Pharmacy Medical Necessity Guidelines: Oxbryta™ (voxelotor)

Effective: April 20, 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

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

Oxbryta (voxelotor) is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of Oxbryta (voxelotor) for Members, when the following criteria are met:

1. Documented diagnosis of sickle cell disease

AND

2. Documentation of a hemoglobin level between 5.5 and 10.5 g/dL

AND

3. Member is at least 12 years of age

AND

4. Prescribed by or in consultation with a hematologist or sickle cell disease specialist

AND

5. Documentation of one of the following:
    a. Member is currently receiving hydroxyurea therapy
    b. Member has a previous treatment failure, intolerance, or contraindication to hydroxyurea therapy

LIMITATIONS

- None

CODES

None

REFERENCES

1. Oxbryta (voxelotor) [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019.
2. Vichinsky E, Hoppe C, Ataga K, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med. 2019;381:509-19.
3. Yawn BP, John-Sowah. Management of sickle cell disease: recommendations from he 2014 Expert Panel Report. Am Fam Physician. 2015 Dec 15;92(12):1069-76A.

APPROVAL HISTORY

April 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

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.