Pulmonary Hypertension Drugs

I. Description

Pulmonary hypertension (PH) is characterized by sustained elevations of pulmonary artery pressure (PAP). PH is defined as a mean PAP greater than 25 mmHg at rest. A mean PAP of 8 to 20 mmHg at rest is considered normal, while a mean PAP of 21 to 24 mmHg at rest has uncertain clinical implications.

Drug therapy of PH includes vasodilators (particularly calcium channel blockers and sildenafil), anticoagulants to reduce in situ thrombosis, inotropic and diuretic agents, and oxygen therapy. Lung transplantation and combined heart-lung transplantation have been performed in patients refractory to medical management.

II. Criteria/Guidelines

A. Drugs that are FDA-approved for the treatment of PH are covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of primary or secondary PH when the following criteria are met:
   1. Therapy is recommended by a pulmonologist or cardiologist
   2. Right heart catheterization demonstrates a mean PAP of more than 25 mm Hg at rest.
   3. Baseline assessment of all of the following is done:
      a. New York Heart Association Class
      b. Echocardiogram

B. Continuation of therapy is covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of primary or secondary PH when the following criteria are met:
   1. There is documentation of the patient's clinical response to therapy including the following:
      a. New York Heart Association Class and
      b. Echocardiogram
   2. Patient is followed by a pulmonologist or cardiologist
III. Limitations/Exclusions

A. PH drugs are not covered for patients with COPD and pulmonary arterial hypertension with a FEV1<30.

B. More than one drug may be appropriate for the treatment of PH. HMSA reserves the right to approve the least costly treatment.

C. Only generic drugs are covered when both brand and generic drugs are available.

D. Sildenafil (Revatio) will be covered at the manufacturer’s recommended dose of 20 mg orally three times a day. A higher dosage of sildenafil is not known to improve health outcomes and will not be covered.

E. Tadalafil (Cialis) and vardenafil (Levitra) are not covered for the treatment of PH.

IV. Administrative Guidelines

A. Precertification is required for the following drugs for the treatment of PH, including, but not limited to:
   1. Injectable/Infused Drugs
      a. Epoprostenol sodium (i.e., Flolan)
      b. Treprostinil (i.e., Remodulin)
   2. Oral/Inhaled Drugs
      a. For private lines of business (PPO/HMO) and QUEST, see the CVS Caremark Drug Policy for precertification requirements.

B. Precertification is required for the initial three months of treatment. The following documentation from the medical record must be submitted:
   1. Current clinical notes
   2. Prescription drug history
   3. Right heart cardiac catheterization results
   4. Echocardiogram
   5. New York Heart Association Class

New York Heart Association Classification:

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
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<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary fatigue, palpitation, or dyspnea (shortness of breath)</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</td>
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<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</td>
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<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken,</td>
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discomfort is increased.

C. To precertify, please complete HMSA's Drug Review Request and mail or fax the form as indicated.

D. Precertification is required for continuation of therapy for each additional 12 months. The following documentation must be submitted:

1. Evidence that patient is followed by a pulmonologist or cardiologist.
2. Recent clinical notes including New York Heart Association Class documenting response to treatment and echocardiogram

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1325</td>
<td>Injection, epoprostenol, 0.5 mg</td>
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<tr>
<td>J3285</td>
<td>Injection, treprostinil, 1 mg</td>
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V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References


38. The Canadian Agency for Drugs and Technologies in Health (CADTH). Health Technology Assessment Rapid Review: drugs for pulmonary hypertension: a systematic review of the clinical effectiveness of combination therapy. April 2009. Available online at: http://www.cadth.ca/media/pdf/M0004_Drugs_for_Pulmonary_Arterial_Hypertension_tr_e.pdf


40. Ventavis, package insert.


43. www.fda.gov/cder/foi/label/2008/022081s002lbl.pdf