Pharmacy Medical Necessity Guidelines
Droxidopa (Northera)

Effective: 2/16/15

<table>
<thead>
<tr>
<th>Clinical Documentation and Prior Authorization Required</th>
<th>✓</th>
<th>Type of Review – Case Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td>✓</td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td></td>
<td>Fax: 617-673-0988</td>
<td></td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX</td>
<td>Department to Review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RxUM</td>
</tr>
</tbody>
</table>

OVERVIEW

FDA-APPROVED INDICATIONS

NORTHERA is indicated 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 (NOH) 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 beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Northera (droxidopa) for members when all of the following criteria are met and limitations do not apply:

- The member has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH)
- The member has tried concomitant therapy with midodrine and fludrocortisone and failed therapy due to adverse effects or an inadequate response

LIMITATIONS

None

CODES

None

REFERENCES


APPROVAL HISTORY
• 2/10/15: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to fully insured Tufts Health Direct offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Together (MassHealth), please refer to the Tufts Health Together Pharmacy Medical Necessity Guidelines.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.