OVERVIEW
Northera, a norepinephrine-type product, is indicated for the treatment of orthostatic dizziness, lightheadedness or the “feeling that one is about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson’s disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. The effectiveness beyond 2 weeks of treatment has not been established. The effectiveness of Northera should be evaluated periodically. The mechanism of action of Northera is unknown. Northera is a synthetic amino acid analog that is metabolized to norepinephrine by dopa-decarboxylase, which is found throughout the body. Northera is thought to exert its effects through norepinephrine, which increases blood pressure (BP) by inducing peripheral arterial and venous vasoconstriction. Northera has a Boxed Warning regarding supine hypertension. Northera may cause or exacerbate supine hypertension in patients with NOH. Supine BP should be measured prior to initiating Northera and after dose increases.

Recommended Authorization Criteria
Coverage of Northera is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Neurogenic Orthostatic Hypotension (NOH). Approve for 1 month if the patient meets the following criteria (a, b, c, d, and e):

   a) Patient is > 18 years of age; AND
   b) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson’s disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; AND
   c) Northera has been prescribed by or in consultation with a cardiologist or a neurologist; AND
   d) Patient meets ONE of the following conditions (i or ii):
      i. Patient has tried midodrine and one of the following other medications (e.g., fludrocortisone, desmopressin, dihydroergotamine, indomethacin, pyridostigmine, erythropoietin); OR
      ii. Patient has a contraindication or intolerance to all of the medications listed above; AND
   e) Patient has initiated non-pharmacological measures including but not limited to elevation of the head of the bed, orthostatic compression garments, and appropriate physical training.
Approval Duration: 30 days (1 month)

References

- Northera™ [prescribing information]. Deerfield, IL: Lundbeck; February 2017.