



SmartPA Criteria Proposal

Drug/Drug Class:	BiDil® Clinical Edit
First Implementation Date:	August 24, 2006
Revised Date:	February 13, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

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

Why was this 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 5.7 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 20mg of isosorbide dinitrate and 37.5mg hydralazine hydrochloride; generic forms of each are individually available in oral tablets at significant lower costs of therapy.

Program-specific information:	Date Range FFS 1-1-2019 to 6-30-2019		
	Drug	Claims	Spend
	BiDil® 20-37.5 mg tab	7	\$2,302.13
	Drug	Cost per unit	Cost per month
	BiDil® 20-37.5 mg tab	\$3.39 per tab WAC	\$610.20 for 180 tabs WAC
	Isosorbide dinitrate 20mg tab	\$0.63 per tab WAC	\$113.40 for 180 tabs WAC
	Hydralazine HCl 25mg tab	\$0.08 per 1&½ tab MAC	\$14.40 for 270 tabs MAC

- 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

- **Aged 18 years or older AND**
- Documented diagnosis of heart failure in the past 2 years **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 no approval criteria are met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception code "682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- BIDIL® (isosorbide dinitrate and hydralazine hydrochloride) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; 2019 March.
- Facts & Comparisons. Isosorbide Dinitrate/Hydralazine Hydrochloride Oral. <https://fco.factsandcomparisons.com/lco/action/search?q=bidil&t=name&va=#max-dose-nested>. Accessed August 5, 2019.
- IPD Analytics. Cardiovascular: Heart Failure. <https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Page/28b33265-7af1-48d7-9f97-80398955a62f#section-group-17218>. Accessed August 5, 2019.