

Pharmacy Exception Criteria Document for Commercial and Medicaid Plans

General Information and Definitions:

- Inclusion in the list by itself does not imply that the drug listed will be approved.
- 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.
- Pharmacy Exception (PE): Drug is on the formulary but requires a Pharmacy Exception 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:

A psychiatrist must initiate therapy.

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 MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 180 days of Prilosec OTC. Prilosec OTC can be prescribed up to 80 mg/day.

AND

The patient must have a claim history within the past 180 days of pantoprazole.

Alternatives: Prilosec OTC, pantoprazole.

- **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.

- **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 on 09/17/2008.

- **Aczone (dapson 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: 1 year.

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

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- **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 on 05/20/2009.

- **Adipex-P (phentermine)**

(Refer to the separate Weight Loss Medication Pharmacy Exception Form, available on www.phs.org)

Indications for Approval:

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

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)**

Indications for Approval:

1) COPD (Prescriber must provide documentation of stage III or stage IV COPD.)

Patient must be on Atrovent or Spiriva and an inhaled corticosteroid for 3 months of continuous use.

2) Moderate-to-severe persistent asthma (prescriber must provide appropriate documentation such as spirometry results).

Patient must be on a bronchodilator in the last 90 days and inhaled corticosteroid for 3 months of continuous use.

Approval: 1 year.

Quantity limits apply: 1 inhaler for 30 days.

Alternatives: Asmanex, Flovent, QVAR, and Pulmicort.

Step Edit Criteria:

The patient must have a claim history of a formulary inhaled corticosteroid within the past 4 months.

Approved by the P&T Committee on 11/27/2007.

- **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 on 09/17/2008.

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- **Alrex (loteprednol etabonate)**

APPLIES TO COMMERCIAL PLANS ONLY

Pharmacy Exception Criteria:

Initial prescription prescribed by an Ophthalmologist.

Approval: 1 year.

The above Criteria will not apply to patients established on loteprednol therapy. Sampling does not qualify as established therapy.

Alternatives: Dexamethasone ophthalmic, prednisolone ophthalmic, fluorometholone ophthalmic.

- **Ambien CR (zolpidem)**

Indications for Approval:

1. 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.

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

- **Androderm transdermal patch (topical testosterone)**

Pharmacy Exception Criteria:

Indications for Approval: Hypogonadism (primary and secondary).

The patient must have one of the following documented by laboratory confirmation (labs results must be received with each request):

At least two low total testosterone levels (two blood draws required on separate days).

OR

At least two low free testosterone levels (two blood draws required on separate days).

OR

One low free testosterone level with an elevated LH and FSH.

OR

One low total testosterone level with an elevated LH and FSH.

*If there is conflict in the results of the total and free testosterone then the free testosterone results will be used to evaluate the request.

Approval: 1 year.

Quantity limit of 30 patches for 30 days of the 2.5mg strength and 60 patches for 30 days of the 5mg strength.

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

Approved by the P&T Committee on 09/19/2007. Revised on 01/21/2009.

- **Androgel (testosterone topical)**

Pharmacy Exception Criteria:

Indications for Approval: Hypogonadism (primary and secondary).

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The patient must have one of the following documented by laboratory confirmation (labs results must be received with each request):

At least two low total testosterone levels (two blood draws required on separate days).

OR

At least two low free testosterone levels (two blood draws required on separate days).

OR

One low free testosterone level with an elevated LH and FSH.

OR

One low total testosterone level with an elevated LH and FSH.

Note: If there is conflict in the results of the total and free testosterone then the free testosterone results will be used to evaluate the request.

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 and 2 pumps for 30 days.

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

Approved by the P&T Committee on 09/19/2007. Revised on 01/21/2009.

- **Aranesp (darbepoetin alfa)**

Pharmacy Exception 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 maintained between 10g/dl to 12g/dl.

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

1. Aplastic anemia
2. B-12 and folate deficiency anemias
3. Iron deficiency anemia
4. 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 on 01/21/2009.

- **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).

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OR

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

Contraindications:

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

Dosing:

Fondaparinux 2.5 mg SQ daily, initiated 6 hours postoperatively for thromboprophylaxis.
Fondaparinux weight adjusted dosing for thromboembolism treatment; 5.0 mg, 7.5 mg, 10 mg for body weights of <50 kg, 50-100 kg, and >100 kg, respectively.
Duration for thromboprophylaxis was up to 11 days. However, benefits of prolonged duration for VTE prophylaxis have been documented.
Duration for thromboembolism treatment is at least 5 days and until oral anticoagulation is within the therapeutic range (INR 2-3).
If platelet counts fall below 100,000mm³, 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).

- **Astepro (azelastine nasal)**

APPLIES TO MEDICAID PLANS ONLY

Pharmacy Exception 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: Fluticasone nasal, fluticasone propionate, Nasonex (ages 2-4), cetirizine OTC, fexofenadine, loratadine.

