Commercial/Healthcare Exchange PA Criteria

Effective: July 25, 2018

Prior Authorization: Noctiva & Nocdurna

Products Affected: Noctiva (desmopressin) nasal spray, Nocdurna (desmopressin) SL tablets

Medication Description:

Noctiva (desmopressin acetate) is a vasopressin analog administered via the intranasal route indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times a night to void. Desmopressin acetate the active ingredient in Noctiva is a synthetic analog of the naturally occurring hormone 8-arginine vasopressin (ADH) and an antidiuretic hormone that affects conservation of water in the kidneys. It is a selective agonist at V2 receptors on renal cells in the collecting ducts, increasing water re-absorption in the kidneys, and reducing urine production.

Nocdurna (desmopressin) is a synthetic analog of vasopressin, which is an endogenous pituitary hormone sometimes referred to as ADH. It is available in its acetate form as a tablet intended for SL administration.

Covered Uses: treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Exclusion Criteria:

1. Current or previous history of hyponatremia
2. Primary nocturnal enuresis
3. Polydipsia
4. Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
5. Concomitant use with loop diuretics, systemic or inhaled glucocorticoids
6. Renal impairment with an estimated glomerular filtration rate (eGFR) below 50 mL/min/1.73 m2
7. Illnesses that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection
8. Uncontrolled hypertension
9. Congestive heart failure (NYHA class II-IV)
10. Pregnancy

Required Medical Information:

1. Diagnosis
2. Current medication regimen
3. Current and previous medical history (documentation required)

Age Restrictions:

Noctiva: 50 years of age and older
Nocdurna: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a urologist, a geriatrician, or an endocrinologist

Coverage Duration: Initiation: 6 months Continuation: 12 months

Other Criteria:

Initial:
Approve if the patient meets the following criteria (A, B, C, D, E, F, G, H, AND I):

A. Patient is 50 year of age or older (**Noctiva**) OR 18 years of age or older (**Nocdurna**); **AND**
B. Patient has been diagnosed with nocturnal polyuria as confirmed by a 24-hour urine collection which notes the presence of greater than one-third of 24-hour urine production occurring at night; **AND**
C. Patient awakens at least 2 times a night to void; **AND**
D. Patient is NOT currently taking ANY of the following agents:
    A. Loop diuretics (bumetanide, furosemide, torsemide)
    B. Inhaled or systemic glucocorticoids (beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, or any combination); **AND**
E. Patient has a documented serum sodium level that is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous 6 months; AND
F. Patient does NOT have a disease state that increases risk for hyponatremia or would be worsened with fluid retention (e.g., excessive fluid intake, an illness that causes fluid or electrolyte imbalances, uncontrolled hypertension, Heart Failure Class II-IV, primary nocturnal enuresis, renal impairment [with an estimated glomerular filtration rate (eGFR) below 50 mL/min/1.73 m2)], syndrome of inappropriate antidiuretic hormone secretion [SIADH]); **AND**

G. Patient has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia (e.g., nighttime fluid restriction, avoidance of caffeine and alcohol, Kegel exercises, bladder diary, or earlier timing of medications).
H. Prescribed by, or in consultation with, a urologist, a geriatrician, or an endocrinologist.
I. For **Nocdurna only**: Patient must have clinical documentation explaining why a sublingual tablet dosage form of desmopressin is necessary.

Continuation:
Approve if the patient meets the following criteria (A, B, AND C):

A. Patient continues to meet all initiation criteria; **AND**
B. Patient has experienced a decrease in nocturnal voiding; **AND**
C. There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).

References:

1. Noctiva [package insert]. Milford, PA; Serenity Pharmaceuticals; March, 2017.
2. Nocdurna [package insert]. Parsippany, NJ; Ferring Pharmaceuticals Inc; January 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/18/2018
2	Policy Revision	Addition of Nodurna	Products Affected Medication Description Age Restrictions Other Criteria	11/07/2018
3	Policy Revision	Added Sodium requirement needed to be within normal limits	Other Criteria	5/2019