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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	October 1, 2018
Subject:	Nocdurna Noctiva	**Page:**	1 of 4

Last Review Date: September 8, 2023

Nocdurna Noctiva

Description

Nocdurna (desmopressin acetate) sublingual tablets, Noctiva (desmopressin acetate) nasal spray

Background

Nocdurna (demopressin acetate) and Noctiva (desmopressin acetate) are vasopressin analogs. The antidiuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water re-absorption in the kidneys, and reducing urine production (1-2).

Regulatory Status

FDA-approved indication: Nocdurna and Noctiva are vasopressin analogs indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void (1-2).

Nocdurna and Noctiva have boxed warnings that they can cause hyponatremia, which may be life-threatening if severe. Nocdurna and Noctiva are contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids. Serum sodium concentration should be normal before starting or resuming Nocdurna or Noctiva and should be measured within 1 week and 1 month after initiating therapy and then periodically during treatment. If hyponatremia occurs, Nocdurna or Noctiva may need to be temporarily or permanently discontinued (1-2).

Nocdurna and Noctiva are contraindicated in: hyponatremia or history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate below 50 mL/min/1.73 m^2, syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, heart failure, and uncontrolled hypertension (1-2).

Nocdurna and Noctiva can cause fluid retention. They are not recommended in patients at risk of increased intracranial pressure or history of urinary retention. Fluid intake should be limited to a minimum from 1 hour before until 8 hours after administration of desmopressin (1-2).

The safety and effectiveness of Nocdurna and Noctiva in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nocdurna and Noctiva may be considered **medically necessary** if the conditions indicated below are met.

Nocdurna and Noctiva may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Nocturia due to nocturnal polyuria

AND ALL of the following:

1. Patient has an average of at least 2 nocturic episodes per night
2. Inadequate treatment response, intolerance, or contraindication to at least **ONE** anticholinergic such as:
    a. Detrol (tolterodine)

b. Enablex (darifenacin)
c. Oxytrol (oxybutynin)
d. Sanctura (trospium)
e. Vesicare (solifenacin)

3. Inadequate treatment response, intolerance, or contraindication to at least **ONE** generic desmopressin product
4. Patient has normal serum sodium concentrations **AND** prescriber agrees to monitor serum sodium
5. eGFR ≥ 50 mL/min/1.73 m^2

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Nocturia due to nocturnal polyuria

AND ALL of the following:

1. Decrease in nocturic episodes from baseline
2. Prescriber agrees to monitor serum sodium

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Quantity Limit
Nocdurna sublingual tablets	90 tablets per 90 days **OR**
Noctiva nasal spray	3 bottles per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Nocdurna (demopressin acetate) and Noctiva (desmopressin acetate) are vasopressin analogs. The antidiuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water re-absorption in the kidneys, and reducing urine production. The safety and effectiveness of Nocdurna and Noctiva in pediatric patients have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nocdurna and Noctiva while maintaining optimal therapeutic outcomes.

References

1. Nocdurna [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2020.
2. Noctiva [package insert]. Chesterfield, MO. Avadel Specialty Pharmaceuticals, LLC; December 2017.

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
December 2019	Annual review
December 2020	Annual review
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.