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

- **Atacand (candesartan)**

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, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ. HCTZ= hydrochlorothiazide

- **Atacand HCT (candesartan/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, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ. HCTZ= hydrochlorothiazide.

- **Avalide (irbesartan/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, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/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 on 09/17/2008.

- **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, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ. HCTZ= hydrochlorothiazide

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

Indications for Approval:

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

AND

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

OR

The patient has documented failure or intolerance to Opana ER (oxymorphone HCl extended release).

Approval: 6 months.

Quantity limit of 30 capsules for 30 days.

Alternatives: Fentanyl transdermal, morphine sulfate extended release tablet (MS Contin), and Opana ER.

Step Edit Criteria:

The patient must have a claim history of morphine sulfate extended release tablet (MS Contin) and fentanyl transdermal or Opana ER within the past 90 days.

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

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

Pharmacy Exception Criteria:

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

AND

The initial prescription is prescribed by a neurologist.

Approval: 1 year.

Alternatives: Rebif and Copaxone.

- **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.

OR

If a patient has a history of utilization of Benicar within the past 180 days, they may continue to receive Benicar without a PA.

Alternatives: Benazepril, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ. HCTZ= hydrochlorothiazide

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

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.

OR

If a patient has a history of utilization of Benicar HCT within the past 180 days, they may continue to receive Benicar HCT without a PA.

Alternatives: Benazepril, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ.

HCTZ= hydrochlorothiazide

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

Pharmacy Exception Criteria:

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

AND

The initial prescription is prescribed by a neurologist.

Approval: 1 year.

Alternatives: Rebif and Copaxone.

- **Botox (botulinum Toxin Type A)**

Indications for Approval:

1. Blepharospasm (doses of 100 units or less).

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2. Cervical Dystonia (doses of 300 units or less).
3. 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®).
4. Strabismus (doses of 100 units or less).
5. Cerebral Palsy (doses of 400 units or less).
6. Facial Nerve Disorder/Hemi-facial Spasm (doses of 100 units or less).
7. Laryngeal Dystonia (doses of 100 units or less).
8. Limb Dystonia (doses of 100 units or less).
9. Migraines (doses of 100 units or less) that meets the following criteria:
 - Documented trials and failures with conventional and prophylactic therapies AND
 - Must be written by a neurologist.
10. Severe palmar 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).
11. Spasmodic Torticollis (doses of 300 units or less).
12. Spasticity resulting from an acquired or congenital brain disorder (doses of 400 units or less).

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

Approval: 1 year.

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

- **Byetta (exenatide)**

Indications for Approval:

The glucose abnormality primarily involves the lack of post-prandial glucose control.

AND

The patient has a current documented HbA1c that is between 6.5% and 8.5%.

AND

The patient has inadequate glycemic control with at least two of the following medications: Metformin at maximum doses (1500mg/day), sulfonylureas, and thiazolidinediones (TZDs) **and** requires the addition of another agent **OR** requires the addition of another agent and has contraindications to, or is unable to tolerate the alternatives.

AND

The patient is not currently on Insulin or Januvia. Byetta will not be approved for use in combination with insulin or with Januvia until more data on the safety and efficacy for those combinations is available.

Approval: 1 year.

Alternatives: Metformin, glyburide, glipizide, glimepiride, Actos, Avandia.

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

- **Campath (alemtuzumab)**

Indications for Approval:

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

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Approval: 1 year.

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

- **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.

- **Celebrex (celecoxib)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

The patient must have a documented failure at therapeutic doses on meloxicam, nabumetone and one other formulary Nonsteroidal anti-inflammatory drugs (NSAIDS).

Approval: 1 year.

Quantity limit of 60 capsules/30 days.)

Alternatives: Meloxicam, nabumetone, diclofenac, diflunisal, etodolac, ibuprofen, ketoprofen, naproxen, piroxicam, salsalate, sulindac.

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

- **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 a generic cerebral stimulant, such as immediate release methylphenidate, within the past 180 days.

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

- **Crestor (rosuvastatin)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

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.

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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).

Approval: 1 year.

Quantity limits:

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

60mg capsules – 30 capsules for 30 days.

Alternatives: Gabapentin, amitriptyline, desipramine, nortriptyline, lamotrigine, carbamazepine, citalopram, paroxetine, fluoxetine, sertraline, venlafaxine, bupropion.

Approved by the P&T Committee on 03/16/2005. Updated by P&T Committee on: 01/16/08, 03/18/2009.

• CytoGam (Cytomegalovirus Immune Globulin)

Indications for Approval:

1. Prevention of cytomegalovirus (CMV) disease in members undergoing transplantation of kidney, lung, liver, pancreas, or heart.
2. Prevention of CMV in recipients of a bone marrow allograft.
3. Treatment of CMV pneumonitis in combination with ganciclovir in recipients of a bone marrow allograft.

Approval: 1 year (for all above diagnoses).

