Pharmacy Medical Necessity Guidelines:
BiDil® (Isosorbide Dinitrate/Hydralazine)

Effective: March 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM:
617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

BiDil, a combination of isosorbide dinitrate, a nitrate vasodilator, and hydralazine hydrochloride, an arteriolar vasodilator, is indicated for the treatment of heart failure as an adjunct therapy to standard therapy in self-identified black patients to improve survival, prolong time to hospitalization for heart failure and to improve patient-rephahahaorted functional status.

- Limitations of use: There is little experience in patients with NYHA class IV heart failure

COVERAGE GUIDELINES

The plan may authorize coverage of BiDil (hydralazine/isosorbide) for members when **all** the following criteria for a particular regimen are met and limitations do not apply:

1. The request is for a member with the diagnosis of heart failure

AND

2. The provider indicates difficulty with the administration of, or a risk of noncompliance with the member taking the individual ingredients, isosorbide dinitrate and hydralazine

LIMITATIONS

None

CODES

None

REFERENCES

1. BiDil (isosorbide dinitrate and hydralazine hydrochloride) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; March 2019.
2. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *JACC.* 2017;70(6):776-803.
3. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2013;128:e240-e327.

APPROVAL HISTORY

October 21, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. June 4, 2014: No Changes
2. June 9, 2015: Approval duration modified to 2 years.

3. September 16, 2015: Approval duration modified to life of plan
4. January 1, 2016: Administrative change to rebranded template.
5. September 13, 2016: No changes
6. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
7. September 12, 2017: No changes.
8. October 16, 2018; Administrative update to template.
9. April 9, 2019: No changes.
10. March 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services