Pharmacy Medical Necessity Guidelines: Northera™ (droxidopa)

Effective: June 9, 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

Neurogenic orthostatic hypotension (nOH) results from failure of the autonomic nervous system to regulate blood pressure in response to postural change due to an inadequate release of norepinephrine. Northera (droxidopa), a synthetic amino acid analog that is directly metabolized to norepinephrine, is Food and Drug Administration (FDA)-approved for treatment of nOH. While the exact mechanism of action of Northera (droxidopa) in the treatment of nOH is unknown, it is believed to exert its pharmacological effects through norepinephrine. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction. In one small, short-term clinical trial, Northera (droxidopa) was shown to improve dizziness symptom scores and increase standing systolic blood pressure within three minutes after standing through one week of treatment.

FDA APPROVED INDICATIONS

Northera (droxidopa) is FDA-approved for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Effectiveness of Northera (droxidopa) beyond two weeks of treatment has not been demonstrated. The continued effectiveness of Northera (droxidopa) should be assessed periodically.

COVERAGE GUIDELINES

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

1. Documented diagnosis of symptomatic neurogenic orthostatic hypotension

AND

2. Documentation the Member has tried and failed both midodrine and fludrocortisone due to inadequate response or adverse effects

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- January 12, 2016: No changes.
- January 10, 2017: No changes. Effective 1/10/17, Medical Necessity Guideline applies to Tufts Health Together.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- January 9, 2018: No changes.
- January 8, 2019: No changes.
- June 9, 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