



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/18/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

NOCDURNA® (desmopressin acetate) oral tablet NOCTIVA™ (desmopressin acetate) nasal spray

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

**NOCDURNA® (desmopressin acetate) oral tablet
NOCTIVA™ (desmopressin acetate) nasal spray (cont.)**

Criteria:

- **Criteria for initial therapy:** Nocdurna (desmopressin acetate) sublingual tablet and Noctiva (desmopressin acetate) nasal spray is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual is **ONE** of the following:
 - **For Nocdurna:** 18 years of age or older
 - **For Noctiva:** 50 years of age or older
 2. A confirmed diagnosis of nocturia due to nocturnal polyuria in an individual who awakens at least 2 times per night to void
 3. Confirmation was made with a 24-hour urine collection that showed nighttime urine production of greater than 33% of the total 24-hour production by use of a 24-hour frequency/volume chart
 4. Individual awakens at least 2 times per night to void
 5. A baseline basic metabolic panel has been completed before initiation of treatment
 6. Individual has failure, contraindication, or intolerance to **oral desmopressin acetate**
 7. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - Serum sodium is within the normal range
 - 24-hour urine collection
 8. There are **NO** of the following contraindications:
 - Contraindications include:
 - Hyponatremia or a history of hyponatremia
 - Polydipsia
 - Primary nocturnal enuresis
 - Simultaneous use with loop diuretics
 - Simultaneous use with glucocorticoids, systemic or inhaled
 - Estimated glomerular filtration rate < 50 mL/min/1.73 m²
 - Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
 - Use during an illness that can cause fluid or electrolyte imbalance such as gastroenteritis, systemic infection, or salt-wasting nephropathies
 - Heart failure
 - Uncontrolled hypertension
 9. There is no history of urinary retention
 10. The individual is not at risk for increased intracranial pressure

**NOCDURNA® (desmopressin acetate) oral tablet
NOCTIVA™ (desmopressin acetate) nasal spray (cont.)**

11. It is not being used for the treatment of nocturia of pregnancy

Initial approval duration:

Noctiva: 1 bottle per month for 6 months

Nocdurna: 1 carton of 30 sublingual tabs (3 blister cards of 10 tablets each) for 6 months

➤ **Criteria for continuation of coverage (renewal request):** Nocdurna (desmopressin acetate) oral tablet and Noctiva (desmopressin acetate) nasal spray is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
 - Response is defined as:
 - Achieved and maintains at least a 50% reduction in nocturia episodes per night
2. Individual has been adherent with the medication
3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
 - Significant adverse effect such as:
 - Hyponatremia
4. There are no significant interacting drugs

Renewal duration:

Noctiva: 1 bottle per month for 12 months

Nocdurna: 1 carton of 30 sublingual tabs (3 blister cards of 10 tablets each) for 12 months

Description:

Nocdurna (desmopressin acetate) oral tablet is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Noctiva (desmopressin acetate) nasal spray is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It has not been studied in individuals younger than 50 years of age.

The International Continence Society (ICS) defines the symptom of nocturia as the complaint of awakening at night one or more times to void urine. Nocturia results from production of nocturnal urine that exceeds the capacity of the bladder to store it comfortably. Evidence suggests that nocturia becomes bothersome when an individual needs to void two or more times a night. It is important to note that nocturia is distinct from nocturnal enuresis which is voiding that occurs during sleep.

**NOCDURNA® (desmopressin acetate) oral tablet
NOCTIVA™ (desmopressin acetate) nasal spray (cont.)**

Many conditions cause or contribute to the symptom of nocturia. These include polyuria, sleep disorders, bladder storage disorders (BPH, OAB, or interstitial cystitis), diabetes mellitus, diabetes insipidus, heart failure, nephrotic syndrome, drugs, advancing age, and many others. Excessive fluid consumption of water, alcohol, and caffeine are also factors to consider when evaluating nocturia. With causes related to urine storage issues and with implementation of therapy for overactive bladder (OAB) or benign prostatic hypertrophy (BPH), the individual may still have nocturnal polyuria (NP). A cornerstone for the evaluation of nocturia is use of frequency-volume chart (FVC) to help characterize and identify the etiology of the symptom of nocturia. FVC quantifies the timing and volume of 24-hour and nocturnal urine output and can be used to calculate the nocturnal polyuria index (NPI).

