

Prior Authorization Criteria Document for
Commercial and Medicaid Plans

General Information and Definitions:

- Inclusion in this list by itself does not imply approval of the drug.
- Established Therapy applies to patients/members who are new to Presbyterian Health Plan, within 90 days from effective eligibility date.
- Sampling does not qualify as Established Therapy. There must be record of use of formulary agents in the patient's profile.
- **Prior Authorization (PA):** Drug is on the formulary but requires a Prior Authorization request from the physician by fax, phone, or regular mail. If the patient meets established criteria for approval, the medication will be covered. Documentation of treatment failures and clinical justification is required with all requests.
- **Step Edit:** Automatic online review of certain medications that are available to patients if they meet established criteria. Coverage of the medication at the pharmacy requires the patient to have a prescription history of specific drugs within a specified time frame. This occurs electronically at the pharmacy.

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- **Abilify Discmelt (aripiprazole orally disintegrating tablet)**

Indications for Approval:

1. A psychiatrist must initiate therapy.
2. The patient is unable to take or swallow oral medication. The patient should not be on other oral medications.

OR

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

Approval: 1 year.

Alternative: Abilify (aripiprazole) tablet.

- **Aciphex (rabeprazole)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 545 days of a 30-day trial of one formulary generic proton pump inhibitor (PPI).

Quantity limit of 60 tablets for 30 days.

Alternatives: Lansoprazole, omeprazole, pantoprazole.

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

Revised by the P&T Committee 03/24/2010.

- **Aciphex (rabeprazole)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 545 days of a 30-day trial of three formulary generic proton pump inhibitors (PPIs).

Quantity limit of 60 tablets for 30 days.

Alternatives: Lansoprazole*, omeprazole, pantoprazole.

*The patient must have a documented failure of omeprazole for formulary coverage of lansoprazole.

Approved by the P&T Committee 07/16/2008.

Revised by the P&T Committee 03/24/2010.

- **Actonel (risedronate)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of a 30-day trial of alendronate within the past 180 days.

Alternative: Alendronate.

- **Actos (pioglitazone)**

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.

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- **Actoplus Met (pioglitazone/metformin)**

Step Edit Criteria:

The patient must have previous use of at least one of the medications (Actos or metformin) that make up the combination medication within the past 120 days.

Alternatives: Actos, metformin.

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

- **Aczone (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: 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)**

Indications for Approval:

1. Patient must have Hodgkin's lymphoma that has failed autologous stem cell transplant (ASCT). Or if patient was not an ASCT candidate, then must have failed at least two prior multi-agent chemotherapy regimens.

OR

2. Patient must have systemic anaplastic large cell lymphoma and has failed at least one prior multi-agent chemotherapy regimen.

Approved by the P&T Committee 09/21/2011.

- **Adderall XR (amphetamine/dextroamphetamine extended release capsule)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of a 30-day trial of a generic cerebral stimulant, such as methylphenidate, within the past 180 days.

Alternatives: Methylphenidate, methylphenidate extended release (Metadate CD, Methylin ER), amphetamine/dextroamphetamine immediate release, and dextroamphetamine.

Quantity Limit: 30 capsules for 30 days.

Approval: 1 year.

Updated by P&T committee 05/20/2009.

- **Adipex-P (phentermine)**

APPLIES TO COMMERCIAL PLANS ONLY

Refer to the separate Weight Loss Medication Prior Authorization Form, available on www.phs.org.

Indications for Approval:

1. The patient has a body mass index (BMI) ≥ 27 with 2 or more co-morbidities or BMI ≥ 30 .

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2. Current height, weight and dates recorded must be provided with each request.

Approval: Initial approval is for a one month supply of medication. If the patient has lost greater than 4 pounds from their initial body weight, then an additional two months supply of medication will be approved.

After three months of therapy, the patient must have maintained a 5% loss of their initial body weight in order to receive a 6 month approval.

- **Advair (fluticasone/salmeterol)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a prescription claim history of an orally inhaled corticosteroid or an orally inhaled anticholinergic within the past 120 days.

Quantity limit: One inhaler for 30 days.

Alternatives for asthma: Asmanex, Flovent, Pulmicort, QVAR.

Alternatives for COPD: Atrovent, Combivent, Spiriva.

Approved by the P&T Committee 11/28/2007.

Revised 09/21/2011.

- **Advair (fluticasone/salmeterol)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

1. Documented trial and failure of either mometasone/formoterol MDI (Dulera®)* or budesonide/formoterol MDI (Symbicort®)* in the past 120 days.

OR

2. Patient is under the age of 12 and has a documented trial and failure of an orally inhaled corticosteroid.

Quantity limit: One inhaler for 30 days.

Alternatives for asthma: Asmanex, Flovent, Pulmicort, QVAR.

Alternatives for COPD: Atrovent, Combivent, Spiriva

* Step Edit criteria applies for Dulera and Symbicort.

Approved by the P&T Committee 11/28/2007.

Revised 09/21/2011.

- **Advicor (lovastatin/niacin)**

Step Edit Criteria:

The patient must have previous use of at least one of the medications (lovastatin or niacin sustained release) that make up the combination medication within the past 120 days.

Alternatives: lovastatin, niacin sustained release.

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

- **Afinitor (everolimus)**

Indications for Approval:

1. Advanced neuroendocrine tumor of pancreatic origin, unresectable, locally advanced or metastatic disease.

2. Advanced renal cell carcinoma, after failure of treatment with sunitinib or sorafenib.

3. Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis in patients who require therapeutic intervention but are not candidates for curative surgical resection.

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* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Alimta (pemetrexed)**

Indications for Approval:

1. Malignant pleural mesothelioma
 - In combination with cisplatin in patients who are not candidates for surgical resection.
2. Nonsquamous non-small cell lung cancer, locally advanced or metastatic.
 - Initial treatment in combination with cisplatin.
 - As a single-agent after prior history of first-line chemotherapy treatment.

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

- **Aloxi (palonosetron) Injection**

Indications for Approval:

The patient has a documented treatment failure with antiemetic regimens that include generic ondansetron injection or generic granisetron injection. Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of complete response.

AND meets one of the following:

- a) Documentation that the patient is receiving a chemotherapy regimen which has high emetogenic potential as defined by ASCO*.
- b) Documentation that the patient is receiving a chemotherapy regimen that has moderate emetogenic potential as defined by ASCO*.
- c) Documentation that the patient is receiving a chemotherapy regimen which includes anthracycline and cyclophosphamide in combination.

* Emetogenic potential as defined by ASCO in *American Society of Clinical Oncology Guidelines for Antiemetics in Oncology: Update 2006*. Available from:

<http://www.asco.org/guidelines/antiemetics>.

Quantity Limit: 5ml (1 vial) for 5 days.

Length of Approval: 6 months.

Alternatives: granisetron injection, ondansetron injection.

References:

1. Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM et al. American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006. *J Clin Oncol*. 2006 June 20; 24(18):2932-2947.
2. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Antiemetics [updated 2010 Feb; cited 2010 April 7] Available from: www.nccn.org

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

- **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.

- **Ambien CR (zolpidem)**

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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)**

APPLIES TO MEDICAID PLANS ONLY

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 07/21/2010.

- **Amitiza (lubiprostone)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of lactulose within the past 120 days.

Quantity Limit: 60 capsules for 30 days.

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

- **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:

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1. Ampyra prescribing information. Hawthorne, NY; Acorda Therapeutics, Inc. Revised January 2010.
2. National Institute of Neurological Disorders and Stroke. Communications and Public Liaison [Revised May 28, 2010] Bethesda, MD. Available at:
http://www.ninds.nih.gov/disorders/multiple_sclerosis/multiple_sclerosis.htm

- **Androderm (testosterone transdermal patch)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Quantity limit of 60 patches for 30 days of the 2mg strength and 30 patches for 30 days of the 4mg strength.

Criteria based on: *ACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

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

Revised 01/21/2009, 05/18/2011, 01/18/2012.

- **Androgel (testosterone topical gel)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (congenital or acquired).
Idiopathic gonadotropin or LHRH deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation.

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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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Quantity limit of 30 packets for 30 days of the 2.5mg strength, 60 packets for 30 days of the 5mg strength, 4 metered-dose pumps (300g) for 30 days of the 1% strength, and 2 metered-dose pumps (150g) for 30 days of the 1.62% strength.

Criteria based on: *AACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

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

Revised 01/21/2009, 05/18/2011.

- **Androxy (fluoxymestron)**

Indications for Approval

1. Breast cancer, palliative treatment
2. Postpartum breast engorgement

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

- **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:

1. Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM et al. American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006. *J Clin Oncol*. 2006 June 20. 24(18):2932-2947.
2. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Antiemetics [updated 2010 Feb; cited 2010 April 7] Available from: www.nccn.org

- **Apokyn (apomorphine)**

Indications for Approval:

All FDA-approved indications

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- 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 mandated.

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 of 120 capsules for 30 days.

Alternative: balsalazide, sulfasalazine

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

- **Aranesp (darbepoetin alfa)**

Prior Authorization Criteria:

Indications for Approval:

1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.
2. For the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

Criteria for Approval:

1. The maximum dose for the first 4 weeks of treatment is 9 mcg/kg.
2. Hemoglobin must be <11g/dl.

The use of Aranesp 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.

Approved by the P&T Committee 07/16/2008.

Revised by the P&T Committee 07/20/2011.

- **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

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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 100,000mm³, fondaparinux should be discontinued.
Overdosage with fondaparinux is not reversible with protamine sulfate.

Approval: One time.

Alternative: Lovenox (Lovenox has a quantity limit of 30 syringes for 90 days).

- **Asacol (mesalamine)**

Step Edit Criteria:

The patient must have a claim history within the past 120 days of a 30-day trial of balsalazide.

Alternatives: Commercial Plans - azathioprine, balsalazide, Entocort EC, hydrocortisone rectal, mercaptopurine, mesalamine rectal, sulfasalazine.

Medicaid Plans - azathioprine, balsalazide, hydrocortisone rectal, mercaptopurine, mesalamine rectal, sulfasalazine.

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

- **Astelin (azelastine nasal 0.1%)**

APPLIES TO MEDICAID PLANS ONLY

Prior Authorization Criteria:

Documented failure of at least one drug from each of the following drug classes:

1. A formulary nasal corticosteroid.
2. A formulary non-sedating antihistamine.

Alternatives: Flunisolide nasal spray, fluticasone propionate nasal spray, triamcinolone nasal spray, cetirizine OTC, fexofenadine, loratadine.

Approved by the P&T Committee 09/15/2010.

- **Avalide (irbesartan/hydrochlorothiazide)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

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The patient must have a claim history within the past 6 months 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

- **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 180 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)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 6 months 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

- **Avastin (bevacizumab)**

Indications for Approval:

Must be prescribed by or in consultation with an oncologist for the diagnosis of:

1. Metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment.
2. Metastatic renal cell carcinoma in combination with interferon alfa.
3. Non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease.
4. Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy.
 - Documentation of the diagnosis and patient history must be received.

Exclusions:

- History of recent hemoptysis or serious hemorrhage.
- Use within 28 days following major surgery or until the surgical incision is fully healed.

Approval: one year.

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

- **Avinza (morphine sulfate extended release capsules)**

Step Edit Criteria:

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The patient must have claim history of fentanyl transdermal patches and Opana ER within the past 90 days.

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.

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

- **Beconase AQ (beclomethasone)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The member must have a claim history of one generic formulary nasal steroid in the past 545 days.

Alternatives: Flunisolide nasal spray, fluticasone propionate nasal spray, triamcinolone nasal spray.

Approved by the P&T Committee 09/15/2010.

- **Benicar (olmesartan)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 6 months 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

- **Benicar HCT (olmesartan/hydrochlorothiazide)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 6 months of a formulary ACE Inhibitor, or ACE inhibitor/diuretic combination.

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

- **Benlysta (belimumab)**

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 SLE.

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- 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 \geq 100mg/day.

Approval length: 6 months.

Reauthorization Criteria: Documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline. Reauthorization will be limited to 12-month intervals.

Approved by the P&T Committee 09/21/2011.

- **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 trials and failures of anticholinergics and 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 trials and failures of anticholinergics and 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:
 - \geq 15 days per month with headache lasting 4 hours a day or longer.
 - Documented trials and failures with conventional and prophylactic therapies.
 - Must be written by a neurologist.
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.

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

Approval: 1 year.

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

Revised 11/16/2011.

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- **Brilinta (ticagrelor)**

Indications for Approval:

1. A documented diagnosis of acute coronary syndrome (unstable angina, non-STEMI, or STEMI)
2. Patient should only be receiving a total daily dose of aspirin of $\leq 100\text{mg/day}$.
3. Documentation of one of the following:
 - Contraindication to clopidogrel (Plavix®)
 - Intolerance to clopidogrel (Plavix®)
 - Failure of an adequate trial of one month of clopidogrel (Plavix®)

Approval Length: Up to one year.

Quantity Limit: 60 tablets for 30 days.

Approved by the P&T Committee 11/16/2011.