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

• Delatestryl (testosterone enanthate injection)

Pharmacy Exception Criteria:

Indications for Approval: Hypogonadism (primary and secondary).

The patient must have one of the following documented by laboratory confirmation (labs results must be received with each request):

At least two low total testosterone levels (two blood draws required on separate days).

OR

At least two low free testosterone levels (two blood draws required on separate days).

OR

One low free testosterone level with an elevated LH and FSH.

OR

One low total testosterone level with an elevated LH and FSH.

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*If there is conflict in the results of the total and free testosterone then the free testosterone results will be used to evaluate the request.

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

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

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

Pharmacy Exception Criteria:

Indications for Approval: Hypogonadism (primary and secondary).

The patient must have one of the following documented by laboratory confirmation (labs results must be received with each request):

At least two low total testosterone levels (two blood draws required on separate days).

OR

At least two low free testosterone levels (two blood draws required on separate days).

OR

One low free testosterone level with an elevated LH and FSH.

OR

One low total testosterone level with an elevated LH and FSH.

*If there is conflict in the results of the total and free testosterone then the free testosterone results will be used to evaluate the request.

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

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

- **Diapers**

APPLIES TO MEDICAID PLANS ONLY

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

Indications for Approval:

1. Pharmacy Exception 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. Pharmacy Exception 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.

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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: 1 year.

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

- **Differin (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.

- **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.

OR

If a patient has a history of utilization of Diovan within the past 180 days, they may continue to receive Diovan without a PA.

Alternatives: Benazepril, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ.

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

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.

OR

If a patient has a history of utilization of Diovan HCTZ within the past 180 days, they may continue to receive Diovan HCTZ without a PA.

Alternatives: Benazepril, enalapril, lisinopril, benazepril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ. HCTZ= hydrochlorothiazide.

- **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 on 09/17/2008.

Commercial and Medicaid Pharmacy Exception Criteria Document

- **Duragesic Patch (fentanyl transdermal)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

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

AND

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.

Alternative: 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.

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 180 days.

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

Quantity limit: 30 capsules in 30 days.

- **Elidel (pimecrolimus cream)**

Step Edit Criteria:

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: Hydrocortisone, fluocinolone, triamcinolone, betamethasone, fluocinonide.

- **Emend (aprepitant)**

Pharmacy Exception 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

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- mechlorethamine
- streptozotocin
- cyclophosphamide (>1500 mg/m²)
- carmustine
- dacarbazine
- dactinomycin

- b) Anthracycline with cyclophosphamide.
- c) Failure of standard antiemetic regimens.

Please note: Emend (aprepitant) can be used in combination with a 5HT₃ antagonist such as ondansetron, granisetron, dolasetron or palonestron) and/or dexamethasone.

Approval: 6 months.

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

Alternatives: Promethazine, prochlorperazine, ondansetron.

- **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 SSRI's (citalopram, fluoxetine, sertraline, paroxetine), and
- b) One SNRI (venlafaxine), and
- c) One miscellaneous antidepressant (bupropion, mirtazapine).

Approval: 1 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

The appropriate Disease Specific Criteria below has been met.

The patient has a diagnosis of one of the following:

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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 Pharmacy Exception 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: 1 year (for all the above diagnoses).

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

- **Flomax (tamsulosin)**

APPLIES TO MEDICAID PLANS ONLY

Commercial and Medicaid Pharmacy Exception Criteria Document

Step Edit Criteria:

The patient must have a claim history of a 90-day trial of a generic alpha blocker, such as terazosin, prazosin, or doxazosin, within the past 180 days.

Alternatives: Terazosin, prazosin, doxazosin.

- **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.

Approval: 1 year.

Alternatives: Alendronate, Actonel*

*Actonel Step Therapy applies for Medicaid plans.

- **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.

- **Glucovance (glyburide/metformin)**

Step Edit Criteria:

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

Alternatives: Glyburide, metformin.

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

- **HepaGam (Hepatitis B Immune Globulin)**

Indications for Approval:

HepaGam will be used for the prevention of hepatitis B recurrence following liver transplantation.

Approval: 1 year (for all above diagnoses).

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

- **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.

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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

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 Pharmacy Exception 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:

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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: 1 year (for all above diagnoses).

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

- **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)
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

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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
 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.
- **Recurrent, spontaneous fetal loss** with previous pregnancies.

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- **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
- 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

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- 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
- Refractory rheumatoid arthritis, adult and juvenile
- Thrombotic thrombocytopenic purpura
- Uveitis

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

Approval: 1 year (for all above diagnoses).

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

- **Janumet (sitagliptin/metformin)**

Indications for Approval:

The patient has a current documented HbA1c that is between 6.5% and 8.5%.

AND

The patient has inadequate glycemic control with at least two of the following medications: Metformin at maximum doses (1500mg/day), sulfonylureas, or thiazolidinediones (TZDs) **and** requires the addition of another agent **OR** requires the addition of another agent and has contraindications to, or is unable to tolerate the alternatives.

