

Policies Repository



Policy Title Isosorbide Dinitrate and Hydralazine Hydrochloride (BiDil®)

Policy Number FS.CLIN.32

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Isosorbide dinitrate and hydralazine hydrochloride (BiDil®)** is indicated for the treatment of heart failure as an adjunct to standard therapy to improve survival, prolong time-to-hospitalization for heart failure, and improve individually-reported functional status for self-identified, African American individuals.

The use of isosorbide dinitrate and hydralazine hydrochloride (BiDil®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Isosorbide dinitrate and hydralazine hydrochloride (BiDil®)** is a combination product containing isosorbide dinitrate and hydralazine hydrochloride. Isosorbide dinitrate is a nitric oxide donor and vasodilator effects both arteries and veins. Its dilator properties result from the release of nitric oxide and the subsequent activation of guanyl cyclase, and causes the ultimate relaxation of the vascular smooth muscle. Hydralazine is an antioxidant and predominantly an arterial vasodilator. As a monotherapy, isosorbide dinitrate is FDA-approved for the prevention of angina pectoris caused by coronary artery disease; and hydralazine is FDA-approved for the treatment of hypertension. Both isosorbide dinitrate and hydralazine are available in generic formulations.

Policy Guideline Inclusion **Isosorbide dinitrate and hydralazine hydrochloride (BiDil®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of heart failure
- Documentation of trial and failure or contraindication or intolerance to concurrent therapy with an isosorbide dinitrate product and a hydralazine product

Policy Guideline Exclusion

Isosorbide dinitrate and hydralazine hydrochloride (BiDil®) is denied when **any** of the following exclusion criteria are present:

- No documentation of heart failure
- No documentation of trial and failure or contraindication or intolerance to concurrent therapy with an isosorbide dinitrate product and a hydralazine product

Policy List of Applicable Drugs

Brand Name	Generic Name
BiDil	isosorbide dinitrate and hydralazine hydrochloride

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

BiDil® (isosorbide dinitrate/hydralazine hydrochloride). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed July 28, 2009.

BiDil® (isosorbide dinitrate/hydralazine hydrochloride). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed July 28, 2009.

Cohn JN, Johnson G, Ziesche S, et al. A comparison of enalapril with hydralazine-isosorbide dinitrate in the treatment of chronic congestive heart failure (V-HeFT II). *N Engl J Med.* 1991;325(5):303-310.

Cohn JN, Archibald DG, Ziesche S, et al. Effect of vasodilator therapy on mortality in chronic congestive heart failure. Results of a Veterans Administration Cooperative Study (V-HeFT). *N Engl J Med.* 1986;31(24):1547-1552.

Taylor AL, Ziesche S, Yancy C, et al. Combination of isosorbide dinitrate and hydralazine in blacks with heart failure (A-HeFT). *N Engl J Med.* 2004;351(20):2049-2057.

Policy Link to Related Policies**Printed**

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