COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	Nocdurna (desmopressin acetate)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Nocdurna is a vasopressin analog initially approved by the FDA in 2018. It is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Nocturnal polyuria is the most frequent cause of nocturia, having been shown in studies to be responsible for up to 88% of cases. It is thought to result from an abnormality of the circadian rhythm of secretion of the antidiuretic hormone, arginine vasopressin (AVP). The antidiuretic effects of Nocdurna are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water re-absorption in the kidneys, and reducing urine production. The efficacy of Nocdurna was established in two 3-month randomized, double-blind, placebo-controlled, multicenter trials in adults over 18 years of age. Patients in both studies experienced a statistically significant reduction in the number of nocturia episodes per night from baseline compared to placebo.

Nocdurna can cause hyponatremia, which may be life threatening if severe. Due to this, it has a Black Box warning regarding hyponatremia. Nocdurna is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake or with illnesses that can cause fluid or electrolyte imbalances, and in patients using loop diuretics or systemic or inhaled glucocorticoids. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia. If hyponatremia occurs, Nocdurna may need to be temporarily or permanently discontinued.

Nocdurna (desmopressin acetate) will be considered for coverage when the following criteria are met:

Nocturia (Due to Nocturnal Polyuria)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has documented history of at least two nocturic episodes per night; AND
3. Member has documentation of 24-hour urine frequency/volume chart where night-time urine production exceeding one-third of the total 24-hour urine production; AND
4. Member has documented normal serum sodium concentrations 1 month prior to initiating therapy per chart notes; AND
5. Member has tried and failed non-pharmacologic interventions for at least one month (see appendix below);

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6. Member is not using Nocdurna in combination with loop diuretics or with systemic or inhaled glucocorticoids; AND
7. Member does not have ANY of the following:
   a) Congestive heart failure (New York Heart Association Class II to IV);
   b) Uncontrolled hypertension;
   c) Polydipsia;
   d) Renal impairment with an estimated glomerular filtration rate (eGFR) below 50 mL/min/1.73 m^2;
   e) Gastroenteritis, salt-wasting nephropathies, or acute systemic infection;
   f) Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion.
8. **Dosage allowed/Quantity limit:** Females: 27.7 mcg once daily one hour before bedtime, Males: 55.3 mcg once daily one hour before bedtime. Quantity limit: 30 sublingual tablets per 30 days.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of condition, demonstrated by reduction in nocturnal voids.
2. Member has normal serum sodium concentrations labs submitted with chart notes.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Appendix: Non-Pharmacologic Interventions

- Reduction of evening intake of diuretic fluids, such as alcohol, coffee, tea and liquids with artificial sweeteners
- Avoiding use of nighttime diuretics
- Treatment of peripheral edema by use of compression stockings or evening elevation of the legs
- Emptying the bladder prior to bedtime
- Weight reduction

CareSource considers Nocdurna (desmopressin acetate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/21/2022	New policy for Nocdurna created.

References:

1. Nocdurna [package insert] Parsippany, NJ: Ferring;.November 2020
2. Weiss JP, Everaert K. Management of nocturia and nocturnal polyuria. Urology. 2019;133S:24-33.
3. Mathias O, et al. A practical approach to the management of nocturia. Int J Clin Pract. 2017. 71(11):e13027.

Effective date: 01/01/2025
Revised date: 04/21/2022