

Tadalafil for the Treatment of Pulmonary Hypertension

DESCRIPTION

Tadalafil is a selective inhibitor of phosphodiesterase type-5 (PDE5), the enzyme responsible for the degradation of cGMP (cyclic guanosine monophosphate). Inhibition of PDE5 leads to high levels of cGMP within pulmonary vascular smooth muscle cells resulting in relaxation/vasodilation.

An example of a preparation of tadalafil is Adcirca™.

REFER TO DECISION SUPPORT TREE

POLICY

- Tadalafil for the treatment of pulmonary arterial hypertension (i.e., pulmonary hypertension classification WHO Group I) is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Tadalafil for the treatment of other classifications of pulmonary hypertension including, but not limited to, the following is considered **investigational**:
 - Pulmonary hypertension with left heart disease (WHO Group II)
 - Pulmonary hypertension associated with lung diseases and/or hypoxemia (WHO Group III)
 - Pulmonary hypertension due to chronic thrombotic and/or embolic disease (WHO Group IV)
 - Pulmonary hypertension miscellaneous (e.g., sarcoidosis, histiocytosis X, lymphangiomatosis, compression of pulmonary vessels) (WHO Group V)

See also:

- [Ambrisentan for the Treatment of Pulmonary Hypertension](#)
- [Bosentan for the Treatment of Pulmonary Hypertension](#)
- [Epoprostenol Sodium for the Treatment of Pulmonary Hypertension](#)
- [Iloprost for the Treatment of Pulmonary Hypertension](#)
- [Treprostinil Sodium for the Treatment of Pulmonary Hypertension](#)
- [Sildenafil Citrate for the Treatment of Pulmonary Hypertension](#)

MEDICAL APPROPRIATENESS

- Tadalafil for the treatment of pulmonary arterial hypertension (i.e., pulmonary hypertension classification WHO Group I) is considered **medically appropriate** in individuals who are not using any form of organic nitrates. **(Note:** Tadalafil was shown to potentiate the hypotensive effects of nitrates).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.



ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

There is insufficient evidence supporting the use of tadalafil for the treatment of other classifications of pulmonary hypertension.

SOURCES

BlueCross BlueShield Association. Medical Policy Reference Manual. (4:2009). *Treatment of pulmonary arterial hypertension with prostacyclin analogues, endothelin receptor antagonists, or phosphodiesterase inhibitors* (5.01.09). Retrieved June 16, 2009 from BlueWeb.

MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009). *Tadalafil*. Retrieved June 16, 2009 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2009, May). Center for Drug Evaluation and Research. Label and Approval History. *Adcirca*. Retrieved June 16, 2009 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022332lbl.pdf.

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EFFECTIVE DATE 12/12/2009

ID_BT



**BlueCross BlueShield
of Tennessee**

Pharmaceutical Decision Support Tree

Tadalafil (Adcirca™) for the Treatment of Pulmonary Hypertension

1. Is tadalafil being used to treat pulmonary hypertension with left heart disease (WHO Group II), pulmonary hypertension associated with lung diseases and/or hypoxemia (WHO Group III), pulmonary hypertension due to chronic thrombotic and/or embolic disease (WHO Group IV), or pulmonary hypertension miscellaneous (e.g., sarcoidosis, histiocytosis X, lymphangiomatosis, compression of pulmonary vessels) (WHO Group V)?

If yes, this does not meet medical necessity and/or medical appropriateness criteria
If no, go to question #2

2. Is tadalafil being used to treat pulmonary arterial hypertension (i.e., pulmonary hypertension classification WHO Group I) in individuals who are not using any form of organic nitrates. (**Note:** Tadalafil was shown to potentiate the hypotensive effects of nitrates).

If yes, this satisfies medical necessity and medical appropriateness criteria
If no, this does not meet medical necessity and/or medical appropriateness criteria