References:

1. Wallentin L, Becker RC, et al. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med.* 2009 Sep 10;361(11):1045-57.
2. Cannon, C, Harrington, R, et al. Comparison of ticagrelor with clopidogrel in patients with a planned invasive strategy for acute coronary syndrome (PLATO): a randomised double-blind study. *The Lancet.* Vol 375, issue9711;283-293, 23 January 2010.
3. Nawarskas, J, Clark, S. Ticagrelor: A Novel Reversible Oral Antiplatelet Agent. *Cardiology in Review.* Mar/Apr 2011, Vol 19, issue 2;95-100. Available online at http://journals.lww.com/cardiologyinreview/Fulltext/2011/03000/Ticagrelor_A_Novel_Reversible_Oral_Antiplatelet.11.aspx#
4. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary
J Am Coll Cardiol 2011 0: j.jacc.2011.08.006
5. AstraZeneca LP, Wilmington, DE. Brilinta prescribing information. Issued July 2011.
6. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically.
7. Brilinta® (Ticagrelor): Chapter 18 Antiplatelet and other Antithrombotic Drugs. *Advances in Cardiovascular Pharmacotherapeutics*. Posted online by cardiovascularpharmacotherapeutics on August 30, 2011. Available online at <http://cardiovascularpharmacotherapeutics.com/2011/08/30/brilinta-ticagrelor-chapter-18-antiplatelet-and-other-antithrombotic-drugs/>

- **Byetta (exenatide)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The member must have a 30-day prescription fill of a metformin product within the past 545 days.

Quantity limit: One pen for 30 days.

Alternative: metformin

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

- **Byetta (exenatide)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

Diabetes Mellitus Type 2 that meets the following criteria:

The patient has a recent (within the past 3 months) documented A1C level of <11 **AND** one of the following:

- 1) 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
- 2) 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 $\geq 2000\text{mg}$ daily.

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- Documented renal disease or renal dysfunction. For example, serum creatinine levels $\geq 1.5\text{mg/dl}$ (males) or $\geq 1.4\text{mg/dl}$ (females).
- Documented hepatic disease. For example, cirrhosis or hepatitis.

Continuation of Therapy Criteria:

The A1C value must be decreasing (it is recommended to measure A1C every 3 months). 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:

- 1) Referral of the member to the PHP disease management team.
- 2) Denial of the request with suggested alternative medications.
- 3) Request for chart notes that describe the treatment plan and /or discussion with the prescribing provider about the treatment plan for the member.

A1C Protocol:

If the initial or subsequent A1C is > 9 then the A1C must decrease by 1% or more.

If the initial or subsequent A1C is between 8.5 – 8.9% then the A1C must decrease by 0.5% or more.

If the initial or subsequent A1C is between 7.5 – 8.4% then the A1C must decrease by 0.25% or more.

If the initial or subsequent A1C is between 7.0 – 7.4% then the A1C must decrease by 0.15% or more.

Approval: 6 months.

Quantity limit of 1 pen for 30 days.

Alternatives: glimepiride, glipizide, glyburide, insulin, metformin.

Approved by the P&T Committee 11/28/2007.

Revised by the P&T Committee 03/24/2010.

Criteria based on:

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007. www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Caduet (amlodipine/atorvastatin)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of one formulary generic statin medication within the past 545 days.

Alternatives: lovastatin, pravastatin, simvastatin.

Quantity limit of 30 tablets for 30 days.

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

- **Campath (alemtuzumab)**

Indication for Approval:

B-cell chronic lymphocytic leukemia (B-CLL).

Approval: 1 year.

Approved by the P&T Committee 05/20/2009.

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- **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).

Criteria based on: National Institute on Alcohol Abuse and Alcoholism. Helping Patients Who Drink Too Much: A Clinicians Guide. Accessed at

<http://pubs.niaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf>

Approved by the P&T Committee 1/20/2010.

- **Caprelsa (vandetanib)**

Indications for Approval:

Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Approved by the P&T Committee 09/21/2011.

- **Casodex (bicalutamide)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of a 30-day trial of flutamide in the past 180 days.

Alternative: Flutamide.

- **CeeNU (lomustine)**

Indications for Approval:

Lomustine has been shown to be useful as a single agent in addition to other treatment modalities, or in established combination therapy with other approved chemotherapeutic agents in the following:

1. **Brain tumors**—both primary and metastatic, in patients who have already received appropriate surgical and/or radiotherapeutic procedures.
2. **Hodgkin's disease**—secondary therapy in combination with other approved drugs in patients who relapse while being treated with primary therapy, or who fail to respond to primary therapy.

* Specialty Pharmacy mandated.

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Approved by the P&T Committee 09/21/2011.

- **Celebrex (celecoxib)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 120 days of meloxicam and nabumetone.

Quantity limit of 60 capsules for 30 days.

Alternatives: Meloxicam, nabumetone.

Approved by the P&T Committee as Prior Authorization Criteria 11/28/2007.

Revised to Step Edit Criteria by the P&T Committee 03/24/2010.

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

Indications for Approval

The patient must have documented hereditary angioedema that requires prophylaxis against angioedema attacks.

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

- **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.

- **Concerta (methylphenidate extended release tablets)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of a 30-day trial of methylphenidate immediate release, Metadate CD, or Methylin ER within the past 180 days.

Alternatives: methylphenidate immediate release, Metadate CD, Methylin ER.

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

- **Cozaar (losartan)**

APPLIES TO MEDICAID PLANS ONLY

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

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

- **Crestor (rosuvastatin)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

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The patient must have a claim history of a generic statin, such as simvastatin, pravastatin, or lovastatin, within the past 180 days.

Alternatives: Lovastatin, simvastatin, pravastatin.

- **Cymbalta (duloxetine)** - criteria is dependent on diagnosis.

Indications for Approval:

1. Depression – the patient must have a documented failure at therapeutic doses on two antidepressants, which include selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), or bupropion.
2. Neuropathic pain – the patient must have a documented failure at therapeutic doses of all of the following:
 - a. Gabapentin (1,200 to 2,400 mg/day).
 - b. One of the following alternatives: a tricyclic antidepressant (TCA) or an anticonvulsant.
3. Fibromyalgia – the patient must have a documented failure of all 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).
4. Generalized anxiety disorder – the patient must have a documented failure at therapeutic doses of two of the following:
 - a. A formulary SSRI
 - b. buspirone
 - c. An anxiolytic benzodiazepine (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam).
5. Chronic musculoskeletal pain – the patient must have a documented three-month trial of the following:
 - a. tramadol at a therapeutic dose
AND
 - b. An acetaminophen product or an NSAID product at therapeutic doses.

Approval: 1 year.

Quantity limits:

20mg and 30mg capsules – 60 capsules for 30 days.

60mg capsules – 30 capsules for 30 days.

Alternatives: alprazolam, amitriptyline, bupropion, buspirone, carbamazepine, chlordiazepoxide, citalopram, clonazepam, clorazepate, desipramine, diazepam, divalproex, fluoxetine, gabapentin, lamotrigine, lorazepam, nortriptyline, paroxetine, sertraline, tramadol, venlafaxine.

Approved by the P&T Committee on 03/16/2005.

Revised by the P&T Committee: 01/16/08, 03/18/2009, 01/19/2011.

- **CytoGam (Cytomegalovirus Immune Globulin)**

Indications for Approval:

Commercial and Medicaid Prior Authorization Criteria Document

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: One year (for all above diagnoses).

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.
 - Severe COPD is defined by the GOLD guidelines as FEV1 < 50% predicted.
3. 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 of 30 tablets for 30 days.

References:

1. "Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2010". Available at: <http://www.goldcopd.org/>.
2. Daliresp® (roflumilast) prescribing information; February 2011.

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

- **Delatestryl (testosterone enanthate injection)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Criteria based on: *AACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

Commercial and Medicaid Prior Authorization Criteria Document

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

Revised 05/18/2011.

- **Depo-Testosterone (testosterone cypionate injection)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction of sexual dysfunction.

Approval: 1 year.

Criteria based on: *AACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

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

Revised 05/18/2011.

- **Dexferrum (iron dextran)**

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.

Note: Documented iron deficiency anemia for the above indications is defined as a hemoglobin <11 g/dl.

Commercial and Medicaid Prior Authorization Criteria Document

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.

References:

1. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy Induced Anemia [updated 2010 Aug; Cited 2010 May 10] Available from: www.nccn.org
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease 2006. [Cited 2010 May 10]. Available at http://www.kidney.org/professionals/kdoqi/guidelines_anemia/cpr32.htm

- **Diapers**

APPLIES TO MEDICAID PLANS ONLY

(Refer to the Salud/NMRx Disposable Diapers Prior Authorization Form, available on www.phs.org)

Indications for Approval:

1. Prior Authorization will be required for diapers provided to non-institutionalized members between the ages of 3 years and 21 years with a diagnosis or a clinical condition that relates to a neurological or neuromuscular disorder, or other diseases associated with incontinence (MAD 754.41.3).
2. Prior Authorization will also be required for diapers provided to non-institutionalized members over 21 years of age with a permanent incontinence (excluding stress incontinence) diagnosis (MAD 754.41.2).
3. Up to 200 disposable diapers per month from the Presbyterian Preferred Diaper List (available on www.phs.org) may be authorized, or up to 150 disposable pads (not both) when provided by a participating pharmacy, and when it is medically necessary.

The level of incontinence must be characterized by **all** of the following:

1. Occurs at least once a day.
2. Is not amenable to bowel/bladder training.
3. Is not amenable to, or appropriate for further medical, urological, or surgical intervention.
4. Produces significant soiling that requires clothes or bed to be immediately changed for which macerates skin or exacerbates decubitus ulcers.
5. Cannot be successfully managed with bedside commode or other assistive devices.
6. Is not being managed with an indwelling catheter.

Approval: One year.

Quantity Limit: 200 diapers per 30 days (from the Preferred Diapers List only).

- **Diastat (diazepam) Rectal Gel**

Step Edit Criteria:

Commercial and Medicaid Prior Authorization Criteria Document

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

Alternatives: clonazepam, diazepam, lorazepam.

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

- **Differin 0.1% (adapalene)** - for patients greater than 40 years of age

Indications for Approval:

The patient has actinic keratosis.

OR

The patient has 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 the fine facial lines associated with aging.

- **Dificid (fidaxomicin)**

Indications for Approval:

A diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)

AND must meet the following:

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 of 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 (valsartan)**

APPLIES TO MEDICAID PLANS ONLY

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

- **Diovan HCT (valsartan/hydrochlorothiazide)**

APPLIES TO MEDICAID PLANS ONLY

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

- **Dolophine (methadone tablets)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

Commercial and Medicaid Prior Authorization Criteria Document

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).

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 (Actos or glimepiride) that make up the combination medication within past 120 days.

Alternatives: Actos, glimepiride.

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

- **Dulera (mometasone/formoterol)**

Step Edit Criteria:

The patient must have a prescription claim history of an orally inhaled corticosteroid or orally inhaled anticholinergic within the past 120 days.

Quantity limit: One inhaler for 30 days.

Alternatives for Asthma: Asmanex, Flovent, Pulmicort, QVAR.

Alternatives for COPD: Atrovent, Combivent, Spiriva

Approved by the P&T Committee 09/21/2011.

- **Duragesic Patch (fentanyl transdermal)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

1. The patient has a documented failure or contraindication to morphine sulfate extended release.

AND

2. The patient is unable to take or swallow oral medications. The patient should not be on other oral medications.

OR

The patient has a documented gastrointestinal intolerance to opioid analgesics.

Approval: 3 months.

Quantity limit of 10 patches for 30 days.

Alternatives: Morphine sulfate extended release tablet (MS Contin).

Step Edit Criteria:

The patient had a failure of morphine sulfate extended release tablets within the past 90 days.

AND

The patient must have a claim history of morphine sulfate extended release tablet (MS Contin) within the past 90 days.

Rationale: Oral medications should be the first line agents for chronic pain control. Extended release morphine (Oramorph SR) is available on the formulary for patients with chronic pain.

Note: All these long-acting drugs should only be used in patients that have already been on other chronic opioid analgesics and are not recommended for patients with acute pain.

Commercial and Medicaid Prior Authorization Criteria Document

Approved by the P&T Committee on 09/19/2007. Updated by P&T Committee on 07/15/2009.

- **Effexor XR (venlafaxine extended release capsules)**

Step Edit Criteria:

The patient must have a claim history of two generic antidepressant agents within the past 545 days.

Alternatives: Citalopram, fluoxetine, paroxetine, sertraline, desipramine, trazodone, amitriptyline, nortriptyline, doxepin, venlafaxine, bupropion, and mirtazapine.

Quantity limit: 30 capsules in 30 days.

Updated by the P&T Committee 07/21/2010.

- **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:

Documented allergy to clopidogrel (Plavix®), such as a rash.

Documented treatment failure with clopidogrel (Plavix®).

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.

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

References:

1. Plavix [package insert]. Bridgewater, NJ; Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; Rev 08/10.
2. Effient [package insert]. Indianapolis, IN; Daiichi Sankyo, Inc and Eli Lilly and Company; July 2009.
3. Wiviott, SD, Braunwald E, et al. TRITON-TIMI 38 Investigators. Prasugrel versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med.* 2007;357(2):2001-2015.
4. Wallentin, L, Becker, RC, et al. Ticagrelor versus Clopidogrel in Patients with Acute Coronary Syndromes. *N Engl J Med* 2009; 361:1045-1057. [September 10, 2009.](#)
5. 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (Updating the 2004 Guideline and 2007 Focused Update) and ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention (Updating the 2005 Guideline and 2007 Focused Update) A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*, 2009; 54:2205-2241, doi:10.1016/j.jacc.2009.10.015 (Published online 18 November 2009).
[© 2009 by the American College of Cardiology Foundation](#)

- **Elidel (pimecrolimus cream)**

Indication for Approval:

Commercial and Medicaid Prior Authorization Criteria Document

The patient must have previous use of at least one formulary topical corticosteroid within the past 90 days.

