

June 10, 2008

Dear Healthcare Practitioner:

Presbyterian Health Plan and Presbyterian Insurance Company's Pharmacy and Therapeutics Committee (P&T Committee) met on May 21, 2008 to promote appropriate use of drugs in maintaining the formularies. We are dedicated to supporting our network of practitioners and would like to share with you the decisions made at that meeting that affect our formularies and pharmacy benefits. Please note that online versions of all Presbyterian formularies are available on our website at www.phs.org/pharmacy/index.htm, as well as on www.nm-formulary.com. All formularies are downloadable onto your handheld Palm device through the **Epocrates Rx** software.

P&T COMMITTEE DECISIONS

ADDITIONS/CHANGES TO PRESBYTERIAN FORMULARIES/PDLs

Crestor (rosuvastatin): Crestor was added to all PHP formularies. Step therapy will be required for the Salud/SCI/NMRX and Senior care formularies. The step therapy requirement is a trial of a generic statin within the past 6 months before going to Crestor. Crestor will be 2nd tier for the Senior Care formulary. Commercial formularies will have Crestor at 2nd tier.

Anagrelide (Agrylin): Generic now available.

Zaleplon (Sonata): Generic now available.

Reclast (Zoledronic acid): Reclast will be the preferred IV bisphosphonate when criteria of coverage has been met.

Immune Globulin: Immune globulin will now require a prior authorization for use. Approved criteria for coverage are listed below. Ongoing input from both national organizations and local experts will be received and adjustments will be made as needed.

Formulary Criteria

Approved Criteria for Medical Exception for Immune Globulin

CMV-IGIV (CytoGam) may be considered medically necessary for the following U.S. Food and Drug Administration (FDA) labeled indications:

- Prevention of CMV disease in members undergoing transplantation of kidney, lung, liver, pancreas, or heart
- Prevention of CMV in recipients of a bone marrow allograft
- Treatment of CMV pneumonitis in combination with ganciclovir in recipients of a bone marrow allograft

SCIG (Vivaglobin) is approvable for members with primary immune deficiency who have experienced infusion reactions with IGIV or problems with IV access.

HBIG (HepaGam B) is approvable for prevention of hepatitis B recurrence following liver transplantation.

[PPC060801]

Intravenous Immune Globulin (IVIG) may be considered medically necessary for the following U.S. Food and Drug Administration (FDA) labeled indications:

- **AIDS:** Children with acquired immune deficiency syndrome (AIDS);
- **Bone marrow and organ transplant** recipients (except corneal), 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**
- **Primary immunodeficiencies** including, but not limited to:
 1. Congenital agammaglobulinemia (X-linked agammaglobulinemia),
 2. Hypogammaglobulinemia,
 3. Common variable immunodeficiency,
 4. X-linked immunodeficiency,
 5. Severe combined immunodeficiency,
 6. Wiskott-Aldrich syndrome
- **Thrombocytopenia purpura**

Intravenous Immune Globulin may be considered medically necessary when standard intervention, treatment, and/or therapy has failed, become intolerable, and/or are contraindicated **for any of the following off-label indications:**

- **Acute inflammatory demyelinating polyneuropathy,** including Guillain-Barré syndrome, in patients who have one or more of the following:
 1. rapid deterioration with acute symptoms for less than two weeks, and/or
 2. rapidly deteriorating ability to ambulate, and/or
 3. unable to ambulate independently for ten meters, and/or
 4. deteriorating pulmonary function tests,
 5. **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, which 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
 4. **NOTE:** Does not include use of IVIG for maintenance. Refer to the listing of conditions that are considered experimental, investigational, and unproven
- **Neonatal alloimmune thrombocytopenia**, severe when other interventions have failed or are contraindicated. (CAUTION - this is not the same as non-immune thrombocytopenia. Refer to the listing of conditions that are considered experimental, investigational, and unproven)
- **Post transfusion purpura** (severe)

