**Policy Title**  Isosorbide Dinitrate and Hydralazine Hydrochloride (BiDil®)

**Policy Number**  FS.CLIN.32

**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

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>BiDil</td>
<td>isosorbide dinitrate and hydralazine hydrochloride</td>
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Dosing and Administration

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

Policy References


Policy Link to Related Policies

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