- Continuous long-term use of Elidel is not recommended by the FDA.
- The length of treatment will be limited to 60 days.

Alternatives: Betamethasone, clobetasol, desonide, fluocinolone, fluocinonide, fluticasone, hydrocortisone, triamcinolone.

Approved by the P&T Committee 09/21/2005.

Updated 11/16/2011.

- **Emcyt (estramustine)**

Indications for Approval:

Metastatic/Progressive prostate cancer - palliative treatment of metastatic and/or progressive carcinoma of the prostate

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Emend (aprepitant) Capsules**

Prior Authorization Criteria:

The prescription must be prescribed by a hematology/oncology specialist.

AND

The patient is currently receiving one of the following chemotherapeutic agents, per ASCO guidelines:

- a) Highly emetogenic risk agents (>90%)
 - cisplatin
 - mechlorethamine
 - streptozotocin
 - cyclophosphamide (>1500 mg/m²)
 - carmustine
 - dacarbazine
 - dactinomycin
- b) Anthracycline with cyclophosphamide.
- c) Failure of standard antiemetic regimens.

Approval: 6 months.

Quantity limit of one 125 mg capsule and two 80 mg capsules per prescription.

Alternatives: Promethazine, prochlorperazine, ondansetron.

- **Emend (fosaprepitant) Injection**

Indications for Approval:

Must meet one of the following criteria:

1. Documentation that the patient is receiving combination therapy with a 5-HT₃ antagonist and dexamethasone for a cancer chemotherapy regimen which has high emetogenic potential as defined by ASCO*.
2. Documentation that the patient is receiving combination therapy with a 5-HT₃ antagonist and dexamethasone for a cancer chemotherapy regimen which includes anthracycline and cyclophosphamide in combination.

Commercial and Medicaid Prior Authorization Criteria Document

3. Documentation that the patient is receiving a cancer chemotherapy regimen which has moderate emetogenic potential as defined by ASCO* and has failed antiemetic therapy with a 5-HT3 antagonist in combination with dexamethasone.

* Emetogenic potential as defined by ASCO in *American Society of Clinical Oncology Guidelines for Antiemetics in Oncology: Update 2006*. Available from:

<http://www.asco.org/guidelines/antiemetics>.

Quantity Limit: 4ml (4 vials) for 30 days.

Length of Approval: 6 months.

Alternatives: Dexamethasone, granisetron injection, ondansetron injection.

References:

1. Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM et al. American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006. *J Clin Oncol*. 2006 June 20. 24(18):2932-2947.
2. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Antiemetics [updated 2010 Feb; cited 2010 April 7] Available from: www.nccn.org

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

- **Emsam Patch (selegiline patch)**

Indications for Approval:

The patient must have a diagnosis of major depressive disorder.

AND

The patient is 18 years of age or older.

AND

The prescription must be prescribed by a psychiatrist.

AND

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 of 30 patches per 30 days.

Alternatives: Citalopram, fluoxetine, sertraline, paroxetine, venlafaxine, bupropion, mirtazapine.

- **Enablex (darifenacin)**

Step Edit Criteria:

The patient must have a claim history of generic oxybutynin XL and Detrol or Detrol LA within the past 180 days.

Alternatives: Oxybutynin, oxybutynin XL, Detrol, and Detrol LA.

- **Enbrel (etanercept)** - criteria is dependent on diagnosis

Indications for Approval:

The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy.

AND

The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.

AND

Commercial and Medicaid Prior Authorization Criteria Document

The appropriate Disease Specific Criteria below has been met.

The patient has a diagnosis of one of the following:

Ankylosing Spondylitis - patients with axial disease and a documented trial and failure, or a contraindication, to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) can be started on Enbrel without a trial of a Disease Modifying Anti-Rheumatic drug (DMARD) first.

Juvenile Rheumatoid Arthritis

Psoriatic Arthritis

Rheumatoid Arthritis

AND

The patient has disease activity with active synovitis in at least 3 sets of joints - for example, bilateral proximal interphalangeal (PIP) involvement = 1 set, or bilateral knee involvement = 1 set.

AND

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

AND

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.

1. Leflunomide
2. Hydroxychloroquine
3. Sulfasalazine
4. Mycophenolate mofetil
5. Azathioprine

AND

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

The patient has a diagnosis of the following:

Plaque Psoriasis

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

1. The patient has involvement of $\geq 10\%$ of their 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.
2. 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.
3. The patient has history of an adequate trial and treatment failure with phototherapy or photochemotherapy or such treatment is contraindicated, not tolerated, or unavailable.
4. The patient has history of an adequate trial and treatment failure with methotrexate or such treatment is contraindicated or not tolerated.

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

Updated by P&T committee on 01/21/2009.

- **Epogen (epoetin alpha)**

Commercial and Medicaid Prior Authorization Criteria Document

Prior Authorization Criteria:

Indications for Approval:

1. Treatment of anemia of chronic renal failure.
2. Treatment of anemia in zidovudine-treated HIV infected patients.
3. Treatment of anemia in cancer patients on chemotherapy.
4. Reduction of allogenic blood transfusions in surgery patients.

Criteria for Approval:

1. The maximum dose for the first 4 weeks of treatment is 1800U/kg.
2. Hemoglobin must be < 11g/dl.

The use of Epogen 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.

Approved by the P&T Committee 07/16/2008.

Updated by the P&T Committee 07/20/2011.

- **Erivedge (vismodegib)**

Indications for Approval:

Treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

Quantity Limit of 30 tablets for 30 days.

*Specialty Pharmacy mandated

Approved by the P&T Committee 03/21/2012

- **Erwinaze (asparaginase Erwinia chrysanthemi)**

Indication for Approval:

Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to E. Coli-derived asparaginase.

*Specialty Pharmacy Mandated.

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

- **Ethyol (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.

Commercial and Medicaid Prior Authorization Criteria Document

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.

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

- **Extavia (interferon beta-1b)**

Prior Authorization Criteria:

The patient must have documented failure or contraindication to Avonex and Copaxone or the patient is new to Presbyterian and is currently taking Extavia.

AND

The initial prescription is prescribed by a neurologist.

Approval: One year.

Alternatives: Avonex and Copaxone.

- **Fareston (toremifene)**

Indications for Approval:

Breast cancer - for the treatment of metastatic breast cancer in postmenopausal women with estrogen receptor-positive or unknown tumors

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Feraheme (ferumoxytol)**

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.

Note: Documented iron deficiency anemia for the above indications is defined as a hemoglobin <11 g/dl.

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.

References:

Commercial and Medicaid Prior Authorization Criteria Document

1. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy Induced Anemia [updated 2010 Aug; Cited 2010 May 10] Available from: www.nccn.org
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease 2006. [Cited 2010 May 10]. Available at http://www.kidney.org/professionals/kdoqi/guidelines_anemia/cpr32.htm

- **Ferrlecit (sodium ferric gluconate complex)**

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.

Note: Documented iron deficiency anemia for the above indications is defined as a hemoglobin <11 g/dl.

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.

References:

1. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy Induced Anemia [updated 2010 Aug; Cited 2010 May 10] Available from: www.nccn.org
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease 2006. [Cited 2010 May 10]. Available at http://www.kidney.org/professionals/kdoqi/guidelines_anemia/cpr32.htm

- **Forteo (teriparatide)**

Indications for Approval:

The patient has failed an adequate therapeutic trial or has a contraindication to alendronate and Actonel

AND

The patient is at high risk for fractures.

AND

The patient has received a bone scan and the T score \leq -2.5.

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Approval: One year.

Alternatives: Commercial Plans - Alendronate, Actonel.
Medicaid Plans – Alendronate.

- **Fortesta (testosterone topical gel)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Quantity limit of two (2) canisters (120 g) for 30 days.

Criteria based on: *AACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

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

- **Gamunex-C (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: 1 year (for all above diagnoses).

Approved by the P&T Committee 1/19/2011.

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- **Gardasil (human papillomavirus, HPV)**

Indications for Approval:

The patient is female.

AND

The patient is between the ages of 9 to 26 years.

Approval: Series of 3 injections.

- **Gleevec (Imatinib)**

Indications for Approval:

1. **Acute lymphoblastic leukemia:** Adults with relapsed or refractory Philadelphia chromosome–positive (Ph+) acute lymphoblastic leukemia (ALL).
2. **Aggressive systemic mastocytosis:** Adults with aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown.
3. **Chronic myeloid leukemia:**
 - Newly diagnosed adults and children with Ph+ chronic myeloid leukemia (CML) in chronic phase.
 - Patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon alpha therapy.
 - Children with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy.
4. **Dermatofibrosarcoma protuberans (DFSP):** Adults with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans.
5. **GI stromal tumors:** Patients with Kit (CD117):
 - Positive unresectable and/or metastatic malignant GI stromal tumors (GIST).
 - Adjuvant treatment of patients following complete gross resection of Kit (CD117)–positive GIST.
6. **Hypereosinophilic syndrome and/or chronic eosinophilic leukemia:** Adults with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1-platelet–derived growth factor receptor (PDGFR) α fusion kinase (mutational analysis or fluorescent in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who are FIP1L1-PDGFR α fusion kinase negative or unknown
7. **Myelodysplastic/Myeloproliferative diseases:** Adults with myelodysplastic/myeloproliferative diseases associated with PDGFR gene rearrangements

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **HepaGam (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).

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

- **Hexalen (altretamine)**

Indications for Approval:

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Ovarian cancer: For use as a single agent in the palliative treatment of patients with persistent or recurrent ovarian cancer following first-line therapy with a cisplatin- or alkylating agent-based combination.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **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 is dependent on Diagnosis

Indications for Approval:

The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.

AND

The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.

AND

The appropriate Disease Specific Criteria below has been met.

The patient has a diagnosis of one of the following:

Ankylosing Spondylitis (patients with axial disease and a documented trial and failure, or a contraindication, to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) can be started on Humira without a trial of a DMARD (Disease Modifying Anti-Rheumatic drug) first).

Psoriatic Arthritis

Rheumatoid Arthritis

AND

The patient has disease activity with active synovitis in at least 3 sets of joints – For example, Bilateral proximal interphalangeal (PIP) involvement = 1 set, or bilateral knee involvement = 1 set.

AND

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

AND

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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.

1. Leflunomide
2. Hydroxychloroquine
3. Sulfasalazine
4. Mycophenolate mofetil
5. Azathioprine

AND

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

The patient has a diagnosis of the following:

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:

1. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide).
2. Sulfasalazine
3. Immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate).
4. 5-aminosalicylic acid (brand names include Rowasa, Pentasa, and Asacol).
5. Antibiotics (e.g., metronidazole, quinolones).

The patient has a diagnosis of the following:

Plaque Psoriasis

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

1. 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.
2. 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.
3. History of an adequate trial and treatment failure with phototherapy or photochemotherapy, or such treatment is contraindicated, not tolerated, or is unavailable.
4. History of an adequate trial and treatment failure with methotrexate, or such treatment is contraindicated or not tolerated.

Approval: One year (for all above diagnoses).

Updated by P&T committee on 01/21/2009.

- **Hycamtin (topotecan)**

Indications for Approval:

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Relapsed small cell lung cancer - For the treatment of relapsed small cell lung cancer (SCLC) in patients with a prior complete or partial response who are at least 45 days from the end of first-line chemotherapy.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Hyzaar (losartan/hydrochlorothiazide)**

APPLIES TO MEDICAID PLANS ONLY

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

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

- **Incivek (telaprevir)**

Indications for Approval (ALL of the following must be met):

1. Documented diagnosis of Chronic Hepatitis C, genotype 1 infection.
2. Patient is ≥ 18 years of age.
3. Must be given in combination with peginterferon alfa AND ribavirin
4. NO previous treatment failure with an HCV protease inhibitor (Incivek or Victrelis).

* Will not be approved for patients with moderate or severe hepatic impairment (Child-Pugh B or C, score ≥ 7) or in patients with decompensated liver disease.

Continuation of Therapy:

- HCV RNA levels must be drawn at treatment week (TW) 4.
- Discontinue the three-medicine regimen if the HCV-RNA level is greater than 1,000 U/mL at treatment week 4.

| <u>Treatment Naïve and Prior Relapse Patients:</u> | | | |
|---|---|---|-----------------------------|
| HCV-RNA Level† | Triple Therapy (Incivek, peginterferon and ribavirin) | Dual Therapy (peginterferon alfa and ribavirin) | Total Treatment Duration |
| Undetectable at TW 4 and 12 | First 12 weeks | Additional 12 weeks | 24 weeks |
| Detectable (1000 IU/mL or less) at TW 4 and/or TW12 | First 12 weeks | Additional 36 weeks | 48 weeks |
| <u>Prior Partial and Null Responder Patients:</u> | | | |
| | Triple Therapy | Dual Therapy | Total Treatment Duration |
| All Patients | First 12 weeks | Additional 36 weeks | 48 weeks |

Treatment week (TW) = from initiation of first HCV medication

† The HCV-RNA assay should have a lower limit of quantification ≤ 25 IU/mL and a limit of detection of approx. 10-15 IU/mL. For the purpose of assessing response-guided therapy eligibility, an “undetectable” HCV-RNA result is required; a confirmed “detectable but below limit of quantification” HCV-RNA result should not be considered equivalent to an “undetectable” HCV-RNA result.