AND

The patient is not currently on Insulin or Byetta. Januvia will not be approved for use in combination with insulin or Byetta until data on the safety and efficacy for those combinations is available.

Approval: 1 year.

Alternatives: Metformin, glyburide, glipizide, glimepiride, Actos, Avandia.

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

- **Januvia (sitagliptin)**

Indications for Approval:

The patient has a current documented HbA1c that is between 6.5% and 8.5%.

AND

The patient has inadequate glycemic control with at least two of the following medications: Metformin at maximum doses (1500mg/day), sulfonylureas, or TZDs **and** requires the addition of another agent **OR** requires the addition of another agent and has contraindications to, or is unable to tolerate the alternatives.

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AND

The patient is not currently on Insulin or Byetta. Januvia will not be approved for use in combination with insulin or Byetta until data on the safety and efficacy for those combinations is available.

Approval: 1 year.

Alternatives: Metformin, glyburide, glipizide, glimepiride, Actos, Avandia.

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

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

Indications for Approval:

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

AND

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

OR

The patient has documented failure or intolerance to Opana ER (oxymorphone HCl extended release).

Approval: 6 months.

Quantity limit of 30 capsules for 30 days.

Alternatives: Morphine sulfate extended release tablet (MS Contin) and fentanyl transdermal and Opana ER.

Step Edit Criteria:

The patient must have a claim history of morphine sulfate SR tablet (MS Contin) and fentanyl transdermal or Opana ER within the past 90 days.

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

- **Kineret (anakinra)**

Pharmacy Exception Criteria

The prescription must be prescribed by a rheumatologist for members 18 years of age or older.

AND

The patient has a diagnosis of moderate to severe active rheumatoid arthritis.

AND

The patient must have had an adequate trial (usually 6 months or more), or contraindication to 2 out of 4 of the following disease modifying anti-rheumatic drugs (DMARDs). Medical records or a typed summary documenting this must be submitted.

AND

The patient has tried and failed 3 months of therapy or is unable to tolerate therapy with one of the tumor necrosis factor (TNF) antagonists.

Approval: 1 year.

Alternatives: Methotrexate, sulfasalazine, hydroxychloroquine, leflunomide.

- **Kytril (granisetron)**

Pharmacy Exception Criteria:

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

AND

Commercial and Medicaid Pharmacy Exception Criteria Document

The patient has a documented failure or contraindication to ondansetron.

Approval: 6 months.

Quantity limit of 20 tablets per prescription.

Alternatives: Promethazine, prochlorperazine, ondansetron.

- **Lexapro (escitalopram)**

Step Edit Criteria:

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

Alternatives: Citalopram, fluoxetine, paroxetine, and sertraline.

- **Lidoderm (lidocaine patch)**

Indications for Approval:

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

OR

The patient has other types of localized neuropathic pain.

AND

The patient has a documented therapeutic trial and failure of at least 2 of the following drug categories:

- a. Tricyclic antidepressants
- b. SSRIs or formulary NSRI (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.

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

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

- **Lotemax (loteprednol etabonate)**

Pharmacy Exception Criteria:

The initial prescription is prescribed by an ophthalmologist.

Approval: 1 year

The above Criteria will not apply to patients established on loteprednol therapy. Sampling does not qualify as established therapy.

Alternatives: Dexamethasone ophthalmic, prednisolone ophthalmic, fluorometholone ophthalmic.

- **Lotrel 5mg/40mg and 10mg/40mg (benazepril/amlodipine)**

Indications for Approval:

Hypertension that is uncontrolled after an adequate therapeutic trial with either a Calcium Channel Blocker or ACE inhibitor alone.

Approval: 1 year.

Alternatives: Amlodipine, benazepril, enalapril, lisinopril, nifedipine, felodipine, and nimodipine.

Step Edit Criteria:

Commercial and Medicaid Pharmacy Exception Criteria Document

Patients with a documented pharmacy fill of a formulary Calcium Channel Blocker or ACE Inhibitor within the past 180 days can receive Lotrel without Pharmacy Exception.

- **Lotronex (alosetron)**

Pharmacy Exception Criteria:

The prescription must be prescribed by a gastroenterologist.

Approval: 3 months.

- **Lunesta (eszopiclone)**

Indications for Approval:

1. 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.

Approved by the P&T Committee on 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).

Approval: 1 year.

Quantity limit of #90 per 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 on 01/16/2008. Updated by the P&T Committee on 11/19/08.

- **Megace ES (megestrol)**

Indications for Approval:

The patient must have a documented failure, or contraindication to megestrol suspension.

AND

Commercial and Medicaid Pharmacy Exception Criteria Document

The patient has a diagnosis of cancer-related cachexia.

OR

The patient has a diagnosis of AIDS Wasting Syndrome.

Approval: 1 year.

Alternative: Megestrol immediate release tablets or suspension.

