

Healthcare Operations

Utilization Management Protocol

Medications for the Treatment of Pulmonary Hypertension

Number
CAR031

HEALTH PLAN OF NEVADA, INC. SM SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC. [®]

For Sierra Health-Care Options products, please review plan documents prior to issuing a determination.

Description	After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.
Medications for the Treatment of Pulmonary Hypertension (Flolan® (epoprostenol sodium, prostacyclin), Remoudulin® (Treprostinil), Tracleer™ (bosentan), Ventavis® (iloprost) Viagra® (sildenafil)).	

Coverage	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.
Commercial, Medicare & Medicaid Coverage Rationale:	
<p>NOTE: These clinical coverage criteria do not apply if the drug is Medicare covered and has Medicare coverage criteria.</p> <p>Viagra® (sildenafil), Flolan® (epoprostenol sodium, prostacyclin), Remoudulin® (Treprostinil), Tracleer™ (bosentan), and Ventavis® (iloprost) is considered medically necessary for members when the following criteria are met:</p> <ol style="list-style-type: none"> 1. The member must have a definitive diagnosis of pulmonary artery hypertension from a recognized pulmonary hypertension specialist. 2. Pulmonary Hypertension Indications for Treatment are: <ol style="list-style-type: none"> a. Idiopathic (familial); b. Collagen vascular disease; c. Congenital systemic-to-pulmonary shunts; d. Portal hypertension; e. HIV infection; f. Drugs and toxins; g. Pulmonary hypertension in a patient with chronic lung diseases such as chronic obstructive pulmonary disease (COPD), restrictive pulmonary disease or interstitial pulmonary disease which has been optimally treated with measures designed to correct the underlying lung disease; h. Pulmonary hypertension in a patient with obstructive sleep apnea or other sleep disorders involving breathing or alveolar hyperventilation disorders which has not been fully treated with surgical or other measures. 3. The diagnosis must be confirmed by: <ol style="list-style-type: none"> a. Right heart catheterization. The right heart catheterization must include: 	

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- i. Cardiac output
 - ii. Cardiac index
 - iii. Peripheral vascular resistance calculation
 - iv. Saturation run to rule out shunts; and
 - b. Six (6) Minute Walk Test
 - i. Must be performed by Southwest Medical Associates Cardiology for patients in Southern Nevada; and
 - c. Baseline echocardiogram
 - i. To be used for comparison with subsequent interval echocardiograms;
 - ii. To be used to access correlation to actual PA catheter readings for future assessments; and
4. The pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition; and
5. When initiating an initial or add-on new therapy, the member's symptoms are New York Heart Associate (NYHA) class III to IV (see below).

Class I	No limitation	Ordinary physical activity does not cause symptoms
Class II	Slight limitation	Comfortable at rest Ordinary activity causes symptoms
Class III	Marked limitation	Comfortable at rest Less than ordinary activity causes symptoms
Class IV	Inability to carry on any physical activity	Symptoms present at rest

Viagra® (sildenafil), Flolan® (epoprostenol sodium, prostacyclin), Remoudulin® (Treprostinil), Tracleer™ (bosentan), and Ventavis® (iloprost) is considered **not medically necessary** for members for the following criteria:

Non-Covered Indications:

1. Diseases of the left atrium and ventricle such as congestive heart failure (CHF) or cardiomyopathy;
2. Diseases of the mitral and aortic valves;
3. Chronic lung diseases such as chronic obstructive pulmonary disease (COPD), restrictive pulmonary disease or interstitial pulmonary disease which has not been optimally treated with measures designed to correct the underlying lung disease;
4. Obstructive sleep apnea or other sleep disorders involving breathing or alveolar hyperventilation disorders which have not been fully treated with surgical or other measures.

Medications:

The first line agent will usually be **Viagra®** (sildenafil). If the PA systolic is >100 or the patient has

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moderate to severe right heart failure, treatment can be initiated with **Flolan**[®] (epoprostenol sodium, prostacyclin). Subsequent add-on therapy can be initiated, if necessary, with **Tracleer**[™] (bosentan), **Flolan**[®] (epoprostenol sodium, prostacyclin), **Remoudulin**[®] (Treprostinil) or **Ventavis**[®] (iloprost).

Reassessment is Required:

The initial pulmonary hypertension therapy and any add-on therapy with another agent will be approved only for a period of 3 months. For subsequent approval, a new echocardiogram and a new 6 minute walk test must be submitted. Continuation of therapy past the initial 3 months will only be approved if a 15% improvement is demonstrated in the 6 minute walk test, echocardiogram C.I., or echocardiogram PA pressures.

After the first 3 month reassessment, the therapy can be approved for a period of one year. For subsequent approvals, 6 minute walk tests and echocardiograms must be submitted showing performance at least equal to any previously submitted 6 minute walk test or echocardiogram.

References and Resources

Tufts Health Plan Clinical Coverage Criteria. Medications for the Treatment of Pulmonary Hypertension. Last updated 11/8/05. Retrieved May 1, 2006, from http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/medsforpulmonaryhypertension.pdf

History/Update Approval

04/24/2009	Corporate Medical Affairs Committee
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