Effective Date **7/1/2023**
Next Review Date… **7/1/2024**
Coverage Policy Number **IP0127**

Desmopressin Sublingual Tablets

Table of Contents

Related Coverage Resources

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. 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

This policy supports medical necessity review for **Nocdurna®** (desmopressin).

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

Medical Necessity Criteria

Desmopressin (Nocdurna) is considered medically necessary for the treatment of nocturia due to nocturnal polyuria when the individual meets ALL of following criteria:

1. 18 years of age or older
2. Nocturnal Polyuria diagnosis confirmed by 24-hour urine collection AND the individual meets **ONE** of the following:
    A. The nocturnal urine volume exceeds 20% of the total 24-hour urine volume in an individual less than 65 years of age
    B. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume in an individual 65 years of age or older

3. Prior to desmopressin therapy, individual awakens at least 2 times per night to void
4. Has serum sodium concentrations within the normal range (135 to 145 mmol/L)
5. Has been evaluated for common causes of nocturia (for example, overactive bladder, benign prostatic hyperplasia, obstructive sleep apnea) and treatment for these conditions has been optimized
6. Provider attests the individual will NOT be taking either of the following concomitantly with Nocdurna:
    A. Loop diuretics
    B. Inhaled or systemic glucocorticoids
7. Provider attests the individual does NOT have a condition that increases the risk for hyponatremia or would be exacerbated by fluid retention (for example, renal impairment, heart failure, SIADH)
8. Has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia
9. Medication is being 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.

Reauthorization Criteria

Continuation of Nocdurna (desmopressin) sublingual tablet is considered medically necessary for the treatment of nocturia due to nocturnal polyuria when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven

Background

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.

References

1. Nocdurna® sublingual tablets [prescribing information]. Parsippany, NJ: Ferring; 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;38(2):478-498.
3. Weiss JP, Everaert K. Management of nocturia and nocturnal polyuria. *Urology*. 2019;133S:24-33.