- **Meridia (sibutramine)**

(Refer to the separate Weight Loss Medication Pharmacy Exception Form, available on www.phs.org)

Indications for Approval:

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

- **Metaglip (glipizide/metformin)**

Step Edit Criteria:

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

Alternatives: Glipizide, metformin.

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

- **Nasacort AQ (triamcinolone nasal)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of generic formulary nasal steroid within the past 180 days.

Alternatives: Flunisolide nasal spray and fluticasone nasal spray.

- **Nasonex (mometasone)**

APPLIES TO MEDICAID PLANS ONLY

AGE Edit Criteria:

The patient must be between ages 2 and 4 years. Nasonex is not covered for ages above 4 years.

Alternatives: Flunisolide nasal spray and fluticasone propionate nasal spray.

- **Norditropin and Norditropin Nordiflex (Recombinant Human Growth Hormone)**

(Must obtain from a preferred specialty pharmacy and submit a completed Specialty Pharmacy Exception Form, available at www.phs.org).

Indications for Approval:

Growth hormone therapy is considered medically necessary when all of the following criteria are met:

Commercial and Medicaid Pharmacy Exception Criteria Document

1. Children (less than 21 years of age) who have a growth rate under the 25th percentile for chronological age.
AND
2. Bone age x-rays are greater than 2 years behind the chronological age.
AND
3. The patient has a growth rate < 4 cm / year.
AND
4. The patient has a documented Growth hormone deficiency (< or = to 10 ng/mL) in at least two provocative stimulation tests.
AND

The prescription must be prescribed by an endocrinologist.

Approval: 1 year.

Approved by the P&T committee on 07/2004.

- **Nutritional Supplementation**

APPLIES TO MEDICAID PLANS ONLY

(Refer to the Oral Nutritional Supplements Pharmacy Exception 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: 1 year. The amount authorized at any given time will relate to the ADA caloric intake for a 24 hour period to sustain life.

- **Nutropin, Nutropin AQ, and Nutropin AQ Pen (Recombinant Human Growth Hormone)**

(Must obtain from a preferred specialty pharmacy and submit a completed Specialty Pharmacy Exception Form, available at www.phs.org).

Indications for Approval:

Growth hormone therapy is considered medically necessary when all of the following criteria are met:

Children (less than 21 years of age) who have a growth rate under the 25th percentile for chronological age.

AND

Bone age x-rays are greater than 2 years behind the chronological age.

AND

The patient has a growth rate < 4 cm / year.

AND

The patient has a documented Growth hormone deficiency (< or = to 10 ng/mL) in at least 2 provocative stimulation tests.

Commercial and Medicaid Pharmacy Exception Criteria Document

AND

The prescription must be prescribed by an endocrinologist.

Approval: 1 year.

Approved by the P&T committee on 07/2004.

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

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.

Approved by the P&T Committee on 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. Azathioprine

AND

- 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

Commercial and Medicaid Pharmacy Exception Criteria Document

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

Approval: 1 year.

Approved by the P&T Committee on 01/21/2009. Updated by P&T Committee on 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 (SSRI's).

Alternatives: Citalopram, fluoxetine, paroxetine, and sertraline.

- **Penlac Nail Lacquer (ciclopirox solution)**

Indications for Approval:

The patient has a diagnosis of onychomycosis with secondary infection of surrounding soft tissue requiring systemic antimicrobial administration.

OR

The patient has a diagnosis of onychomycosis, which causes pain that markedly limits the patient's ability to ambulate.

OR

The patient has a diagnosis of Onychomycosis with severe peripheral vascular disease, and is at high risk from complications including secondary infection or amputation.

AND

The patient has a documented failure or contraindication to Lamisil (terbinafine) tablets.

Note: Chart notes are required with every Pharmacy Exception request.

Approval: 9 months.

Quantity limit of 1 bottle (6.6ml) per year.

Alternative: Terbinafine tablets.

Rationale: Onychomycosis is an extremely common condition. In most patients, the condition is asymptomatic and does not warrant treatment with systemic antifungal agents. Many patients can control the condition with a combination of topical antifungals and good foot care. Treatment of patients that do not have complications will be considered cosmetic. All Plans exclude cosmetic therapies from coverage.

- **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.

Commercial and Medicaid Pharmacy Exception Criteria Document

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

- **Procrit (epoetin alpha)**

Pharmacy Exception Criteria:

Indications for Approval:

- 1) Treatment of anemia of chronic renal failure.
- 2) Treatment of anemia in zidovudine-treated HIV infected patients.
- 2) Treatment of anemia in cancer patients on chemotherapy.
- 3) 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 maintained between 10g/dl to 12g/dl.

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

- b) Aplastic anemia
- c) B-12 and folate deficiency anemias
- d) Iron deficiency anemia
- e) 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.

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

- **Protonix (pantoprazole)**

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 180 days of Prilosec OTC. Prilosec OTC can be prescribed up to 80 mg/day.

Alternative: Prilosec OTC.

