Clinical Edit Criteria Proposal

Drug/Drug Class:	**BiDil® Tablets Clinical Edit**
Date:	**December 20, 2007** **(Updated September 21, 2017)**
Prepared for:	
Prepared by:	MO HealthNet

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose:

Ensure appropriate utilization and control of BiDil® (isosorbide dinitrate 20mg/hydralazine HCl 37.5mg tablets).

Why was this Issue Selected:

BiDil® is a fixed-dose combination of isosorbide dinitrate, a vasodilator with effects on both arteries and veins, and hydralazine hydrochloride, a predominantly arterial vasodilator. BiDil® is indicated for the treatment of heart failure as an adjunct 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. Standard therapy generally includes a loop diuretic, ACE inhibitor or ARB, along with a beta blocker. Many patients also receive a cardiac glycoside or an aldosterone antagonist. BiDil® contains 20mg of isosorbide dinitrate and 37.5mg hydralazine hydrochloride. Although the FDA has not established the generic forms of the individual components as being bioequivalent to BiDil®, the American College of Cardiology and the American Heart Association heart failure guidelines recommend using "a combination of hydralazine and nitrates". The fixed-dose combination dosage form is roughly 4 times more expensive than the cost of the generic products.

Program-specific information:

Drug	Dosage Form	Cost per Tablet
• BiDil®	20mg/37.5mg tab	$3.107 WAC
• Isosorbide Dinitrate	20mg tab	$0.7127 MAC
• Hydralazine	25mg tab	$0.0542 MAC
• Hydralazine	50mg tab	$0.0607 MAC
BiDil® Utilization	Claims	FFS Spend
8/24/12 – 8/25/17	469	$118,894

Setting & Population:

All patients

Type of Criteria:	☐ **Increased risk of ADE**	☐ **Non-Preferred Agent**
	☒ **Appropriate Indications**	☐
Data Sources:	☐ **Only administrative databases**	☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug/drug class for review: BiDil® (isosorbide dinitrate/hydralazine tablets)
- Age range: All patients
- Gender: Male and female

Approval Criteria

- **Diagnosis of Heart Failure**
- Trial and failure each of individual generic active ingredients in the past 45 days
- Documented ADE/ADR to individual generic products
- ~~**Patient race = African American**~~

Denial Criteria

- Therapy will be denied if approval criteria are not met

Required Documentation

Laboratory results:		Progress notes:	X
MedWatch form:			

Disposition of Edit

- **Denial Code:** Edit 682 "Clinical Edit"

References

1. Adams K, Carson P, Cohn N, D'Agostino R, Ferdinand K, et al. Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure. N Engl J Med. Nov 11, 2004;351(20):2049-2057.
2. Butler J, Cole RT, Georghiade M, Georgiopoulou VV, Kalogeropoulos AP, Quyyumi A, Yancy C. Hydralazine and Isosorbide Dinitrate in Heart Failure: Historical Perspective, Mechanisms, and Future Directions. Circulation. May 31, 2011;123(21):2414-2422.
3. BiDil® Package Insert. Arbor Pharmaceuticals, LLC. Revised March 2016.
4. Department of Health and Human Services. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Letter Regarding Bioequivalence of BiDil® Tablets, dated May 3, 2006.
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2017.
6. USPDI, Micromedex; 2017.
7. Drug Facts and Comparisons On-line; 2017.