Discontinuation of Treatment Based on Treatment Futility (all patients):

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- Discontinue the three-medicine regimen if the HCV-RNA level is greater than 1000 IU/mL at treatment week 4.
- Discontinue peginterferon alfa and ribavirin if the HCV-RNA level is greater than 1000 IU/mL at treatment week 12 (Incivek is complete).
- Discontinue peginterferon alfa and ribavirin if the HCV-RNA level is detectable at treatment week 24.

* Specialty Pharmacy mandated.

Approval: Up to 12 weeks. Length of approval is dependent upon response to therapy.

Quantity Limit of 180 tablets for 30 days.

Approved by the P&T Committee on 07/20/2011. Updated on 09/21/2011.

Criteria based on:

1. Incivek prescribing information. Cambridge, MA. Vertex Pharmaceuticals Incorporated. Accessed at http://pi.vrtx.com/files/uspi_telaprevir.pdf
2. Ghany MG, Strader DB, Thomas DL, and Seef LB. ASSLD practice guidelines: Diagnosis, management, and treatment of hepatitis C: An update. *Hepatology*. 2009;49(4):1335-1374

- **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 mandated.

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

- **INFeD (iron dextran)**

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.

Note: Documented iron deficiency anemia for the above indications is defined as a hemoglobin <11 g/dl.

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

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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.

References:

1. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy Induced Anemia [updated 2010 Aug; Cited 2010 May 10] Available from: www.nccn.org
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease 2006. [Cited 2010 May 10]. Available at http://www.kidney.org/professionals/kdoqi/guidelines_anemia/cpr32.htm

- **Inlyta (axitinib)**

Indication for Approval:

Treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.

*Specialty pharmacy mandated.

Approved by the P&T Committee 03/21/2012

- **Iressa (gefitinib)**

Indications for Approval:

Non-small cell lung cancer - As monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies.

Approved by the P&T Committee 09/21/2011.

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

Indications for Approval:

The patient has a diagnosis of one of the following:

AIDS: Children with acquired immunodeficiency syndrome (AIDS).

Bone marrow and organ transplant recipients (except corneal) who are at risk for cytomegalovirus (CMV) and pneumonia due to immunosuppressant agents.

Bone Marrow Transplant: Post bone marrow transplant setting.

HIV: Adults with human immunodeficiency virus (HIV) who are immunosuppressed in association with AIDS or AIDS-related complex (ARC).

Infection, prevention in:

1. HIV-infected patients
2. Patients with primary defective antibody synthesis
3. Hypogammaglobulinemia and/or recurrent bacterial infections, with B-cell chronic lymphocytic leukemia

Kawasaki syndrome (446.1)

Primary immunodeficiencies including, but not limited to:

1. Congenital agammaglobulinemia (X-linked agammaglobulinemia) (279.04)
2. Hypogammaglobulinemia (279.06)
3. Common variable immunodeficiency (279.06)
4. X-linked immunodeficiency (279.05)

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5. Severe combined immunodeficiency (279.2)

6. Wiskott-Aldrich syndrome (279.12)

Thrombocytopenia purpura: Treatment of idiopathic or immune thrombocytopenia purpura (ITP).

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:

- **Acute inflammatory demyelinating polyneuropathy**, including Guillain-Barré Syndrome, in patients who have one or more of the following:
 1. rapid deterioration with acute symptoms for less than two weeks, and/or
 2. rapidly deteriorating ability to ambulate, and/or
 3. unable to ambulate independently for ten meters, and/or
 4. 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);
- **Autoimmune hemolytic anemia** that does not respond to corticosteroids.
- **Autoimmune neutropenia** that does not respond to other modalities, or when the later are contraindicated.
- **Chronic inflammatory demyelinating polyneuropathy (CIDP)** - used either alone or following therapeutic plasma exchange to prolong its effect.
- **Hyperimmunoglobulin E (HIE) syndrome** (Job's Syndrome, Hyper IgE Syndrome)
- **Infections** in high-risk, preterm, low-birth-weight neonates, as prophylaxis and/or treatment adjunct.
- **Inflammatory myopathies:** Refractory inflammatory myopathies (e.g., polymyositis, dermatomyositis) for corticosteroid-resistant patients, or patients in whom corticosteroids are contraindicated.
- **Lambert-Eaton myasthenic syndrome (LEMS)**, not controlled by anticholinesterases and diaminopyridine.
- **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.
- **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.
- **Multiple Sclerosis (MS)**, severe manifestations of relapsing-remitting type only, when other therapy has failed, become intolerable, and/or is 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.
- **Myasthenia gravis**, with the following conditions:
 1. acute severe decompensation when other treatments have been unsuccessful or are contraindicated, or

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2. myasthenia crisis (i.e., an acute episode of respiratory muscle weakness) in patients with contraindications to plasma exchange, or
 3. chronic debilitating disease in spite of treatment with cholinesterase inhibitors, and/or complications from or failure of steroids and/or azathioprine.
- **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.
 - **Post transfusion purpura** (severe).
 - **Pure red cell aplasia** with documented parvovirus B19 infection and with severe, refractory anemia.
 - **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.
 - **Solid-organ transplant**, following transplant for treatment of antibody-mediated rejection.
 - **Stiff Person Syndrome** (Moersch-Woltman Syndrome) when:
 1. Anti-GAD antibody is present, and
 2. 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.
 - **Toxic Shock Syndrome** or Toxic Necrotizing Fasciitis due to streptococcal or staphylococcal organisms, when:
 1. Infection is refractory to several hours of aggressive therapy, and/or
 2. An undrainable focus is present, and/or
 3. The patient has persistent oliguria with pulmonary edema.
 - **Vasculitis Syndrome** in patients with severe active illness for whom other interventions have been unsuccessful or intolerable.

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

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- 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: One year (for all above diagnoses).

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

- **Jakafi (ruxolitinib)**

Indications for Approval:

Treatment for patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.

*Specialty pharmacy mandated.

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

- **Janumet (sitagliptin/metformin)**

Step Edit Criteria:

The member must have a 30-day prescription fill of metformin within the past 545 days.
Quantity limit of 60 tablets for 30 days.

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Alternative: metformin

Approved by the P&T Committee 09/15/2010.

Criteria based on:

American Diabetes Association (ADA):

Executive Summary: Standards of Medical Care in Diabetes – 2010. *Diabetes Care*. 33 (suppl 1):S4-S10, 2010.

http://care.diabetesjournals.org/content/33/Supplement_1/S4.full.pdf

Standards of Medical Care in Diabetes – 2007 (Position Statement). *Diabetes Care*. 30 (suppl 1):S4-S41, 2007.

http://care.diabetesjournals.org/content/30/suppl_1/S4.full.pdf

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007.

www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Janumet XR (sitagliptin/metformin ER)**

Step Edit Criteria:

The member must have a 30-day prescription fill of metformin within the past 545 days.

Quantity limit of 60 tablets for 30 days.

Alternative: metformin

Approved by the P&T Committee 03/21/2012.

Criteria based on:

American Diabetes Association (ADA):

Executive Summary: Standards of Medical Care in Diabetes – 2010. *Diabetes Care*. 33 (suppl 1):S4-S10, 2010.

http://care.diabetesjournals.org/content/33/Supplement_1/S4.full.pdf

Standards of Medical Care in Diabetes – 2007 (Position Statement). *Diabetes Care*. 30 (suppl 1):S4-S41, 2007.

http://care.diabetesjournals.org/content/30/suppl_1/S4.full.pdf

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007.

www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Januvia (sitagliptin)**

Step Edit Criteria:

The member must have a 30-day prescription fill of metformin within the past 545 days.

Quantity limit of 30 tablets for 30 days.

Alternative: metformin

Approved by the P&T Committee 09/15/2010.

Criteria based on:

American Diabetes Association (ADA):

Executive Summary: Standards of Medical Care in Diabetes – 2010. *Diabetes Care*. 33 (suppl 1):S4-S10, 2010.

http://care.diabetesjournals.org/content/33/Supplement_1/S4.full.pdf

Standards of Medical Care in Diabetes – 2007 (Position Statement). *Diabetes Care*. 30 (suppl 1):S4-S41, 2007.

http://care.diabetesjournals.org/content/30/suppl_1/S4.full.pdf

American Association of Clinical Endocrinologists (AACE):

Commercial and Medicaid Prior Authorization Criteria Document

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007. www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Kadian (morphine extended release capsules)**

Step Edit Criteria:

The patient must have claim history of fentanyl transdermal patches and Opana ER within the past 90 days.

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

- **Kombiglyze XR (saxagliptin/metformin ER)**

Indications for Approval:

Diabetes Mellitus Type 2 that meets the following criteria:

The patient has a recent (within the past 3 months) documented A1C level of <11

AND

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.

Continuation of Therapy Criteria:

The A1C value must be decreasing (it is recommended to measure A1C every 3 months). 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:

- 1) Referral of the member to the PHP disease management team.
- 2) Denial of the request with suggested alternative medications.
- 3) Request for chart notes that describe the treatment plan and /or discussion with the prescribing provider about the treatment plan for the member.

A1C Protocol:

If the initial or subsequent A1C is > 9 then the A1C must decrease by 1% or more.

If the initial or subsequent A1C is between 8.5 – 8.9% then the A1C must decrease by 0.5% or more.

If the initial or subsequent A1C is between 7.5 – 8.4% then the A1C must decrease by 0.25% or more.

If the initial or subsequent A1C is between 7.0 – 7.4% then the A1C must decrease by 0.15% or more.

Approval: 6 months.

Alternatives: glimepiride, glipizide, glyburide, insulin.

Approved by the P&T Committee 01/19/2011.

Criteria based on:

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007. www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

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- **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:

1. Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM et al. American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006. J Clin Oncol. 2006 June 20. 24(18):2932-2947.
2. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Antiemetics [updated 2010 Feb; cited 2010 April 7] Available from: www.nccn.org

- **Leukeran (chlorambucil)**

Indications for Approval:

Leukemia/Lymphomas - For the treatment of chronic lymphatic (lymphocytic) leukemia, malignant lymphomas including lymphosarcoma, giant follicular lymphoma, and Hodgkin's disease.

It is not curative in any of these disorders but may produce clinically useful palliation

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Lexapro (escitalopram)**

Step Edit Criteria:

The patient must have a 30-day trial and failure on two formulary generic SSRIs within the past 180 days.

Quantity limit of 30 tablets for 30 days of the 5mg strength, 45 tablets for 30 days of the 10mg strength and 30 tablets for 30 days of the 20mg strength.

Alternatives: Citalopram, fluoxetine, paroxetine, and sertraline.

Updated by the P&T Committee 07/20/2011.

- **Lidoderm (lidocaine patch)**

Indications for Approval:

1. The patient has a FDA indication of post-herpetic neuralgia pain.

OR

2. The patient has other types of localized neuropathic pain.

AND

The patient has a documented therapeutic trial and failure of at least two of the following drug categories:

- a. Tricyclic antidepressants
- b. SSRIs or formulary SNRI (i.e. venlafaxine)
- c. Anticonvulsants in doses associated with pain management (i.e. gabapentin 1200mg daily)
- d. Opioid analgesics

Quantity limit: 30 patches/30 days for Medicaid and Commercial Plans

Note: Patches measure approximately 4" x 5.5" and may be cut to fit smaller areas

Approval: 3 months.

Commercial and Medicaid Prior Authorization Criteria Document

Alternatives: Amitriptyline, citalopram, fluoxetine, paroxetine, sertraline, venlafaxine, gabapentin, lamotrigine, carbamazepine, divalproex.

Approved by the P&T Committee 11/16/2005.

- **Lipitor (atorvastatin)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of one formulary generic statin medication within the past 545 days.

Alternatives: lovastatin, pravastatin, simvastatin.

Quantity limit of 30 tablets for 30 days.

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

- **Lotemax (loteprednol etabonate 0.5% suspension)**

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.

- **Lunesta (eszopiclone)**

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.

- **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 and post-herpetic neuralgia:**

The patient must have a documented failure at therapeutic doses of all of the following:

- a) Gabapentin (1,200 to 2,400 mg/day).
- b) One of the following preferred alternatives: an antidepressant (tricyclic, SSRI, or venlafaxine), lamotrigine, divalproex or carbamazepine.

3. **Fibromyalgia:**

The patient must have a documented failure of:

- 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).

Commercial and Medicaid Prior Authorization Criteria Document

Approval: One year.

Quantity limit of 90 capsules for 30 days.

Alternatives: Gabapentin, amitriptyline, desipramine, nortriptyline, citalopram, 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. Revised 11/19/08.

- **Matulane (procarbazine)**

Indications for Approval:

Hodgkin's disease - For use in combination with other anticancer drugs for the treatment of Stage III and IV Hodgkin's disease. Matulane is used as part of the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) regimen.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **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.

- **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 on 11/16/2009.

Criteria based on the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation. Available at:

http://www.acc.org/qualityandscience/clinical/guidelines/atrial_fib/pdfs/af_full_text.pdf

Commercial and Medicaid Prior Authorization Criteria Document

- **Myleran (busulfan)**

Indications for Approval:

For the palliative treatment of chronic myelogenous (myeloid, myelocytic, granulocytic) leukemia.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Nasonex (mometasone)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The member must have a claim history of one generic formulary nasal steroid prescription in the past 545 days.

Alternatives: Alternatives: Flunisolide nasal spray, fluticasone propionate nasal spray, triamcinolone nasal spray.

Approved by the P&T Committee 09/15/2010.

- **Neulasta (pegfilgrastim)**

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:

- 1) Documented diagnosis of severe chronic neutropenia (idiopathic) with an ANC of less than $500/\text{mm}^3$ on three separate occasions over the previous 6 months.
 - OR**
 - 2) Documented diagnosis of severe chronic neutropenia (*cyclic*) with five consecutive days per cycle with an ANC less than $500/\text{mm}^3$ 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.