- **Protopic (tacrolimus ointment)**

Step Edit Criteria:

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: Hydrocortisone, fluocinolone, triamcinolone, betamethasone, fluocinonide.

- **Provigil (modafinil)**

Indications for Approval:

Commercial and Medicaid Pharmacy Exception Criteria Document

The prescription must be prescribed by a sleep specialist or neurologist for one of the following conditions:

1. A documented diagnosis of narcolepsy – when other formulary/preferred treatments (methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine salt combination), have been ineffective or not tolerated.
OR
2. A documented diagnosis of Multiple Sclerosis (MS) Fatigue – diagnosis of MS.
OR
3. A documented diagnosis of Obstructive Sleep Apnea/Hypopnea Syndrome – documentation that the patient has been on CPAP for at least 2 months and is using it for 4 or more hours per night.
OR
4. A documented diagnosis of Shift work Sleep Disorder (SWSD) - letter from employer indicating patient is working variable, alternating or 3rd shift.

Approval: 1 year.

Alternatives: Methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine.

- **Ranexa (ranolazine)**

Indication for approval:

- 1) The member has a documented diagnosis of chronic angina from a cardiologist.
AND
- 2) The member has a documented inadequate response to an appropriate trial (anginal attacks) with ALL of the following agents:
 - a) Amlodipine
 - b) Beta-blockers
 - c) NitratesAND
- 3) The member will be concurrently using one of the previously noted medications above.

Approval: 1 year.

Quantity limit of 60 tablets for 30 days.

Alternatives: Amlodipine, propranolol, metoprolol, atenolol, nitroglycerin

Approved by the P&T Committee on 09/20/2006.

- **Reclast (zoledronic acid)**

Indications for Approval:

The treatment of Paget's disease of the bone in men and women.

The treatment of postmenopausal osteoporosis.

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 bisphosphonate (alendronate or Actonel)
Example: Heartburn, indigestion, ulcer, dyspepsia, etc.
OR
- b) GI contraindication for an oral bisphosphonate.
For 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

Commercial and Medicaid Pharmacy Exception Criteria Document

- c) Non-responder (anticipated or documented) to both formulary bisphosphonates;
1. Malabsorption
 2. Significant loss of bone density as determined by bonemarker 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: 1 year.

Alternatives: Actonel*, alendronate.

*Step Therapy required for Medicaid.

- **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 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 Pharmacy Exception request.

The patient has a diagnosis of one of the following:

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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 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 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)
4. Surgery for refractory disease.

Approval: 1 year (for all above diagnoses).

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

- **Restasis (cyclosporine ophthalmic emulsion)**

Indications for Approval:

It is prescribed by an optometrist or ophthalmologist.

AND

The patient has a diagnosis of keratoconjunctivitis sicca.

OR

Commercial and Medicaid Pharmacy Exception Criteria Document

The patient has a diagnosis of Sjogren's disease.

Approval: 1 year.

Approved by the P&T committee on 03/17/2007.

- **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: 1 year.

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

Note: maximum FDA dosage is 60mg/day.

- **Rhinocort Aqua (budesonide nasal)**

APPLIES TO COMMERCIAL PLANS ONLY

Step Edit Criteria:

The patient must have a claim history of generic formulary nasal steroid within the past 180 days.

Alternatives: Flunisolide nasal spray and fluticasone nasal spray.

- **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. Rheumatoid Arthritis (RA) – must meet all of the following:
 - a. The patient is 18 years or older.

Commercial and Medicaid Pharmacy Exception Criteria Document

- 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 Pharmacy Exception 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.

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)
- 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)
- Wegener's granulomatosis

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

Approval: For NHL – 1 year.

For RA and all other diagnoses – a single round of therapy. Subsequent

Commercial and Medicaid Pharmacy Exception Criteria Document

doses based on the patient's clinical evaluation prior to the next dose.

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

Updated by P&T Committee on 01/21/2009. Revised by P&T committee on 05/20/2009.

- **Rozerem (ramelteon)**

Indications for Approval:

1. 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.

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

- **Sanctura (trospium)**

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.

- **Sensipar (cinacalcet)**

Indications for Approval:

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

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: 1 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 on 09/17/2008.

- **Singulair (montelukast)**

APPLIES TO COMMERCIAL PLANS ONLY

Indications for Approval:

1. The patient has a diagnosis of asthma and meets the following criteria:

- A documented failure of an orally inhaled corticosteroid (ICS).

Alternatives: Asmanex, Flovent, QVAR, and Pulmicort, Aerobid, Azmacort, Advair*, Symbicort*.

*Step Therapy required.

2. The patient has a diagnosis of allergic rhinitis and meets the following criteria:

A documented failure of at least one drug in all of the following groups:

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

Commercial and Medicaid Pharmacy Exception Criteria Document

- A formulary nasal anticholinergic or nasal antihistamine.

