Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Northera (droxidopa)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Northera (droxidopa).

Northera (droxidopa) 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 hypotension (NOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency (DβH), and non-diabetic autonomic neuropathy (NDAN).

DEFINITIONS

Autonomic Neuropathy – a nerve disorder that affects autonomic (involuntary) functions of the body, such as heart rate, blood pressure, bowel and bladder emptying, sweating and digestion. It is an auto-regulation disorder that occurs when damage to the autonomic nerves disrupt signals from the brain to various parts of the autonomic nervous system (ANS) such as the heart and the blood vessels. Autonomic neuropathy is a widespread condition which affects a variety of individuals. The exact incidence is unknown as it is not a disease but rather a complication of a pre-existing disease or

injury.

Non-Diabetic Autonomic Neuropathy (NDAN) – can occur as a result of injury or secondary to various diseases such as: amyloidosis, autoimmune disease, certain infections (such as: syphilis, Lyme, HIV/AIDS), Multiple Sclerosis, renal failure, vitamin B-12 deficiency, alcohol abuse and Parkinson's Disease. NDAN may also occur as a side effect of medications, such as: certain cytotoxic chemotherapeutic agents and amiodarone.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Northera (droxidopa), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a cardiologist or a neurologist
- Must be age 18 years or older
- Must have a diagnosis of symptomatic neurogenic hypotension (NOH) caused by one of the following conditions:
    - Primary autonomic failure (Parkinson's disease, multiple system atrophy or pure autonomic failure)
    - Dopamine beta-hydroxylase deficiency
    - Non-diabetic autonomic neuropathy
- Must include chart documentation demonstrating how the diagnosis was made, including blood pressure readings showing a systolic blood pressure decrease of at least 20 mmHg or a diastolic blood pressure decrease of at least 10 mmHg within 3 minutes of standing
- Must provide documentation that the member is symptomatic as a result of low pressure readings, including documentation to support that the member is experiencing at least one of the following symptoms: dizziness, lightheadedness, feeling faint or feeling like member might black out

- Must provide chart documentation of discontinuation or dosage reductions of medications which can cause orthostatic hypotension, such as: anti-hypertensive agents, nitrates, _-1 adrenergic blockers (i.e. terazosin, prazosin), antiparkinsonian agents (i.e. levodopa, bromocriptine, ropinirole, pramipexole), diuretics, monoamine oxidase inhibitors, narcotics/tranquilizers/sedatives, medications used for erectile dysfunction, tricyclic antidepressants
- Must have chart documentation demonstrating that the member has tried nonpharmacologic interventions to treat their condition such as:
    - Elevation of the bed by 5-20 degrees
    - Use of compression stockings
    - Increase of salt and water intake
    - Avoidance of precipitating factors such as: arising too quickly from supine to sitting or standing, standing motionless, large meals, alcohol consumption, heat, hot baths, hot environment
    - Performance of physical counter-maneuvers such as: crossing legs stooping, squatting and tensing muscles
- Must have an adequate trial of midodrine and fludrocortisone
    - ➢ Note: most patients respond to these medications within 1 week

Reauthorization Criteria:

All prior authorization renewals are reviewed every 6 months to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy, as evidenced by an improvement in the symptoms the member was experiencing (i.e. dizziness, lightheadedness, feeling faint or feeling like member might black out). Also, chart documentation must be provided to support that the member continues to be monitored for adverse effects such as supine hypertension and that additional drug therapies have not been added to the member's medication regimen that would potentiate the risk of supine hypertension.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 month
Reauthorization	Up to 6 months
Quantity Level Limit	
100mg	540 capsules per lifetime
200mg and 300mg	180 capsules per month

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Northera [prescribing information]. Deerfield, IL: Lundbeck. 2014.
2. Northera [AMCP Dossier]. Deerfield, IL: Lundbeck.
3. Northera (droxidopa): Summary of the trials which established the efficacy and safety of Northera (droxidopa) for the treatment of neurogenic orthostatic hypotension: pivotal studies. Deerfield, IL: Lundbeck.
4. Northera (droxidopa): Summary of the trials which established the efficacy and safety of Northera (droxidopa) for the treatment of neurogenic orthostatic hypotension: supportive studies. Deerfield, IL: Lundbeck.
5. Kaufman H, Freeman R, Biagginoi I, et. al. Droxidopa for Neurogenic Orthostatic Hypotension. A Randomized, Placebo-Controlled, Phase 3Trial. *Neurology*. 2014;83:1-8.
6. Kaufmann H, Malamut R, Norcliffe-Kaufmann L, Rosa K, Freeman R. The Orthostatic Hypotension Questionnaire (OHQ): validation of a novel symptom assessment scale. *Clin Auton Res*. 2012;22(2):79-80.
7. Freeman R. Clinical Practice. Neurogenic orthostatic hypotension. *N Engl J Med*. 2008;358(6);615-624.
8. Goldstein, D, Sharabi Y. Neurogenic Orthostatic Hypotension: A Pathophysiological Approach. *Circulation*. 2009;119:139-146.
9. Autonomic neuropathy. Mayo Clinic website. Available at: http://www.mayoclinic.org/diseasesconditions/autonomic-neuropathy/basics/definition/CON-20029053?p=1. Accessed November 11, 2014.
10. Jasmin L. Autonomic neuropathy. Medline Plus website. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/000776.htm. Updated October 3, 2012. Accessed November 11, 2014.
11. Ganjehei L, Massumi A, Razavi M, Wilson JM. Orthostatic hypotension as a manifestation of vitamin B12 deficiency. Tex Heart Inst J 2012; 39:722.
12. Ng WF, Stangroom AJ, Davidson A, et al. Primary Sjogrens syndrome is associated with impaired autonomic response to orthostasis and sympathetic failure. QJM 2012; 105:1191.
13. Freeman R. Autonomic peripheral neuropathy. The Lancet. 2005;365:1259.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*