Executive Summary

**Purpose:** Ensure appropriate utilization and control of BiDil® (isosorbide dinitrate and hydralazine hydrochloride)

**Why Issue Selected:** BiDil® (isosorbide dinitrate and hydralazine hydrochloride) is a combination of isosorbide dinitrate, a nitrate vasodilator, and hydralazine hydrochloride, an arteriolar vasodilator, initially FDA approved in 2005. It is still only available in a brand name formulation. BiDil is indicated for the treatment of heart failure as an adjunct therapy to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status. There are 6.5 million people living with heart failure in the United States, with about 670,000 people diagnosed each year. By 2030, the prevalence is expected to exceed 8 million. BiDil contains 20 mg of isosorbide dinitrate and 37.5 mg hydralazine hydrochloride; generic forms of each are individually available in oral tablets at significant lower costs of therapy.

<table>
<thead>
<tr>
<th>Program-Specific Information:</th>
<th>Date Range FFS 10-01-2020 to 9-30-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>Claims</td>
</tr>
<tr>
<td>BIDIL 20-37.5 MG TABLET</td>
<td>35</td>
</tr>
<tr>
<td>Drug</td>
<td>Cost per tablet</td>
</tr>
<tr>
<td>BIDIL 20-37.5 MG TABLET</td>
<td>$3.70 MAC</td>
</tr>
<tr>
<td>ISOSORBIDE DINITRATE 20 MG TABLET</td>
<td>$0.34 MAC</td>
</tr>
<tr>
<td>HYDRALAZINE HCL 25 MG TABLET</td>
<td>$0.03 MAC</td>
</tr>
</tbody>
</table>

**Type of Criteria:**
- ☛ Increased risk of ADE
- ☑ Appropriate Indications
- ☑ Clinical Edit

**Data Sources:**
- ☛ Only Administrative Databases
- ☐ Databases + Prescriber-Supplied

**Setting & Population**

- Drug class for review: BiDil® (isosorbide dinitrate and hydralazine hydrochloride)
- Age range: All appropriate MO HealthNet participants aged 18 years and older
Approval Criteria

- Participant is aged ≥ 18 years **AND**
- Documented diagnosis of heart failure **AND**
- Documented compliance to previous BiDil therapy (defined as 90 days in the past 120 days) **OR**
- Documented trial of generic isosorbide dinitrate tablets and hydralazine tablets (defined as 60 days in the past 90 days)

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th></th>
<th>Progress Notes:</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedWatch Form:</td>
<td></td>
<td>Other:</td>
<td></td>
</tr>
</tbody>
</table>

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

References

- BIDIL® (isosorbide dinitrate and hydralazine hydrochloride) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; March 2019.