

# SmartPA Criteria Proposal

|                                   |  |
|-----------------------------------|--|
| <b>Drug/Drug Class:</b>           | BiDil Clinical Edit  |
| <b>First Implementation Date:</b> | August 24, 2006  |
| <b>Proposed Date:</b>             | December 16, 2021  |
| <b>Prepared for:</b>              | MO HealthNet   |
| <b>Prepared by:</b>               | MO HealthNet/Conduent  |
| <b>Criteria Status:</b>           | <input type="checkbox"/> Existing Criteria<br><input checked="" type="checkbox"/> Revision of Existing Criteria<br><input type="checkbox"/> New Criteria |

## 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.

### Program-Specific Information:

| Date Range FFS 10-01-2020 to 9-30-2021 |                 |             |                       |
|--|-----------------|-------------|-----------------------|
| Drug                                   | Claims          | Spend       | Avg Spend per Claim   |
| BIDIL 20-37.5 MG TABLET                | 35              | \$12,476.60 | \$356.47              |
| Drug                                   | Cost per tablet |             | Cost per month        |
| BIDIL 20-37.5 MG TABLET                | \$3.70 MAC      |             | \$666.00 for 180 tabs |
| ISOSORBIDE DINITRATE 20 MG TABLET      | \$0.34 MAC      |             | \$61.20 for 180 tabs  |
| HYDRALAZINE HCL 25 MG TABLET           | \$0.03 MAC      |             | \$8.10 for 270 tabs   |

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 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  $\geq 18$  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

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

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

## Default Approval Period

3 months

## References

- BIDIL<sup>®</sup> (isosorbide dinitrate and hydralazine hydrochloride) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; March 2019.
- Facts & Comparisons. Isosorbide Dinitrate/Hydralazine Hydrochloride Oral. Accessed November 8, 2021.
- IPD Analytics. Cardiovascular: Heart Failure. Accessed November 8, 2021.