



Drug Coverage Policy

Effective Date 6/15/2024
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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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 m² 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.

Medical Necessity Criteria

Nocdurna is considered medically necessary when the following criteria are 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 ≥ 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 if the patient is < 65 years of age; OR
 - ii. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume if the patient is ≥ 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 m²; 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.

Preferred product criteria is met for the product(s) as listed in the below table(s)

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Nocdurna® 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

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

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