SmartPA Criteria Proposal

Drug/Drug Class:	BiDil Clinical Edit
First Implementation Date:	August 24, 2006
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 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 10-01-2019 to 9-30-2020			
Drug	**Claims**		**Spend**
BIDIL 20-37.5 MG TABLET	29		$9,616.96
Drug	**Cost per tablet**		**Cost per month**
BIDIL 20-37.5 MG TABLET	$3.58	NADAC	$644.40 for 180 tabs
ISOSORBIDE DINITRATE 20 MG TABLET	$0.46	NADAC	$82.80 for 180 tabs
HYDRALAZINE HCL 25 MG TABLET	$0.05	MAC	$13.50 for 270 tabs

Type of Criteria:
- ☐ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **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

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	

Disposition of Edit

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

Default Approval Period

1 year

References

- BIDIL® (isosorbide dinitrate and hydralazine hydrochloride) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; March 2019.
- Facts & Comparisons. Isosorbide Dinitrate/Hydralazine Hydrochloride Oral. Accessed October 26, 2020.
- IPD Analytics. Cardiovascular: Heart Failure. Accessed October 26, 2020.