UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2145-8
Program	Prior Authorization/Medical Necessity
Medication	Nocdurna (desmopressin acetate)
P&T Approval Date	5/2018, 7/2018, 10/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

1. Background:

Nocdurna (desmopressin acetate) sublingual tablets are indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. Prior to initiating treatment with Nocdurna, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia.

Desmopressin should be avoided in older adults (those 65 or older) due to the risk of hyponatremia. This medication is included in the American Geriatrics Society Beers Criteria. Nocdurna has a Black Box Warning for hyponatremia listed in the FDA prescribing information. Nocdurna use is contraindicated in patients with hyponatremia or a history of hyponatremia, SIADH, eGFR <50 mL/min/1.7m^2, uncontrolled hypertension, and New York Heart Association Class II – IV congestive heart failure. See package insert for full listing of contraindications and safety warnings.

This prior authorization program is intended to ensure appropriate prescribing of Nocdurna prior to initiating therapy.

2. Coverage Criteria[a]:

A. <u>Nocdurna</u>

1. **Initial Authorization**

a. **Nocdurna** will be approved based on **<u>all</u>** of the following:

(1) Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

-AND-

(2) Patient wakes at least twice per night on a reoccurring basis to void

-AND-

(3) Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months.

-AND-

(4) The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes (e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure)

-AND-

(5) Prescriber attests that the risks have been assessed and benefits outweigh the risks

Authorization will be issued for 6 months

B. Reauthorization

1. **Nocdurna** will be approved based on **all** of the following:

   a. Documentation of positive clinical response to Nocdurna therapy

   -AND-

   b. Patient has routine monitoring for serum sodium levels

   -AND-

   c. Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Johnson, TM. Nocturia: Clinical presentation, evaluation and management in adults. O'Leary, MP, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on December 8, 2022.)
2. Nocdurna® (desmopressin) sublingual tablets [package insert]. Ewing, NJ: Antares Pharma, Inc; November 2020.
3. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults*J Am Geriatr Soc*. 2019; 67(4):674-94.

Program	Prior Authorization/Medical Necessity – Nocdurna
Change Control	
Date	Change
5/2018	New program
7/2018	Updated information to program background to include all contraindications. Simplified language regarding other evaluation of other causes of nocturia. Added prescriber attestation that benefits outweigh the risk.
10/2018	Added Nocdurna to program. Updated references. Updated language for serum sodium testing to provide clarity.
2/2019	Added criteria for history of failure, contraindication or intolerance to Nocdurna for Noctiva approval.
2/2020	Annual review. Updated references.
2/2021	Noctiva removed from the criteria since product has been discontinued.
2/2022	Annual review. Updated references.
2/2023	Annual review. Updated initial authorization to 6 months. Updated references.