Alternatives: Flunisolide nasal, fluticasone propionate nasal, Beconase AQ, Rhinocort Aqua, Nasonex (ages 2-4 only), Nasacort AQ*, fexofenadine, ipratropium nasal, Astepro.

*Step Therapy required.

Approval: 1 year.

Step Edit Criteria:

The patient must have a claim history of a formulary inhaled corticosteroid within the past 120 days.

Approved by the P&T Committee on 11/28/2007. Updated on 09/16/2009.

- **Singulair (montelukast)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

1. The patient has a diagnosis of asthma and meets the following criteria:

- A documented failure of an orally inhaled corticosteroid (ICS).

Alternatives: Asmanex, Flovent, QVAR, and Pulmicort.

2. The patient has a diagnosis of allergic rhinitis and meets the following criteria:

A documented failure of at least one drug in all of the following groups:

- A formulary nasal corticosteroid.
- A formulary non-sedating antihistamine
- A formulary nasal anticholinergic or nasal antihistamine.

Alternatives: flunisolide nasal, fluticasone propionate nasal, Nasonex (ages 2-4 only), cetirizine OTC, fexofenadine, loratadine, ipratropium nasal, *Astepro.

*Step Therapy required.

Approval: 1 year.

Step Edit Criteria:

The patient must have a claim history of a formulary inhaled corticosteroid within the past 120 days.

Approved by the P&T Committee on 11/28/2007. Updated on 09/16/2009.

- **Soliris (eculizumab)**

Indications for Approval

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

The prescribing physician is a hematology/oncology specialist.

OR

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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.

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: I.V. 600 mg once weekly for 4 weeks, followed by 900 mg 1 week later; then maintenance: 900 mg. every 2 weeks thereafter.

Approval: If this request is approved, the approval will be for a total of 3 months, chart notes and laboratory results must document patient response for an extension of Pharmacy Exception.

- **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:

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), amphetamine/dextroamphetamine immediate release, and dextroamphetamine.

- **Suboxone sublingual tablets (buprenorphine/naloxone)**

Indications for Approval: Maintenance therapy for the treatment of opioid dependence.

Criteria for Approval:

1. The patient has the prescription benefit in their plan for the coverage of medications for treating opioid dependence.

AND

2. The prescriber has been approved to prescribe buprenorphine which is verified using the following website:

http://www.suboxone.com/patients/resources/find_a_doctor.aspx?found=no.

Exclusions:

Commercial and Medicaid Pharmacy Exception Criteria Document

- Will not be approved for use in conjunction with opiates.
- Will not be approved for the treatment of pain.

Quantity Limit: 90 tablets for 30 days.

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

Updated by P&T Committee on 05/20/2009.

- **Subutex sublingual tablets (buprenorphine)**

Indications for Approval:

1. Induction therapy for the treatment of opioid dependence up to a maximum of 7 days.
2. Maintenance therapy for the treatment of opioid dependence that meets the following criteria:
 - Documented hypersensitivity or intolerance to Suboxone. Documentation must include either a past prescription claim history of a Suboxone trial or chart notes documenting use of Suboxone. Intolerance to Suboxone cannot be due to the use of opiates while taking Suboxone.
 - Will not be approved for use in conjunction with opiates or for the treatment of pain.

Criteria for Approval:

1. The patient has the prescription benefit in their plan for the coverage of medications for treating opioid dependence.
AND
2. The prescriber has been approved to prescribe buprenorphine which is verified using the following website:
http://www.suboxone.com/patients/resources/find_a_doctor.aspx?found=no.

Approval: 3 months, then re-evaluate narcotic use

Note: Buprenorphine will not be covered for the treatment of pain.

Approval: 3 months, then re-evaluate narcotic use.

Updated by the P&T committee on November 19, 2008.

- **Symbicort (budesonide/formoterol)**

Indications for Approval:

- 1) COPD (Prescriber must provide documentation of stage III or stage IV COPD)
Patient must be on Atrovent or Spiriva and inhaled corticosteroid for 3 months of continuous use.
- 2) Moderate-to-severe persistent asthma (prescriber must provide appropriate documentation such as Spirometry results).
Patient must be on a bronchodilator in the last 90 days and inhaled corticosteroid for 3 months of continuous use.

Approval: 1 year.

Alternatives: Asmanex, Flovent, QVAR, and Pulmicort.

Step Edit Criteria:

The patient must have a claim history of a formulary inhaled corticosteroid within the past 4 months.

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

Commercial and Medicaid Pharmacy Exception Criteria Document

- **Symlin (pramlintide)**

Pharmacy Exception Criteria: Initial requests must be prescribed by endocrinologist.

Indications for Approval:

A Pharmacy Exception may be requested for refills only after therapy initiation by an endocrinology provider, due to the stringent blood glucose monitoring requirements.

Approval: 1 year.

