PRIOR AUTHORIZATION POLICY

POLICY: Desmopressin Products – Nocdurna Prior Authorization Policy

- Nocdurna® (desmopressin acetate sublingual tablets [27.7 mcg and 55.3 mcg] – Ferring)

REVIEW DATE: 10/07/2020

OVERVIEW

Nocdurna, a vasopressin analog, is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void.[1] Before initiating therapy it is recommended that the diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection.

Disease Overview

Nocturnal polyuria is defined as nocturnal urine volume exceeding 33% of the total 24-hour urine volume in patients ≥ 65 years of age or exceeding 20% of 24-hour urine volume in younger patients.[2] Nocturnal polyuria may improve via lifestyle and behavior modifications, which should be implemented prior to pharmacotherapy.[3] Such modifications include minimizing fluid intake before bed (particularly caffeine and alcohol), restriction of total fluid consumption, emptying the bladder before bed, increasing exercise and fitness levels, earlier dosing of medications such as diuretics, and elevating the legs above heart level for a few hours before going to bed (for patients with peripheral edema).

Safety

Nocdurna has a Boxed Warning regarding hyponatremia.[1] Use of Nocdurna is contraindicated in patients at increased risk of severe hyponatremia such as patients with excessive fluid intake, illness that may cause fluid or electrolyte imbalances, and in patients using loop diuretics or systemic or inhaled glucocorticoids. It is recommended to check serum sodium concentrations prior to initiating or resuming Nocdurna and throughout treatment. If hyponatremia occurs, Nocdurna may need to be temporarily or permanently discontinued.

Nocdurna is contraindicated in patients with hyponatremia or among those with a history of hyponatremia.[1] Also, patients with polydipsia should not use Nocdurna. Do not administer Nocdurna concomitantly with loop diuretics or with systemic or inhaled glucocorticoids. Patients with renal impairment with an estimated glomerular filtration rate below 50 mL/min/1.73 m^2 should not use Nocdurna. Those with known or suspected syndrome of inappropriate antidiuretic hormone secretion should not use Nocdurna. Do not utilize Nocdurna during illnesses that may cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection. Nocdurna is contraindicated in patients with heart failure or among those with uncontrolled hypertension because the fluid retention in these conditions increases the risk of worsening the underlying condition. Also, Nocdurna is not recommended in patients at risk for increased intracranial pressure or those with a history of urinary retention. Trials involving Nocdurna have not included pediatric patients.

Guidelines

A consensus statement on the diagnosis and treatment of nocturia was published by the International Continence Society in 2019.[2] There was consensus that fluid restriction should be advised for all desmopressin-treated patients. Newer desmopressin formulations, including Nocdurna and Noctiva® (desmopressin acetate nasal spray), are generally regarded as low-dose desmopressin. Low-dose formulations are appropriate in the absence of contraindications to desmopressin therapy.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Nocdurna. All approvals are provided for the duration noted below. Due to the specialized skills required for evaluation and diagnosis of patients treated with Nocdurna, as well as the monitoring required for adverse events and long-term efficacy, approval requires Nocdurna to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Nocdurna is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Nocturia due to Nocturnal Polyuria.** Approve for 1 year if the patient meets all of the following criteria (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection before treatment initiation and the patient meets one of the following (i or ii):
     - **i.** The nocturnal urine volume exceeds 20% of the total 24-hour urine volume in patients < 65 years of age; OR
     - **ii.** The nocturnal urine volume exceeds 33% of the total 24-hour urine volume in patients ≥ 65 years of age; AND
   - **C)** Prior to desmopressin therapy, patient awakens at least two times per night to void; AND
   - **D)** Patient has serum sodium concentrations within the normal range (135 to 145 mmol/L); AND
   - **E)** Prescriber has verified that the patient does not have the following conditions/circumstances in which use of Nocdurna is not recommended (i, ii, iii, iv, v, or vi):
     - **i.** Currently receiving loop diuretics (e.g., furosemide, torsemide, bumetanide); OR
     - **ii.** Currently receiving systemic or inhaled glucocorticoids; OR
     - **iii.** Renal impairment with an estimated glomerular filtration rate < 50 mL/min/1.73 m^2; OR
     - **iv.** Heart failure; OR
     - **v.** Polydipsia; OR
     - **vi.** Known or suspected syndrome of inappropriate antidiuretic hormone secretion; AND
   - **F)** Patient has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia; AND
     Note: Examples of non-pharmacologic techniques include nighttime fluid restriction, avoidance of caffeine and alcohol, earlier timing of medications, leg elevation, or use of compression stockings.
   - **G)** Nocdurna is prescribed by or in consultation with a urologist, geriatrician, or endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Nocdurna is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nocdurna® sublingual tablets [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; June 2018.
2. Everaert K, Hervé F, Bosch R, et al. International Continence Society consensus on the diagnosis and treatment of nocturia. *Neurourol Urodyn*. 2019 Feb;38(2):478-498.
3. Weiss JP, Everaert K. Management of nocturia and nocturnal polyuria. *Urology*. 2019;133S:24-33.