Compendial Uses: Non-FDA approved uses for Neulasta 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 Neulasta 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 for Neulasta will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Commercial and Medicaid Prior Authorization Criteria Document

References:

1. Neupogen prescribing information. Thousand Oaks, CA; Amgen; revised 3/2010.
2. Neulasta prescribing information. Thousand Oaks, CA; Amgen; revised 2/2010.
3. Micromedex Healthcare Series Website. Available at <http://www.thomsonhc.com/hcs/librarian>. Accessed on April 27, 2010.

Approval Length: For severe chronic neutropenia – one year.

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 mandated.

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

- **Neupogen (filgrastim)**

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:

- 1) Documented diagnosis of severe chronic neutropenia (idiopathic) with an ANC of less than $500/\text{mm}^3$ on three separate occasions over the previous 6 months.

OR

- 2) Documented diagnosis of severe chronic neutropenia (*cyclic*) with five consecutive days per cycle with an ANC less than $500/\text{mm}^3$ 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.

Compendial Uses: Non-FDA approved uses for Neupogen 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 Neupogen 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 for Neupogen will be considered through the Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Commercial and Medicaid Prior Authorization Criteria Document

References:

1. Neupogen prescribing information. Thousand Oaks, CA; Amgen; revised 3/2010.
2. Neulasta prescribing information. Thousand Oaks, CA; Amgen; revised 2/2010.
3. Micromedex Healthcare Series Website. Available at <http://www.thomsonhc.com/hcs/librarian>. Accessed on April 27, 2010.

Approval Length: For severe chronic neutropenia – one year.

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

- **Nexavar (sorafenib)**

Indications for Approval:

1. Advanced renal cell carcinoma – For the treatment of patients with advanced renal cell carcinoma.
2. Hepatocellular carcinoma – For the treatment of patients with unresectable hepatocellular carcinoma.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Norditropin, Norditropin Flexpro, Norditropin Nordiflex (recombinant human growth hormone)**

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. Subnormal response (≤ 10 ng/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.
 - For patients with documented panhypopituitarism or a history of cranial radiation no simulation tests required.
 - In a neonate with hypoglycemia, but not metabolic disorder, a peak GH level less than 20 ng/ ml is usually diagnostic of GHD.
- c. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender
- d. Predicted adult height more than 1.5 SD below mid-parental height.
- e. 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.
- f. Documentation of bone age between 1 to 2 SD below the normal for chronological age.
- g. Epiphyses are not closed.

Notes: Provocative stimulation tests include arginine, clonidine, glucagon, insulin, and levodopa.

- 2. Turner Syndrome in females**

- a. Diagnosis of Turner Syndrome confirmed by appropriate genetic testing.
- b. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender
- c. 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.
- d. Bone age less than 14 years.
- e. Documentation provided that epiphyses are not closed.

- 3. Chronic Renal Insufficiency**

- a. Documented clinical diagnosis of chronic renal insufficiency.
- b. Baseline height ≤ 2 standard deviations below the mean for age or gender, or at or below the 3rd percentile for age or gender.

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- c. Patient has a growth rate < 7 cm per year if less than 3 years of age and < 4 cm per year if greater than 3 years of age.
- d. Existing metabolic derangements (such as acidosis, secondary hyperparathyroidism, malnutrition) have been corrected.
- e. Documentation provided that epiphyses are not closed.
- f. 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.

5. Idiopathic short stature

- a. Documented baseline height less than 2.25 SD below the mean for age or gender.
- b. Expected adult height is less than 63 inches (160 cm) for boys and 59 inches (150 cm) for girls.
- c. Absence of other comorbid conditions that should be observed or treated by other means.
- d. Documentation provided that epiphyses are not closed.

6. Noonan Syndrome and Prader-Willi Syndrome

- a. Diagnosis confirmed by appropriate genetic testing.
- b. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender.
- c. Patient has a growth rate <7 cm per year if less than 3 years of age and <4 cm per year if greater than 3 years of age.
- d. Documentation provided that epiphyses are not closed.

Continuation of Therapy Criteria and Approval Length: Length of authorization will be for 1 year, after which documentation will be required to support improvement in growth. Coverage of GH therapy will be terminated if the patient fails to respond to GH or if documented fusion of the epiphyses occurs and the patient has not met the criteria for adult GH therapy.

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 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.

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- 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: 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 Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Approved by the P&T Committee 07/2004. Revised by the P&T Committee on 07/21/2010.

References:

1. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children-2003 update. *Endocr Pract* 2003 Jan-Feb; 9(1):34-76.
2. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients-2009 update. *Endocr Pract* 2009 Sept-Oct; 15(Suppl 2)1-23.

- **Nutritional Supplementation**

APPLIES TO MEDICAID PLANS ONLY

(Refer to the Oral Nutritional Supplements Prior Authorization Form, available on www.phs.org)

Indications for Approval:

1. Presbyterian Salud may reimburse medically necessary oral formula feeding supplements provided by a participating Pharmacy when it is medically necessary for non-institutionalized eligible members.
2. The patient must have a 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.
3. Conditions may be 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.

Approval: One year. The amount authorized at any given time will relate to the ADA caloric intake for a 24 hour period to sustain life.

- **Oforta (fludarabine)**

Indications for Approval:

As a single agent for the treatment of adult patients with B-cell CLL whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating agent-containing regimen.

Commercial and Medicaid Prior Authorization Criteria Document

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Onglyza (saxagliptin)**

Indications for Approval:

Diabetes Mellitus Type 2 that meets the following criteria:

The patient has a recent (within the past 3 months) documented A1C level of <11 **AND** one of the following:

- 1) 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
- 2) 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 ≥ 2000 mg daily.
 - Documented renal disease or renal dysfunction. For example, serum creatinine levels ≥ 1.5 mg/dl (males) or ≥ 1.4 mg/dl (females).
 - Documented hepatic disease. For example, cirrhosis or hepatitis.

Continuation of Therapy Criteria:

The A1C value must be decreasing (it is recommended to measure A1C every 3 months). 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:

- 1) Referral of the member to the PHP disease management team.
- 2) Denial of the request with suggested alternative medications.
- 3) Request for chart notes that describe the treatment plan and /or discussion with the prescribing provider about the treatment plan for the member.

A1C Protocol:

If the initial or subsequent A1C is > 9 then the A1C must decrease by 1% or more.

If the initial or subsequent A1C is between 8.5 – 8.9% then the A1C must decrease by 0.5% or more.

If the initial or subsequent A1C is between 7.5 – 8.4% then the A1C must decrease by 0.25% or more.

If the initial or subsequent A1C is between 7.0 – 7.4% then the A1C must decrease by 0.15% or more.

Approval: 6 months.

Quantity limit of 30 tablets for 30 days.

Alternatives: glimepiride, glipizide, glyburide, insulin, metformin.

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

Criteria based on:

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007. www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Opana ER (oxymorphone HCl SR)**

Commercial and Medicaid Prior Authorization Criteria Document

Indications for Approval:

The patient has a documented failure or intolerance to morphine sulfate extended release tablets.

OR

The patient has a documented failure or intolerance to fentanyl transdermal patches.

Approval: 6 months

Alternatives: morphine sulfate extended release tablet (MS Contin).

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 of 60 tablets for 30 days.

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

- **Orencia (abatacept)**

Indications for Approval:

1. Rheumatoid Arthritis (RA)
2. Juvenile Idiopathic Arthritis

Criteria for Approval:

- a. The patient has disease activity with active synovitis in at least 3 sets of joints – for example, bilateral proximal interphalangeal (PIP) involvement = 1 set, or bilateral knee involvement = 1 set.
AND
- b. 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:
 1. Leflunomide
 2. Hydroxychloroquine
 3. Sulfasalazine
 4. Mycophenolate mofetil
 5. AzathioprineAND
- c. The patient must have had a documented trial and failure of both Remicade (infliximab) and Humira (adalimumab).
AND
- d. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.
AND
- e. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23, Pnu-Immune 23, or Prevnar) prior to initiation of therapy.
AND
- f. Medical records or a typed summary documenting all of the above must be submitted with the Prior Authorization request.

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.

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- Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orencia without an intravenous loading dose.
- Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

Approval: 1 year.

Approved by the P&T Committee 01/21/2009. Revised 05/20/2009.

- **Oxytrol (oxybutynin transdermal)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of generic oxybutynin XL and Detrol or Detrol LA within the past 180 days.

Alternatives: Oxybutynin, oxybutynin XL, Detrol, and Detrol LA.

- **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).

Alternatives: Citalopram, fluoxetine, paroxetine, and sertraline.

- **Pentasa (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.

Alternative: balsalazide, sulfasalazine

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

Revised 01/18/2012.

- **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.

- **Prevacid (lansoprazole capsule)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 545 days of a 30-day trial of omeprazole.

Quantity limit of 60 capsules for 30 days.

Alternatives: Omeprazole.

Approved by P&T Committee 03/24/2010.

- **Prevacid SoluTabs (lansoprazole orally disintegrating tablet)**

Indications for Approval:

1. Patients with a feeding tube.

OR

2. Patients under one year of age.

Commercial and Medicaid Prior Authorization Criteria Document

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

- **Procrit (epoetin alpha)**

Prior Authorization Criteria:

Indications for Approval:

1. Treatment of anemia of chronic renal failure.
2. Treatment of anemia in zidovudine-treated HIV infected patients.
3. Treatment of anemia in cancer patients on chemotherapy.
4. Reduction of allogenic blood transfusions in surgery patients.

Criteria for Approval:

1. The maximum dose for the first 4 weeks of treatment is 1800U/kg.
2. Hemoglobin must be < 11g/dl.

The use of Procrit 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.

Approved by the P&T Committee 07/16/2008.

Revised 07/20/2011.

- **Prolia (denosumab)**

Indications for Approval:

1. Post-menopausal women with osteoporosis.
2. To increase bone mass in women at high risk for fracture currently receiving adjuvant aromatase inhibitor therapy (anastrozole, letrozole, exemestane) for breast cancer.
3. To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy with orchiectomy, gonadotropin-releasing hormone antagonists (degarelix, goserelin, histrelin, leuprolide, triptorelin) or anti-androgen therapy (bicalutamide, flutamide, nilutamide) for non-metastatic prostate cancer.

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 $\geq 3\%$ or a 10-year major osteoporosis-related fracture probability of $\geq 20\%$ based on the US-adapted WHO absolute fracture risk model, FRAX®, available at <http://www.shef.ac.uk/FRAX>.

- b. Inadequate response to, or is unable to tolerate intravenous bisphosphonates† or a creatinine clearance (CrCl) of less than 35mL/min.
 - Inadequate response defined as no improvement in BMD determined by DEXA can, after one year of treatment.
 - Intolerance defined as an allergy to the product.

† *Zoledronic acid (Reclast®) requires a trial and failure of an oral bisphosphonate.*

Commercial and Medicaid Prior Authorization Criteria Document

Approval Length: One year.

* Use of a specialty pharmacy is required for this medication.

Alternatives: Commercial Plans - Alendronate, Actonel, Atelvia.

Medicaid Plans – Alendronate.

Approved by the P&T committee 01/19/2011.

Revised 11/16/2011.

References:

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) Breast Cancer. Version 2.2011 Update. Available at NCCN.org
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) Prostate Cancer. Version 4.2011. Available at NCCN.org
3. Amgen, Inc. Prolia (denosumab) Prescribing Information. Thousand Oaks, CA: Amgen; 2010. Available at http://pi.amgen.com/united_states/prolia/prolia_pi.pdf
4. Serpa NA, Tobias-Machado M et al. Bisphosphonate therapy in patient under androgen deprivation therapy for prostate cancer: a systematic review and meta-analysis. *Prostate Cancer Prostatic Dis.* 2011 Sep 6, [epub ahead of print].
5. Gnant M, Mlineritsch B, et al. Adjuvant endocrine therapy plus zoledronic acid in premenopausal women with early-stage breast cancer: 62 month follow-up from the ABCSG-12 randomised trial. *Lancet Oncol.* 2011 Jul;12(7):631-41. Epub 2011 Jun 5.

- **Protopic (tacrolimus ointment)**

Indication for Approval:

The patient must have previous use of at least one formulary topical corticosteroid within the past 90 days.

- Continuous long-term use of Protopic is not recommended by the FDA.
- The length of treatment will be limited to 60 days.

Alternatives: Betamethasone, clobetasol, desonide, fluocinolone, fluocinonide, fluticasone, hydrocortisone, triamcinolone.

Approved by the P&T Committee 09/21/2005.

Revised 11/16/2011.

- **Provenge (sipuleucel-T)**

Indications for Approval (all must be met):

1. Documented diagnosis of metastatic castrate resistant (hormone refractory) prostate cancer with radiologic evidence of metastatic disease in lymph nodes and/or bone with evidence of progression* at either site.
2. Patient is asymptomatic or minimally asymptomatic, without cancer-related bone pain or use of opioid analgesics for cancer pain.
3. Patient does not have visceral disease (metastases to liver, lung, or brain).
4. Patient has baseline testosterone levels of <50ng/ml with documented “hormone refractory” prostate cancer defined as:
 - a. Surgical (bilateral orchiectomy) castration; or
 - b. Three months of chemical castration (LHRH agonists or antagonists)
5. Chemotherapy and/or immunosuppressive therapies are not given concurrently.
6. Patient does not have a life expectancy of less than six months.
7. Patient has an ECOG performance status of 0-1.