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

- **Testim topical gel (testosterone topical gel)**

Pharmacy Exception Criteria:

Indications for Approval: Hypogonadism (primary and secondary)

The patient must have one of the following documented by laboratory confirmation (labs results must be received with each request):

At least two low total testosterone levels (two blood draws required on separate days).

OR

At least two low free testosterone levels (two blood draws required on separate days).

OR

One low free testosterone level with an elevated LH and FSH.

OR

One low total testosterone level with an elevated LH and FSH.

*If there is conflict in the results of the total and free testosterone then the free testosterone results will be used to evaluate the request.

Approval: 1 year.

Quantity limit of 60 packets in 30 days.

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

Approved by the P&T Committee on 09/19/2007. Revised on 01/21/2009.

- **Topamax Sprinkles (topiramate capsules)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

1. Seizure disorders
2. Migraine prophylaxis - the patient must have had a documented failure in two of the following drug classes for migraine suppression:
 - Calcium channel blockers
 - Beta-Blockers
 - Tricyclic antidepressants
 - Anticonvulsants

Quantity Limit: 60 capsules for 30 days.

Approval: 1 year.

Alternatives include: Propranolol, metoprolol, divalproex, nortriptyline, amitriptyline, desipramine, verapamil.

Updated by P&T committee on 05/22/2009.

Commercial and Medicaid Pharmacy Exception Criteria Document

- **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 10ml/min.

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

- **Vancocin oral solution or capsules (vancomycin oral solution or 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.

Note: Clostridium difficile overgrowth generally occurs in patients recently treated with antibiotics, which may be referred to as antibiotic-associated colitis.

Approval: 1 time, no refills.

Alternative: Metronidazole.

Rationale: This Pharmacy Exception 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 been demonstrated to be more effective.

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

Step Edit Criteria:

The patient must have a claim history of two generic antidepressant agents within the past 180 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 on 01/21/2009.

- **VESIcare (solifenacin)**

Step Edit Criteria:

Commercial and Medicaid Pharmacy Exception Criteria Document

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.

- **Vivaglobin (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 on 05/21/2008.

- **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: Ibuprofen, naproxen, meloxicam, nabumetone, diclofenac, etodolac, indomethacin, piroxicam, ketoprofen, sulindac.

Quantity limit: Three 100 gram tubes for 30 days.

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

- **Vytorin (ezetimibe/simvastatin)**

Step Edit Criteria:

The patient must have a trial and failure on at least one of the following statins within the past 180 days: lovastatin, pravastatin, or simvastatin.

Alternatives: Lovastatin, pravastatin, and simvastatin.

- **Vyvance (lisdexamfetamine)**

APPLIES TO MEDICAID PLANS ONLY

Indications for Approval:

Member must have a claim history of a 30 day trial or a documented trial and failure of one cerebral stimulant such as dextroamphetamine, amphetamine/dextroamphetamine immediate release, or amphetamine/dextroamphetamine extended release* within the past 180 days.

Alternatives: Dextroamphetamine, amphetamine/dextroamphetamine immediate release, or amphetamine/dextroamphetamine extended release*.

*amphetamine/dextroamphetamine extended release requires Step Edit Therapy on all medicaid plans.

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

Commercial and Medicaid Pharmacy Exception Criteria Document

- **Xenical (orlistat)**

(Refer to the separate Weight Loss Medication Pharmacy Exception Form, available on www.phs.org)

Indications for Approval:

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

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.

- **Xifaxan (rifaximin)**

Indications for Approval

1. Travelers' diarrhea – 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 – 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 for 3 days for any one 30-day period.

For hepatic encephalopathy – up to 180 tablets for 30 days.

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

- **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 on 11/16/2005.

Commercial and Medicaid Pharmacy Exception Criteria Document

- **Xyrem (sodium oxybate)**

Indications for Approval:

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

AND

The patient has a documented diagnosis of narcolepsy.

AND

The patient is enrolled in the Xyrem Success Program.

The Xyrem Success Program is a limited distribution program designed to ensure safe use of the drug. Under the Program, it will be available to prescribers through a single centralized pharmacy, which is Express Scripts Specialty Distribution Services (**1-866-997-3688**).

Approval: 1 year.

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

APPLIES TO MEDICAID PLANS ONLY

Step Edit Criteria:

The patient must have a claim history within the past 180 days of Prilosec OTC. Prilosec OTC can be prescribed up to 80 mg/day.

AND

The patient must have a claim history within the past 180 days of pantoprazole.

Alternatives: Prilosec OTC and pantoprazole.

- **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

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: 1 year.

Alternatives: Alendronate, Actonel.

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

Commercial and Medicaid Pharmacy Exception Criteria Document

Indications for Approval:

The patient is 60 years of age or older.

AND

The patient does not have a contraindication to Zostavax.

Approval: One time.

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

- **Zyprexa Zydys (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: 1 year.

Quantity limit of 30 tablets for 30 days.

Alternative: Zyprexa (olanzapine) tablet.

- **Zyvox (linezolid)**

Indications for Approval:

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

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.