

**Adcirca<sup>®</sup> and Revatio<sup>®</sup>**  
**To Initiate a Coverage Review, Call 1 800 753-2851**

**Covered Medication**

- Sildenafil (*Revatio*<sup>®</sup>)
- Tadalafil (*Adcirca*<sup>®</sup>)

**What It Does and How It's Used**

- Pulmonary arterial hypertension (PAH) is a condition characterized by unusually high pressure in the vessels carrying blood between the heart and the lungs.
- Patients initially experience respiratory symptoms such as shortness of breath (dyspnea). They may also experience tiredness (fatigue), and fainting (syncope). As the disease progresses, symptoms become more acute and patients may develop bluish lips and skin (cyanosis), swelling of the legs and ankles (edema), and chest pain (angina). The disease is progressive and eventually leads to right-sided heart failure and death.
- Approximately 100,000 individuals are affected by this rare but severe lung disease. According to a 4-year study (1981-1985) done by the National Institutes of Health (NIH), the median survival of patients with idiopathic PAH was 2.8 years. Actual survival rates differ between patients and range from months to years after diagnosis.
- Treatment options focus on relieving respiratory symptoms and increasing exercise ability. These include drugs to lessen the constriction of pulmonary vessels such as calcium channel blockers and nitrates. Adjunctive treatments consist of anticoagulants (i.e., blood thinners), inotropic agents (i.e., digoxin), diuretics (i.e., water pills), and oxygen.
- Several agents have been developed in recent years to specifically target the mechanisms involved in PAH. High pressures within the lungs from pulmonary vascular resistance are in part due to the effects of phosphodiesterase, an enzyme whose actions result in constriction of the pulmonary vessels. *Revatio*<sup>®</sup> and *Adcirca*<sup>®</sup> work by inhibiting a specific phosphodiesterase enzyme found in the smooth muscle of the pulmonary vasculature, thus resulting in a relaxation of pulmonary smooth muscles and ultimately, a decrease in resistance. *Revatio*<sup>®</sup> is dosed three times per day and *Adcirca*<sup>®</sup> is dosed once daily.
- Prostacyclin is a naturally occurring prostaglandin that has been found to have vasodilatory effects as well as anti-platelet effects and is known to be produced by the vascular epithelium. *Flolan*<sup>®</sup>, *Remodulin*<sup>®</sup>, and *Ventavis*<sup>®</sup>, are analogs of prostacyclin, and decrease pulmonary vascular resistance by taking advantage of the vasodilatory effects of this prostaglandin. *Flolan*<sup>®</sup> is given as an intravenous continuous infusion, *Remodulin*<sup>®</sup> is given as a subcutaneous or intravenous infusion, and *Ventavis*<sup>®</sup> is inhaled up to nine times per day.
- Endothelin, a potent blood vessel constrictor, is present in higher amounts in the blood and lungs of patients with pulmonary hypertension. *Tracleer*<sup>®</sup> and *Letairis*<sup>™</sup> work by blocking endothelin's ability to bind to receptors on lung blood vessels thus preventing constriction of these vessels. *Letairis*<sup>™</sup> is dosed once daily and *Tracleer*<sup>®</sup> is taken twice per day.

**Benefit Design**

- Coverage is determined through prior authorization for every claim.

**Rationale for Coverage Authorization**

To provide coverage for tadalafil (*Adcirca*<sup>®</sup>) or sildenafil (*Revatio*<sup>®</sup>) for the treatment of PAH in situations where treatment is likely to provide benefit. *Adcirca*<sup>®</sup> and *Revatio*<sup>®</sup> are not covered for the treatment of erectile dysfunction. *Revatio*<sup>®</sup> contains the same active ingredient found in *Viagra*<sup>®</sup>, while *Adcirca*<sup>®</sup> contains the same active ingredient found in *Cialis*<sup>®</sup>.

**Coverage Authorization Criteria**

- Coverage for *Revatio*<sup>®</sup> is provided in accord with the following:
- Coverage is provided for the treatment of pulmonary arterial hypertension (PAH) and for no other diagnosis.
  - The patient must be under the care or referral of a pulmonologist or cardiologist.
  - Coverage is provided for combination use of two or more drugs with different pharmacology in patients who have not adequately responded to monotherapy.
  - Coverage is not provided in situations where patients are receiving nitrate therapy.
- Coverage duration: 12 months. Coverage may be renewed.

**References**

- *Adcirca*<sup>®</sup> (tadalafil). Prescribing information. Eli Lilly and Company. Indianapolis, IN: May 2009
- Badesch DB, Abman SH, Ahearn GS, et al. Medical therapy for pulmonary arterial hypertension: Updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131; 1917-1928.
- *Flolan*<sup>®</sup> (epoprostenol). Prescribing information. GlaxoSmithKline. Research Triangle Park, NC: September 2002.
- Gaine SP, Rubin LJ. Primary pulmonary hypertension. *Lancet*. 1998; 352:719-725.
- *Letairis*<sup>™</sup> (ambrisentan). Prescribing information. Gilead Sciences, Inc. Foster City, CA: June 2007.
- McLaughlin VV, Presberg KW, Doyle RL, Abman SH, McCrory DC, Fortin T, Ahearn G. Prognosis of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. *Chest*. 2004 Jul;126:78S-92S.
- *Remodulin*<sup>®</sup> (treprostinil). Prescribing information. United Therapeutics Corp. Research Triangle Park, NC: March 2006.

- Revatio® (sildenafil). Prescribing information. Pfizer. New York: July 2006.
- Tracleer® (bosentan). Prescribing information. Actelion Pharmaceuticals. South San Francisco, CA: February 2007.
- Ventavis® (iloprost). Prescribing information. CoTherix, Inc. South San Francisco, CA: January 2006.