OR

Patient has a Karnofsky score of 80-100.

* Progression of disease defined as:

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- Progressive measurable disease, as evidenced by changes in size of lymph nodes on parenchymal masses on physical examination or radiographic studies;
Or
- Bone scan progression, as evidenced by one or more lesions or increase in size of lesions (not including “flare” that occurs at commencement of hormonal therapy or chemotherapy);
Or
- PSA progression: An increase in PSA over a previous reference value, where the PSA value is measured a minimum of one week from the reference value, and the PSA measurement is a minimum of 25% greater than the reference value, and an absolute-value increase in PSA of at least 5 ng/ml over the reference value, and this PSA increase is confirmed by a second value.

ECOG (Eastern Oncology Cooperative Group) Score

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 Dead

Karnofsky Score

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity; minor signs or symptoms of disease
- 80 Normal activity with effort; some sign or symptoms of disease
- 70 Cares for self; unable to carry on normal activity or do active work
- 60 Requires occasional assistance, but is able to care for most personal needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization is indicated, although death not imminent
- 20 Very sick; hospitalization necessary; active support treatment is necessary
- 10 Moribund; fatal processes progressing rapidly
- 0 Dead

Approved by the P&T Committee on 03/21/2012

References:

1. Provenge prescribing information. Seattle, WA. Dendreon Corporation. Issued June 2011. Accessed at: <http://www.provenge.com/pdf/prescribing-information.pdf>
2. Zytiga prescribing information. Horsham, PA. Janssen Biotech, Inc. Issued December 2011. Accessed at: www.zytigahcp.com/pdf/full_prescribing_info.pdf
2. Kantoff PW, Higano CS, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med 2010; 363:411-22.
3. <http://www.cancer.org/Cancer/ProstateCancer/DetailedGuide/prostate-cancer-key-statistics>
4. http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/provenge.pdf
5. [http://www.rmhp.org/pdf/rx/preauthforms/Provenge_\(sipuleucel-T\).pdf](http://www.rmhp.org/pdf/rx/preauthforms/Provenge_(sipuleucel-T).pdf)

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6. Mohler J, Bahnson RR, Boston B, Busby JE, D'Amico A, Eastham JA, et al. NCCN clinical practice guidelines in oncology: prostate cancer.

Update Version 4.2011. *J Natl Compr Canc Netw*. 2010 Feb;8(2):162-200.

- **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 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 multiple sclerosis (MS) fatigue
 - The member must also have a documented diagnosis of MS.
3. 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.
4. 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.

Quantity Limit: 30 tablets for 30 days.

Alternatives: methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine

Approved by the P&T Committee 09/15/2010.

Revised 11/16/2011.

- **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: Amlodipine, acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, diltiazem, isosorbide dinitrate, isosorbide mononitrate, labetalol, metoprolol, nadolol, nebivolol, nifedipine, nitroglycerin, pindolol, propranolol, sotalol, timolol, 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.

- **Rebif (interferon beta-1a)**

Prior Authorization Criteria:

The patient has a documented failure or contraindication to Avonex or Copaxone, or the patient is new to Presbyterian Health Plan and is currently taking Rebif.

AND

The initial prescription is prescribed by a neurologist.

Approval: 1 year.

Alternatives: Avonex and Copaxone.

*Specialty Pharmacy mandated.

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

- **Reclast (zoledronic acid)**

Indications for Approval:

1. Osteoporosis:
 - Postmenopausal women and men with osteoporosis that have a hip, spine, or radius T-score ≤ -2.5 .
 - *Note: Will be approved with yearly dosing.
2. Osteopenia (low bone mass):
 - The prevention of osteoporosis in postmenopausal women with hip, spine, or radius T-score between -1.0 and -2.5.
 - *Note: Will be approved with every 24 month dosing.
3. Glucocorticoid-induced osteoporosis:
 - Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months.
 - *Note: Will be approved with yearly dosing.
4. The patient does not meet criteria for any of the above indications but does have a 10-year hip fracture probability $\geq 3\%$ or a 10-year major osteoporosis-related fracture probability $\geq 20\%$ based on the US-adapted WHO absolute fracture risk model, FRAX®, available at <http://www.shef.ac.uk/FRAX>.
- *Note: Will be approved with yearly dosing.

AND FOR ALLOF THE ABOVE INDICATIONS ONE OF THE FOLLOWING MUST BE MET:

- a) Gastrointestinal (GI) intolerance to **one** oral bisphosphonate. Examples: Heartburn, indigestion, ulcer, or dyspepsia. **OR**
- b) GI contraindication to **one** oral bisphosphonate. Examples: Esophageal stricture, achalasia, an inability to stand or sit upright for at least 30 minutes, an increased risk of aspiration, Barrett's esophagus or erosive esophagitis. **OR**
- c) A non-responder to at least **one** oral bisphosphonate (anticipated or documented).

Examples:

- Patient has a disease state that involves malabsorption.
 - Patient has a significant loss of bone mineral density (BMD).
 - Patient has failed to significantly suppress bone turnover after at least 3 months of treatment as defined by a $<30\%$ decrease in bone resorption markers such as urinary N-telopeptide or if serum N-telopeptide markers are used then a $<10-15\%$ decrease.
5. Paget's disease:
 - The treatment of Paget's disease of bone in men and women.
 - *Note: Will be approved with yearly dosing.

Criteria for Continuation of Therapy:

- Osteopenia and osteoporosis patients must demonstrate no decrease or an increase in BMD after 12 months of therapy.
- For osteoporosis patients already receiving Reclast who's T-scores have since improved to a low bone mass range (between -1.0 to -2.5), future approvals will be based on the original osteoporosis qualifying criteria listed above.

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Quantity Limits:

- For osteoporosis or Paget's disease the quantity limit is one 5mg infusion every 12 months.
- For osteopenia the quantity limit is one 5mg infusion every 24 months.

Alternatives: Commercial Plans – Alendronate, Actonel, Atelvia.

Medicaid Plans - Alendronate.

Criteria based on: National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis*. Washington, DC, National Osteoporosis Foundation, 2008. Available at: http://www.nof.org/professionals/Clinicians_Guide.htm

Approved by the P&T Committee 3/19/2008. Revised 1/20/2010.

- **Relpax (eletriptan)**

APPLIES TO MEDICAID PLANS ONLY

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 injection, sumatriptan nasal spray, sumatriptan tablets.

Quantity Limit: 18 tablets for 30 days.

Approved by the P&T Committee 07/21/2010.

- **Remicade (infliximab)** - criteria is dependent on diagnosis

Indications for Approval:

The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.

AND

The patient should have documentation of having received pneumococcal immunization (Pneumovax 23, Pnu-Immune 23 or Prevnar) prior to initiation of therapy.

AND

The appropriate Disease Specific Criteria below has been met.

The patient has a diagnosis of one of the following:

Ankylosing Spondylitis (patients with axial disease and a documented trial and failure, or a contraindication, to NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) can be started on Remicade without a trial of a DMARD (Disease Modifying Anti-Rheumatic drug) first).

Juvenile Rheumatoid Arthritis

Psoriatic Arthritis

Rheumatoid Arthritis

AND

The patient has disease activity with active synovitis in at least 3 sets of joints - ex. Bilateral proximal interphalangeal (PIP) involvement = 1 set, or bilateral knee involvement = 1 set.

AND

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

AND

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

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methotrexate, then an adequate trial (3 months or more) of one of the following other DMARDs must have been tried.

1. Leflunomide
2. Hydroxychloroquine
3. Sulfasalazine
4. Mycophenolate mofetil
5. Azathioprine

AND

Medical records or a typed summary must be submitted along with the Prior Authorization request.

The patient has a diagnosis of one of the following:

**Crohn's Disease,
Fistulizing Crohn's Disease;**

OR

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 three or more of the following:

1. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
2. Sulfasalazine
3. Immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate)
4. 5-aminosalicylic acid (brand names include Rowasa[®], Pentasa[®] and Asacol[®])
5. Antibiotics (e.g., metronidazole, quinolones).

The patient has a diagnosis of one of the following:

Plaque Psoriasis

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

1. 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.
2. 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.
3. History of an adequate trial and treatment failure with phototherapy or photochemotherapy or such treatment is contraindicated, not tolerated, or unavailable.
4. History of an adequate trial and treatment failure with methotrexate or such treatment is contraindicated or not tolerated.

The patient has a diagnosis of one of the following:

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:

1. Topical and oral aminosalicylates
2. Topical, oral or IV corticosteroids
3. Oral or IV immunotherapy (e.g., azathioprine, 6-mercaptopurine, cyclosporine)

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4. Surgery for refractory disease.

Approval: One year (for all above diagnoses).
Updated by the P&T committee 01/21/2009.

- **Restasis (cyclosporine ophthalmic emulsion)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

It is prescribed by an optometrist or ophthalmologist.

AND

The patient has a diagnosis of keratoconjunctivitis sicca.

OR

The patient has a diagnosis of Sjogren's disease.

Approval: One year.

Approved by the P&T committee 03/17/2004

- **Retin-A (tretinoin)**

Indications for Approval: (for patients greater than 40 years of age)

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 purpose, such as to decrease the fine facial lines associated with aging.

- **Revatio (sildenafil)**

Indications for Approval:

The patient has a diagnosis of Primary Pulmonary Hypertension

Approval: One year.

Quantity limit: 90 tablets per month for Primary Pulmonary Hypertension.

Note: maximum FDA dosage is 60mg/day.

- **Revlimid (lenalidomide)**

Indications for Approval:

1. Multiple myeloma – In combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy.

2. Myelodysplastic syndromes – For the treatment of patients with transfusion-dependent anemia because of low- or intermediate-1–risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Rhinocort Aqua (budesonide nasal)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The member must have a claim history of one generic formulary nasal steroid within the past 545 days.

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Alternatives: Flunisolide nasal spray, fluticasone nasal spray, triamcinolone nasal spray.

Approved by the P&T Committee 09/15/2010

- **Risperdal M-Tab (risperidone orally disintegrating tablet)**

Indications for Approval:

A psychiatrist must initiate therapy.

AND

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).

Alternatives: risperidone immediate release tablets.

Approval: 1 year.

- **Rituxan (rituximab)**

Indications for Approval:

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. Documented presence of moderate to severe rheumatoid arthritis.
 - c. The patient must have had a documented trial and failure of both Remicade (*infliximab*) and Humira (*adalimumab*).
 - d. Must be given in conjunction with methotrexate or leflunomide if the patient is intolerant to methotrexate.
 - e. Will not be approved for use in combination with a TNF-inhibiting drug such as Enbrel, Humira, and Remicade or with Orencia (*abatacept*).

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 after 6 months have passed from the last course of treatment, and only if retreatment is necessary to control symptoms.

4. Wegener’s granulomatosis (WG) in combination with glucocorticoids.
5. Microscopic polyangiitis (MPA) in combination with glucocorticoids.

The following indications listed below will be considered for approval for treatment with Rituxan if the dosing, frequency, and length of therapy are supported by, and are 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.

- Corticosteroid refractory pemphigus vulgaris or pemphigus foliaceus
- Graft versus host disease
- Multicentric Castleman’s disease (angiofollicular lymph node hyperplasia)

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- 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.

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

Revised 01/21/2009, 05/20/2009, 03/24/2010, 05/18/2011.

- **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.

- **Sanctura (trospium)**

Step Edit Criteria:

The patient must have a claim history of generic oxybutynin XL within the past 545 days.

Alternatives: oxybutynin XL

Approved by the P&T Committee 09/15/2010.

- **Sensipar (cinacalcet)**

Indications for Approval:

The patient has a diagnosis of secondary hyperparathyroidism with chronic kidney disease on chronic dialysis.

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OR

The patient has a diagnosis of Parathyroid Carcinoma prior to surgical intervention; in a patient who is not a surgical candidate; or recurrence despite surgical intervention.

Approval: One year.

- **Simcor (simvastatin/niacin)**

Step Edit Criteria:

The patient must have previous use of at least one of the medications (simvastatin or niacin sustained release) that make up the combination medication within past 120 days.

Alternatives: simvastatin, niacin sustained release.

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

- **Singulair (montelukast)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have claim history of one of the following within the past 120 days:

- A formulary orally inhaled corticosteroid
- A formulary nasal corticosteroid
- A formulary nasal antihistamine

Quantity limit of 30 tablets for 30 days.

Alternatives: Asmanex, Flovent, Pulmicort, QVAR, azelastine nasal spray, flunisolide nasal spray, fluticasone propionate nasal spray, triamcinolone nasal spray.

- **Singulair (montelukast)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have claim history of one of the following within the past 120 days:

- A formulary orally inhaled corticosteroid
- A formulary nasal corticosteroid
- A formulary nasal antihistamine

Quantity limit of 30 tablets for 30 days.

Alternatives: Asmanex, Flovent, Pulmicort, QVAR, flunisolide nasal spray, fluticasone propionate nasal spray, triamcinolone nasal spray.

- **Soliris (eculizumab)**

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

The following diagnostic tests performed (documentation required) must accompany the request:

- Flow Cytometric Immunophenotyping (FCMI)
- PNH Gel Card Test (GAT)
- Ham Test
- Sucrose Lysis Test (SLT).

AND

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The prescribing physician is a hematology/oncology specialist.

OR

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

OR

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

OR

The patient has history of failure of 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.

2. A documented diagnosis of atypical hemolytic uremic syndrome (aHUS).

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**).

