



## Drug Coverage Policy

Effective Date.....3/1/2026

Coverage Policy Number.....IP0127

Policy Title.....Nocdurna

# Desmopressin Products – Nocdurna

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

### **INSTRUCTIONS FOR USE**

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

### **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.<sup>1</sup> 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  $\geq 65$  years of age or exceeding 20% of 24-hour urine volume in younger patients.<sup>2</sup> Nocturnal polyuria may improve via lifestyle and behavior modifications, which should be implemented prior to pharmacotherapy.<sup>3</sup> 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).

## **Guidelines**

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

## **Safety**

Nocdurna has a Boxed Warning regarding hyponatremia.<sup>1</sup> 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.<sup>1</sup> 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  $< 50$  mL/min/1.73 m<sup>2</sup> 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.

## **Coverage Policy**

### **POLICY STATEMENT**

Prior Authorization is required for benefit coverage of Nocdurna. All approvals are provided for the duration noted below. Because of 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.

**Nocdurna is considered medically necessary when the following criteria is met:**

### **FDA-Approved Indication**

- 1. Nocturia due to Nocturnal Polyuria.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
- A)** Patient is  $\geq 18$  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.** Patient is  $< 65$  years of age: The nocturnal urine volume exceeds 20% of the total 24-hour urine volume; OR
    - ii.** Patient is  $\geq 65$  years of age: The nocturnal urine volume exceeds 33% of the total 24-hour urine volume; 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; OR  
Note: Examples of loop diuretics include furosemide, torsemide, bumetanide.
    - ii.** Currently receiving systemic or inhaled glucocorticoids; OR
    - iii.** Renal impairment with an estimated glomerular filtration rate  $< 50$  mL/min/1.73 m<sup>2</sup>; 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 for nocturia include nighttime fluid restriction, avoidance of caffeine and alcohol, earlier timing of medications, leg elevation, or use of compression stockings.
  - G)** The medication is prescribed by or in consultation with a nephrologist, urologist, geriatrician, or endocrinologist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

### Conditions Not Covered

**Nocdurna for any other use is considered not medically necessary. Criteria will be updated as new published data are available.**

## References

1. Nocdurna<sup>®</sup> sublingual tablets [prescribing information]. Ewing, NJ: Antares; November 2020.
2. Everaert K, Hervé F, Bosch R, et al. International Continence Society consensus on the diagnosis and treatment of nocturia. *Neurourol Urodyn*. 2019;38(2):478-498.
3. Weiss JP, Everaert K. Management of nocturia and nocturnal polyuria. *Urology*. 2019;133S:24-33.

## Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No clinical content changes.	6/15/2024
Annual Revision	No criteria changes.	3/15/2025
Annual Revision	<b>Nocturia due to Nocturnal Polyuria:</b> Moved examples of loop diuretics to a Note.	3/1/2026

The policy effective date is in force until updated or retired.

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