- **Pure red cell aplasia** with documented parvovirus B19 infection and with severe, refractory anemia
- **Solid organ transplant**, prior to transplant for treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ
- **Solid-organ transplant**, following transplant for treatment of antibody-mediated rejection
- **Stiff person syndrome** (Moersch-Woltman syndrome) when:
 1. anti-GAD antibody is present, and
 2. other therapy has failed (i.e., benzodiazepines and/or baclofen, phenytoin, clonidine, tizanidine)
- **Systemic lupus erythematosus (SLE)** in patients with severe active illness for whom other interventions have been unsuccessful or intolerable
- **Toxic shock syndrome** or toxic necrotizing fasciitis due to streptococcal or staphylococcal organisms, when:
 1. infection is refractory to several hours of aggressive therapy, and/or
 2. an undrainable focus is present, and/or
 3. the patient has persistent oliguria with pulmonary edema
- **Vasculitis syndromes** 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	Factor VIII inhibitors, acquired
Acquired von Willebrand's syndrome	Hemolytic transfusion reaction (except post-transfusion purpura)
Acute lymphoblastic leukemia	Hemolytic uremic syndrome
Acute renal failure	Hemophagocytic syndrome
Adrenoleukodystrophy	Inclusion-body myositis
Amyotrophic lateral sclerosis (ALS)	Membranous nephropathy
Antiphospholipid Ab syndrome	Motor neuron syndromes
Aplastic anemia	Multiple myeloma (except multiple myeloma with stable plateau phase disease who are at high risk of recurrent infections—see Off-Label indications above)
Asthma and inflammatory chest disease	Myelopathy, HTLV-1 associated
Behcet's syndrome	Neonatal hemolytic disease

Burns	Nephrotic syndrome
Chronic (primary or secondary) progressive multiple sclerosis	Nonimmune thrombocytopenia
Chronic fatigue syndrome	Paraproteinemic neuropathy
Congenital heart block	Post-infectious sequelae
Cystic Fibrosis	Progressive lumbosacral plexopathy
Demyelinating optic neuritis	Recent-onset dilated cardiomyopathy
Diabetes mellitus	Recurrent otitis media
Diamond-Blackfan anemia	Recurrent, spontaneous fetal loss
Endotoxemia	Refractory rheumatoid arthritis
Epilepsy	Thrombotic thrombocytopenic purpura
Euthyroid ophthalmopathy	Uveitis

EXCEPTIONS:

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

**SUMMARY OF P&T COMMITTEE DECISIONS
ADDITIONS/CHANGES TO PRESBYTERIAN FORMULARIES/PDLs**

Drug Name	Commercial 2-Tier	Commercial 4-Tier	Salud, SCI, NMRx	Medicare, Senior
Immune Globulin IV/SC	PA	PA	PA	PA
Crestor (rosuvastatin)	Formulary	2 nd Tier	Formulary Step Edit (Generic First)	2nd Tier Step Edit (Generic First)
Anagrelide (Agrylin) 0.5mg and 1.0mg	Tier 1	Tier 1	Formulary	Tier 1
Zaleplon (Sonata) 5mg, 10mg	Tier 1	Tier 1	Formulary	Tier 1
Reclast IV(zoledronic acid) 5mg/100ml	PA (Preferred)	PA (Preferred)	PA (Preferred)	PA (Preferred)

Safety

For complete information please go to the following website:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#chronological>

Enbrel: Wyeth has added a Boxed warning to strengthen and clarify information regarding the risk of infections, including tuberculosis (TB) in patients taking Enbrel: namely the new recommendation to screen for latent tuberculosis infection before beginning Enbrel.

Neupro: Schwarz Pharma has recalled Neupro transdermal patches. The recall is due to the formation of rotigotine crystals in the patches. When the drug crystallizes, less drug is available to be absorbed through the skin. Therefore, the efficacy of the affected product may vary.

Digitek: All lots of Digitek have been recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than appropriate.

The changes to the formularies, as outlined above, are based on requests from our practitioners and the recommendations of the P&T Committee. We value your input. If you have any concerns, please contact Larry Georgopoulos, R.Ph, by e-mail at lgeorgop@phs.org or by phone at (505) 923-5530. He can be reached Monday through Friday from 8:00 a.m. to 5:00 p.m. As always, thank you for partnering with us to improve the health of individuals, families and communities

In addition to the formulary changes, we would like to remind you that our phone numbers have changed. The new numbers are (505) 923-5757 (in the Albuquerque area) or 1-888-923-5757 (outside the Albuquerque area). Pharmacy Department hours are Monday through Friday from 8:00 a.m. to 5:00 p.m. Pres Online is also available for you to verify eligibility and submit prior authorizations. Please visit the Provider page of www.phs.org for more information.

Thank you for partnering with us to improve the health of individuals, families, and communities.

Sincerely,



Larry Georgopoulos, BSP Pharm. R.Ph.
Pharmacy Director
Presbyterian Health Plan
(505) 923-5530
lgeorgop@phs.org