Quantity limit: PNH: IV 600 mg once weekly for 4 weeks, followed by 900 mg one week later; then maintenance: 900 mg. every 2 weeks.

aHUS: IV 900mg once weekly for 4 weeks, followed by 1,200mg one week later; then maintenance: 1,200mg every 2 weeks.

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.

Updated by the P&T Committee 11/16/2011.

- **Sprycel (dasatinib)**

Indications for Approval:

1. Acute lymphoblastic leukemia - For the treatment of adults with Philadelphia chromosome–positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy.
2. Chronic myeloid leukemia
 - For the treatment of adults with newly diagnosed Ph+ chronic myeloid leukemia (CML) in chronic phase.
 - For the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+CML with resistance or intolerance to prior therapy, including imatinib.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Strattera (atomoxetine)**

Step Edit Criteria:

The patient must have a documented trial at therapeutic doses within the past 180 days of a methylphenidate compound AND an amphetamine compound in Presbyterian’s claim system.

Alternatives:

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Commercial Plans - methylphenidate, methylphenidate extended release (Metadate CD, Methylin ER), Concerta, dextroamphetamine, amphetamine/dextroamphetamine immediate release, and amphetamine/dextroamphetamine extended release.

Medicaid Plans - methylphenidate, methylphenidate extended release (Metadate CD, Methylin ER), dextroamphetamine, and amphetamine/dextroamphetamine immediate release.

- **Suboxone (buprenorphine/naloxone)**

Indication for Approval:

- Maintenance therapy for the treatment of opioid dependence.

All of the following must be met:

1. The patient has the prescription benefit in their plan for the coverage of medications for treating opioid dependence.
2. The prescriber is a qualified physician under the Drug Abuse Treatment Act (DATA) to prescribe Suboxone.
3. Documentation of the patient diagnosis and a treatment plan must be submitted with each request.
4. 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.
5. Buprenorphine use in combination with benzodiazepines or other sedative hypnotics has been associated with significant respiratory depression. Therefore, if concurrent use of a benzodiazepine or other sedative/hypnotic is identified, a justification for combined use must be submitted with the request.
6. Recent urine drug screen results must be submitted with each request.
7. The Board of Pharmacy Prescription Monitoring Program report must be submitted with each request (<https://www.pmp.state.nm.us/pmpwebcenter>).

Exclusions:

- Will not be approved for use in conjunction with any opioid analgesic (medication that has agonist action at the μ -opioid receptor).
- Will not be approved for the sole purpose of pain management.

Quantity Limit: 90 strips or tablets for 30 days

Approval: 1 month initially, then an additional 3 months, then every 6 months thereafter.

Approved by P&T Committee 11/19/2008.

Revised 05/20/2009, 03/16/2011, 11/16/2011.

- **Subutex sublingual tablets (buprenorphine)**

Indications for Approval:

- Induction therapy for the treatment of opioid dependence up to a maximum of 7 days.
- Maintenance therapy for the treatment of opioid dependence.

All of the following must be met:

1. The patient has the prescription benefit in their plan for the coverage of medications for treating opioid dependence.
2. The prescriber is qualified physician under the Drug Abuse Treatment Act (DATA) to prescribe Subutex.
3. Documentation of patient diagnosis and treatment plan must be submitted

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with each request.

4. 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.
5. Buprenorphine use in combination with benzodiazepines or other sedative hypnotics has been associated with significant respiratory depression. Therefore, if concurrent use of a benzodiazepine or other sedative hypnotic is identified, then a justification for combined use must be submitted with the request.
6. Recent urine drug screen results must be submitted with each request.
7. The Board of Pharmacy Prescription Monitoring Program report must be submitted with each request (<https://www.pmp.state.nm.us/pmpwebcenter>).
8. Documented intolerance to Suboxone (i.e. patients who have shown to be hypersensitive to naloxone) or the member is pregnant or lactating.

Exclusions:

- Will not be approved for use in conjunction with any opioid analgesic (medication that has agonist action at the μ -opioid receptor).
- Will not be approved for the sole purpose of pain management.

Quantity Limit: 90 tablets for 30 days

Approval: 1 month initially, then an additional 3 months, then every 6 months thereafter.

Approved by the P&T Committee 11/19/2008.

Revised 03/16/2011, 11/16/2011.

- **Sutent (sunitinib)**

Indications for Approval:

1. Advanced pancreatic neuroendocrine tumors (pNET) - For the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.
2. Advanced renal cell carcinoma - For the treatment of advanced renal cell carcinoma.
3. GI stromal tumor (GIST) – For the treatment of GI stromal tumor after disease progression on or intolerance to imatinib.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Sylatron (peginterferon alfa-2b)**

Indications for Approval

Documentation that the patient has melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

Approval: one year.

Specialty Pharmacy mandated.

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

- **Symbicort (budesonide/formoterol)**

Step Edit Criteria:

The patient must have a prescription claim history of an orally inhaled corticosteroid or orally inhaled anticholinergic within the past 120 days.

Quantity limit: One inhaler for 30 days.

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Alternatives for Asthma: Asmanex, Flovent, Pulmicort, QVAR.

Alternatives for COPD: Atrovent, Combivent, Spiriva

Approved by the P&T Committee 09/21/2011.

- **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.

- **Tabloid (thioguanine)**

Indications for Approval:

Acute nonlymphocytic leukemias - Remission induction and remission consolidation treatment.

It is not recommended for use during maintenance therapy or similar long-term continuous treatments due to the high risk of liver toxicity.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Tarceva (erlotinib)**

Indications for Approval:

1. Non-small cell lung cancer NSCLC)

- Maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy.
- Treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.

2. Pancreatic cancer - For the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Targretin (bexarotene)**

Indications for Approval:

Cutaneous T-cell lymphoma (CTCL) - For the treatment of cutaneous manifestations of CTCL in patients who are refractory to at least one prior systemic therapy.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Tasigna (nilotinib)**

Indications for Approval:

1. Adults with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in chronic phase.
2. Resistant or intolerant Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in chronic phase and accelerated phase in adult patients.

Commercial and Medicaid Prior Authorization Criteria Document

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Temodar (temozolomide)**

Indications for Approval:

1. Anaplastic astrocytoma - For the treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine.
2. Glioblastoma multiforme - For the treatment of adults with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Testim (testosterone topical gel)**

Indications for Approval:

Patient must be male, over the age of 18 and meet one of the following:

1. Primary hypogonadism (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 (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.

Exclusions:

- 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.
- Testosterone replacement will not be covered for the treatment of sexual dysfunction.

Approval: 1 year.

Quantity limit of 60 packets for 30 days.

Criteria based on: *AACE Medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update*. Available online at www.acce.com.

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

Revised 01/21/2009.

Revised 05/18/2011.

- **Tev-Tropin (recombinant human growth hormone)**

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.

Commercial and Medicaid Prior Authorization Criteria Document

- b. Subnormal response (≤ 10 ng/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.
 - For patients with documented panhypopituitarism or a history of cranial radiation no stimulation tests required.
 - In a neonate with hypoglycemia, but not metabolic disorder, a peak GH level less than 20 ng/ml is usually diagnostic of GHD.
- c. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender
- d. Predicted adult height more than 1.5 SD below mid-parental height.
- e. 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.
- f. Documentation of bone age between 1 to 2 SD below the normal for chronological age.
- g. Epiphyses are not closed.

Notes: Provocative stimulation tests include arginine, clonidine, glucagon, insulin, and levodopa.

2. Turner Syndrome in females

- a. Diagnosis of Turner Syndrome confirmed by appropriate genetic testing.
- b. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender
- c. 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.
- d. Bone age less than 14 years.
- e. Documentation provided that epiphyses are not closed.

3. Chronic Renal Insufficiency

- a. Documented clinical diagnosis of chronic renal insufficiency.
- b. Baseline height ≤ 2 standard deviations below the mean for age or gender, or at or below the 3rd percentile for age or gender.
- c. Patient has a growth rate < 7 cm per year if less than 3 years of age and < 4 cm per year if greater than 3 years of age.
- d. Existing metabolic derangements (such as acidosis, secondary hyperparathyroidism, malnutrition) have been corrected.
- e. Documentation provided that epiphyses are not closed.
- f. 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.

5. Idiopathic short stature

- a. Documented baseline height less than 2.25 SD below the mean for age or gender.
- b. Expected adult height is less than 63 inches (160 cm) for boys and 59 inches (150 cm) for girls.
- c. Absence of other comorbid conditions that should be observed or treated by other means.
- d. Documentation provided that epiphyses are not closed.

6. Noonan Syndrome and Prader-Willi Syndrome

- a. Diagnosis confirmed by appropriate genetic testing.
- b. Baseline height ≤ 2 SD below mean (or below the 3rd percentile) for age or gender.
- c. Patient has a growth rate < 7 cm per year if less than 3 years of age and < 4 cm per year if greater than 3 years of age.
- d. Documentation provided that epiphyses are not closed.

Continuation of Therapy Criteria and Approval Length: Length of authorization will be for 1 year, after which documentation will be required to support improvement in growth. Coverage of GH therapy will be terminated if the patient fails to respond to GH or if documented fusion of the epiphyses occurs and the patient has not met the criteria for adult GH therapy.

Indications for approval in ADULTS:

Commercial and Medicaid Prior Authorization Criteria Document

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 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: 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 Prior Authorization process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Approved by the P&T Committee 07/2004. Revised by the P&T Committee on 07/21/2010.

References:

1. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children-2003 update. *Endocr Pract* 2003 Jan-Feb; 9(1):34-76.
2. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients-2009 update. *Endocr Pract* 2009 Sept-Oct; 15(Suppl 2)1-23.

• **Thalomid (thalidomide)**

Indications for Approval:

1. Multiple myeloma - In combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.
2. Erythema nodosum leprosum
 - Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).
 - Maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Approved by the P&T Committee 09/21/2011.

• **Tykerb (lapatinib)**

Commercial and Medicaid Prior Authorization Criteria Document

Indications for Approval:

Breast cancer

- In combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth receptor type 2 (HER2) and who have received prior therapy, including an anthracycline, a taxane, and trastuzumab.
- In combination with letrozole for the treatment of postmenopausal women with hormone receptor–positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **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 \leq 30ml/min.

Quantity limit of 30 tablets for 30 days.

Alternatives: Allopurinol, colchicine.

Approved by the P&T Committee 03/19/2009.

- **Valcyte (valganciclovir)**

Indications for Approval:

1. Treatment of cytomegalovirus (CMV) retinitis in adult AIDS patients.
2. Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant adults patients at high risk.
3. Prevention of CMV disease in kidney and heart pediatric transplant patients at high risk.

Quantity limit: 60 tablets for 30 days.

Alternative: ganciclovir.

Criteria based on: Valcyte prescribing information. Nutley, NJ. Roche Laboratories Inc. Revised August 2009. Accessed at <http://www.gene.com/gene/products/information/valcyte/pdf/pi.pdf>

Approved by the P&T Committee 1/20/2010.

- **Vancocin (vancomycin capsules)**

Indications for Approval:

A microbial culture or toxin is positive for Clostridium difficile.

AND

The patient has a documented failure to respond or is intolerant to metronidazole.

Commercial and Medicaid Prior Authorization Criteria Document

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.

Alternative: Metronidazole.

Rationale: This Prior Authorization is based on the recent 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.

Dose: The recommended dose of oral vancomycin to treat Clostridium difficile is 125 mg PO QID for 10 days. Higher doses have not demonstrated to be more effective.

- **Vandetanib (vandetanib)**

Indications for Approval

Documentation that the patient has symptomatic or progressive medullary thyroid cancer and the cancer is unresectable locally advanced or metastatic disease, and has failed other therapies.

Specialty Pharmacy Mandated

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

- **Venlafaxine ER (venlafaxine extended release tablets)**

Step Edit Criteria:

The patient must have a claim history of two generic antidepressant agents within the past 545 days.

Alternatives: Citalopram, fluoxetine, paroxetine, sertraline, desipramine, trazodone, amitriptyline, nortriptyline, doxepin, venlafaxine, bupropion, and mirtazapine.

Quantity limit: 30 tablets in 30 days.

Approved by the P&T Committee 01/21/2009.

Updated by the P&T Committee 07/21/2010.

- **Venofer (iron sucrose)**

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.

Note: Documented iron deficiency anemia for the above indications is defined as a hemoglobin <11 g/dl.

Commercial and Medicaid Prior Authorization Criteria Document

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.

References:

1. National Comprehensive Cancer Network [homepage on the internet]. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy Induced Anemia [updated 2010 Aug; Cited 2010 May 10] Available from: www.nccn.org
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease 2006. [Cited 2010 May 10]. Available at http://www.kidney.org/professionals/kdoqi/guidelines_anemia/cpr32.htm

- **VESicare (solifenacin)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of generic oxybutynin XL and Detrol or Detrol LA within the past 180 days.

Alternatives: Oxybutynin, oxybutynin XL, Detrol, and Detrol LA.

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

- **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/Test/ViewDetail.asp?NodeID=4&id=1299>.

Approved by the P&T Committee 11/16/2009.

Criteria based on:

Commercial and Medicaid Prior Authorization Criteria Document

1. Clinical Practice Guidelines for the Management of Candidiasis: 2009 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2009;48:503-35.
2. Treatment of Aspergillosis: Clinical Practice Guidelines of the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2008;46:327-60.

- **Victoza (liraglutide)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The member must have a 30-day prescription fill of a metformin product within the past 545 days.

Quantity limit: Three (3) pens for 30 days.

