 01/17/2019.

• **Zyvox (linezolid)**
  Indications for Approval:
  
  1. An infectious disease specialist consult, chart notes and culture and sensitivities must be received with the request.
    
    AND
    
    2. The patient must have failed other antibacterials that the culture shows sensitivities to or the patient has a contraindication to the other antibacterials.

Approval: One time.