Nocdurna Noctiva

Description

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

Background

Nocdurna (desmopressin 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 m², 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

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 in patients 18 years of age and older with nocturia due to nocturnal polyuria and if the conditions indicated below are met.

Nocdurna and Noctiva are considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Diagnosis

The 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 m²

**Prior – Approval Renewal Requirements**

**Age**
18 years of age and older

**Diagnosis**

The 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**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limit per 90 days</th>
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<tbody>
<tr>
<td>Nocdurna sublingual tablets</td>
<td>90 tablets per 90 days OR</td>
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<tr>
<td>Noctiva nasal spray</td>
<td>3 bottles per 90 days</td>
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**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


### Policy History

<table>
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<tr>
<th>Date</th>
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<tr>
<td>October 2018</td>
<td>Addition to PA</td>
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<tr>
<td>November 2018</td>
<td>Annual review</td>
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<tr>
<td>December 2019</td>
<td>Annual review</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.