Alternative: metformin

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

- **Victoza (liraglutide)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

Diabetes Mellitus Type 2 that meets the following criteria:

The patient has a recent (within the past 3 months) documented A1C level of <11 **AND** one of the following:

- 1) 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
- 2) 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 ≥ 2000 mg daily.
 - Documented renal disease or renal dysfunction. For example, serum creatinine levels ≥ 1.5 mg/dl (males) or ≥ 1.4 mg/dl (females).
 - Documented hepatic disease. For example, cirrhosis or hepatitis.

Continuation of Therapy Criteria:

The A1C value must be decreasing (it is recommended to measure A1C every 3 months). 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:

- 1) Referral of the member to the PHP disease management team.
- 1) Denial of the request with suggested alternative medications.
- 2) Request for chart notes that describe the treatment plan and /or discussion with the prescribing provider about the treatment plan for the member.

A1C Protocol:

If the initial or subsequent A1C is > 9 then the A1C must decrease by 1% or more.

If the initial or subsequent A1C is between 8.5 – 8.9% then the A1C must decrease by 0.5% or more.

If the initial or subsequent A1C is between 7.5 – 8.4% then the A1C must decrease by 0.25% or more.

If the initial or subsequent A1C is between 7.0 – 7.4% then the A1C must decrease by 0.15% or more.

Approval: 6 months.

Commercial and Medicaid Prior Authorization Criteria Document

Quantity limit of 3 pens for 30 days.

Alternatives: glimepiride, glipizide, glyburide, insulin, metformin.

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

Criteria based on:

American Association of Clinical Endocrinologists (AACE):

AACE/ACE Consensus Statement. *Endocrine Practice*. Vol 15, (6), Sept/Oct 2009.

<http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>

AACE medical guidelines for clinical practice for the management of diabetes mellitus. *Endocrine Practice*. Vol 13, (1), May/June 2007. www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf

- **Victrelis (boceprevir)**

Indications for Approval (ALL of the following must be met):

1. Documented diagnosis of Chronic Hepatitis C, genotype 1 infection.
2. Patient is ≥ 18 years of age.
3. Must be given in combination with peginterferon alfa AND ribavirin
4. NO previous treatment failure with an HCV protease inhibitor (Incivek or Victrelis).
5. Has completed 4 weeks of ribavirin and peginterferon.

Continuation of Therapy:

HCV-RNA levels must be drawn at treatment weeks 8, 12 and 24.

| <u>Treatment Naïve Patients:</u> | | |
|---|--------------|--|
| HCV-RNA Level† | | Continuation of Therapy |
| At TW 8 | At TW 24 | |
| Undetectable | Undetectable | Complete three-medicine regimen at TW 28. |
| Detectable | Undetectable | 1. Continue all three medicines through TW 36; then 2. Continue peginterferon alfa and ribavirin through TW 48. |

| <u>Previously Treated Patients (partial responders or relapsers):</u> | | |
|--|--------------|---|
| HCV-RNA Level† | | Continuation of Therapy |
| At TW 8 | At TW 24 | |
| Undetectable | Undetectable | Complete three-medicine regimen at TW 36. |
| Detectable | Undetectable | 1. Continue all three medicines through TW 36; then 2. Continue peginterferon alpha and ribavirin through TW 48. |

Treatment week(TW) = from initiation of first HCV medication

† The HCV-RNA assay should have a lower limit of quantification ≤ 25 IU/mL and a limit of detection of approx. 10-15 IU/mL. For the purposes of assessing Response-Guided Therapy milestones, a confirmed “detectable but below limit of quantification” HCV-RNA result should not be considered equivalent to an “undetectable” HCV-RNA result.

Patients with Cirrhosis at Baseline:

- Receive 4 weeks of peginterferon alfa and ribavirin followed by 44 weeks of the three-medicine regimen.

Discontinuation of Treatment Based on Treatment Futility (all patients):

- Discontinue the three-drug regimen at treatment week 12 if the HCV-RNA level is greater than 100 U/mL.

Commercial and Medicaid Prior Authorization Criteria Document

- Discontinue the three-drug regimen at treatment week 24 if the HCV-RNA level is detectable.

*Specialty Pharmacy mandated.

Approval: Up to 32 weeks (up to 44 weeks in patients with cirrhosis). Length of approval is dependent upon response to therapy.

Quantity Limit of 360 capsules for 30 days.

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

Criteria based on:

1. Victrelis prescribing information. Whitehouse Station, NJ. Schering Corporation, a subsidiary of MERK & CO. INC. Accessed at http://www.merck.com/product/usa/pi_circulars/v/victrelis/victrelis_pi.pdf
2. Ghany MG, Strader DB, Thomas DL, and Seef LB. ASSLD practice guidelines: Diagnosis, management, and treatment of hepatitis C: An update. *Heptology*. 2009;49(4):1335-1374

- **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 of 30 tablets for 30 days.

Alternatives: citalopram, fluoxetine, paroxetine, sertraline, venlafaxine.

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

- **Vivitrol (naltrexone injection)**

Indications for Approval:

1. Opioid dependence
All of the following must be met:
 - A documented trial and failure of oral naltrexone tablets.
AND
 - 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.
2. Alcohol dependence
All of the following must be met:
 - A documented trial and failure of oral naltrexone tablets plus one other oral deterrent agent such as disulfiram.
AND
 - 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 Length: 6 months.

Quantity Limit: One (1) vial for 30 days.

Alternatives: disulfiram, naltrexone.

Commercial and Medicaid Prior Authorization Criteria Document

*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).

Criteria based on: National Institute on Alcohol Abuse and Alcoholism. Helping Patients Who Drink Too Much: A Clinicians Guide. Accessed at <http://pubs.niaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf>

Approved by the P&T Committee 1/20/2010.
Revised 11/17/2010, 07/20/2011.

- **Voltaren Gel (diclofenac gel)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of at least three formulary oral NSAID medications within the past 180 days.

Alternatives: diclofenac, etodolac, ibuprofen, indomethacin, ketoprofen, meloxicam, nabumetone, naproxen, piroxicam, sulindac.

Quantity limit: Three 100 gram tubes for 30 days.

Approved by the P&T Committee on 7/16/2008.

- **Votrient (pazopanib)**

Indications for Approval:

Renal cell carcinoma - For the treatment of patients with advanced renal cell carcinoma.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Vytorin (ezetimibe/simvastatin)**

APPLIES TO MEDICAID PLANS ONLY

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)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of a 30-day trial of one cerebral stimulant such as dextroamphetamine, amphetamine/dextroamphetamine immediate release or methylphenidate within the past 180 days.

Alternatives: Amphetamine/dextroamphetamine immediate release, dextroamphetamine, methylphenidate, methylphenidate extended release (Metadate CD, Methylin ER).

Quantity Limit: 30 capsules for 30 days.

Approved by the P&T Committee on 01/21/2009.

- **Xalkori (crizotinib)**

Indications for Approval:

Commercial and Medicaid Prior Authorization Criteria Document

Non–Small Cell Lung Cancer - For the treatment of patients with locally advanced or metastatic non–small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)–positive as detected by an FDA-approved test.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Xeloda (capecitabine)**

Indications for Approval:

1. Colorectal cancer - Dukes' stage C colon cancer.
2. Metastatic Breast cancer
 - In combination with docetaxel after failure of prior anthracycline-containing chemotherapy.
 - Monotherapy in patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline–containing chemotherapy regimen.
3. Metastatic Colorectal Cancer - First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Xenical (orlistat)**

APPLIES TO COMMERCIAL PLANS ONLY

Refer to the separate Weight Loss Medication Prior Authorization Form, available on www.phs.org.

Indications for Approval:

1. The patient has a body mass index (BMI) ≥ 27 with 2 or more co-morbidities or BMI ≥ 30 .
2. Current height, weight and dates recorded must be provided with each request.

Approval: Initial approval is for a one month supply of medication. If the patient has lost greater than 4 pounds from their initial body weight, then an additional two months supply of medication will be approved. After three months of therapy, the patient must have maintained a 5% loss of their initial body weight in order to receive a 6 month approval.

- **Xgeva (denosumab)**

Indications for Approval:

ALL of the following must be met for approval:

1. Documented diagnosis for the prevention of skeletal related events with bone metastases from solid tumors.
2. Documented failure or intolerance, or clinical rationale for the avoidance of Zometa or Aredia.
 - a. Example of failure would be a pathologic fracture while receiving Zometa or Aredia with compliance for at least 3 continuous months.
 - b. Example of clinical rationale for avoidance of Zometa or Aredia would be a CrCl <35 .
3. Documented serum calcium.
4. 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.

Commercial and Medicaid Prior Authorization Criteria Document

Use of a specialty pharmacy is required.

Approved by the P&T Committee 03/16/2011

- **Xifaxan (rifaximin)**

Indications for Approval

1. Travelers' diarrhea (200mg strength only) – Patient must meet all of the following criteria:
 - Documented diagnosis of travelers' 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.

Quantity Limits: For travelers' diarrhea – 9 tablets (200mg) for 3 days for any one 30-day period.

For hepatic encephalopathy – up to 180 tablets (200mg) for 30 days.

Approved by the P&T Committee 07/15/2009.

Revised 05/19/2010.

- **Xolair (omalizumab)**

Indications for Approval:

The requesting physician is an allergist or pulmonologist.

AND

The patient's age is 12 years or greater.

AND

The patient has a documented IgE level ≥ 30 IU/ml.

AND

The specific evidence of "allergic asthma," is supported by clinical and lab findings such as positive skin tests, symptom patterns, etc.

AND

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.

AND

There is sufficient evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, or emergency room visits.

Approval: Initial approval for 6 months, then evaluate for effectiveness and discontinue if not useful.

Approved by the P&T Committee 11/16/2005.

- **Yervoy (ipilimumab)**

Indication for Approval:

Documentation that the patient has unresectable or metastatic melanoma and has failed on previous systemic therapy.

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

- **Zegerid (omeprazole/sodium bicarbonate - powder packets)**

APPLIES TO COMMERCIAL PLANS ONLY

Commercial and Medicaid Prior Authorization Criteria Document

Step Edit Criteria:

The patient must have a claim history within the past 545 days of a 30-day trial of three formulary generic proton pump inhibitors (PPIs).

Quantity limit of 60 capsules or powder packets for 30 days.

Alternatives: Lansoprazole, omeprazole, pantoprazole.

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

Revised by the P&T Committee 03/24/2010.

- **Zegerid (omeprazole/sodium bicarbonate)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 545 days of a 30-day trial of three formulary generic proton pump inhibitors (PPIs).

Quantity limit of 60 capsules or powder packets for 30 days.

Alternatives: Alternatives: Lansoprazole*, omeprazole, pantoprazole.

*The patient must have a documented failure of omeprazole for formulary coverage of lansoprazole.

Approved by the P&T Committee 07/16/2008.

Revised 03/24/2010.

- **Zelboraf (vemurafenib)**

Indications for Approval:

Melanoma - For the treatment of unresectable or metastatic melanoma with BRAF^{V600E} mutation as detected by an FDA- approved test. Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Zolinza (vorinostat)**

Indications for Approval:

Cutaneous T-cell lymphoma (CTCL) - For the treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent, or recurrent disease on or following two systemic therapies.

* Specialty Pharmacy mandated.

Approved by the P&T Committee 09/21/2011.

- **Zometa (zoledronic acid)**

Indications for Approval:

The patient has a diagnosis of hypercalcemia of malignancy.

The patient has a diagnosis of multiple myeloma and bone metastases of solid tumors.

One of the following criteria must be met before a patient is eligible for zoledronic acid for treatment of **postmenopausal osteoporosis**:

- a) Gastrointestinal (GI) intolerance to **one** formulary bisphosphonates (alendronate or Actonel)

Example: heartburn, indigestion, ulcer, dyspepsia, etc.

OR

Commercial and Medicaid Prior Authorization Criteria Document

- b) GI contraindication for an oral bisphosphonate.

Example: esophageal stricture, achalasia, inability to stand or sit upright for at least 30 minutes, increased risk of aspiration, Barrett's esophagus, erosive esophagitis etc.

OR

- c) Non-responder (anticipated or documented) to both formulary bisphosphonates
 - 1) Malabsorption.
 - 2) Significant loss of bone density as determined by bone marker scores.
 - 3) Failure to suppress bone turnover after at least 3 months of treatment (less than 30% decrease in bone resorption markers such as urinary NTX).

Approval: One year.

Alternatives: Commercial Plans - alendronate, Actonel.

Medicaid Plans – alendronate.

- **Zostavax (zoster vaccine, live)**

Indications for Approval:

The patient is 50 years of age or older.

AND

The patient does not have a contraindication to Zostavax.

Approval: One time.

Approved by the P&T Committee 11/15/2006.

Updated 4/01/2011.

- **Zyprexa Zydis (olanzapine orally disintegrating tablets)**

Indications for Approval:

A psychiatrist must initiate therapy.

AND

The patient is unable to take or swallow oral medications and 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).

Approval: One year.

Quantity limit of 30 tablets for 30 days.

Alternative: Zyprexa (olanzapine) tablet.

- **Zytiga (abiraterone)**

Indication for Approval:

Castration-resistant prostate cancer - In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) who have received prior chemotherapy containing docetaxel.

*Specialty pharmacy mandated.

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

- **Zyvox (linezolid)**

Indications for Approval:

An infectious disease specialist consult, chart notes and culture and sensitivities must be received with the request.

Commercial and Medicaid Prior Authorization Criteria Document

AND

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.