The ICS definition of NPI is nocturnal urine volume divided by the 24-hour urine volume. NP may be defined as voiding an abnormal nocturnal urine volume from the time of first sleep until the time of first void after arising in the morning. Younger adults with a NPI of greater than 20% and adults > 65 years of age with a NPI of greater than 33% have an abnormal NPI. However, the definition of NP and what is considered normal urine production are not universally agreed upon. Other definitions of NP include nocturnal urine volume > 6.4 mL/kg, nocturnal urine output > 0.9 mL/min, or nocturnal urine production (NUP) of > 90 mL/hour regardless of age.

Treatment of NP involves life-style modification to decrease the amount of urine produced at night. These life-style behaviors include: void immediately before going to bed, avoid fluids (such as caffeine and alcohol) especially in the evening, take diuretic agent earlier (mid-afternoon), and elevate the legs in the evening to mobilize fluids. Pharmacologic treatment of nocturia due to NP includes use of desmopressin.

The anti-diuretic hormone (ADH), also known as arginine vasopressin (AVP) stimulates the reabsorption of fluid from renal tubules. Under normal conditions secretion of AVP follows a circadian rhythm and is released at night which would prevent nocturnal polyuria. Individuals with severe nocturia have been found to lack the normal nocturnal increase in AVP levels. Desmopressin is a synthetic analogue of AVP that acts on the distal renal tubule and collecting duct to reabsorb water during the night to reduce amount of urine and nocturia. Desmopressin can be administered by intranasal spray, oral tablets, or by injection. Oral desmopressin has demonstrated efficacy using doses ranging from 0.1-0.4 mg at bedtime. The dosage depends on the pharmaceutical formulation of the drug.

Definitions:

Polyuria:

Production of more than 2.8 L of urine in 24-hours for a 70 kg adult or 40 mL/kg of body weight

Nocturia:

Complaint of having to wake at night one or more times to void

Nocturnal polyuria:

A nocturnal polyuria index that exceeds 1/3 (33%) of the 24-hour nocturnal urine production

Nocturnal Polyuria Index (NPI):

Nocturnal urine volume divided by the 24-hour urine volume

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NPI of >33% for all ages indicates presence of nocturnal polyuria

Frequency volume chart (FVC):

Volumes voided and times of each void, throughout the day and night, for at least 24-hours

Resources:

Nocdurna. Package insert revised by manufacturer 8/2018. Accessed 11/02/18, 04/18/19

Noctiva product information accessed 04-30-18 at DailyMed:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8014020e-a547-4251-ba9b-2ff36fd4e9ed>

Noctiva (desmopressin acetate) nasal spray. Package Insert. Revised by manufacturer 03-2017. Accessed 03-21-2017

van Kerrebroeck P, Abrams P, Chaikin D, et al.: The Standardization of Terminology in Nocturia: Report from the Standardization Subcommittee of the International Continence Society. *Neurourol Urodyn* 2002; 21:179-183

Moon DG, Jin MH, Lee JG, et al.: Antidiuretic hormone in elderly male patients with severe nocturia: A circadian study. *BJU International* 2004; 94:571-575

van Kerrebroeck P, Rezapour M, Cortesse A, et al.: Desmopressin in the Treatment of Nocturia: A double-blinded, placebo controlled study. *Eur Urol* 2007; 52:221-229

Cornu JN, Abrams P, Chapple CR, et al.: A contemporary assessment of nocturia: Definition, epidemiology, pathophysiology, and management – a systematic review and meta-analysis. *Eur Urol* 2012; 62: 877-890

Weiss JP, Blaivas JG, Blanker MH, et al.: The New England research Institutes, Inc (NERI) Nocturia Advisory Conference 2012: Focus on outcomes of therapy. *BJU International* 2013; 111:700-716

Ebell MH, Radke T, Gardner J. A systematic review of the efficacy and safety of desmopressin for nocturia in adults. *J Urol* 2014; 192:829-835

Bergman AM, Sih AM, Weiss JP. Nocturia: An overview of evaluation and treatment. *Bladder* 2015; 2(2):1-5

Barkin J. Nocturia: Diagnosis and management for the primary care physicians. *Can J Urol* 2016; 23 (Suppl 1)16-19

UpToDate: Nocturia: Clinical presentation, evaluation, and management in adults. Current through Mar, 2018.

https://www.uptodate-com.mwu.idm.oclc.org/contents/nocturia-clinical-presentation-evaluation-and-management-in-adults?search=nocturnal%20polyuria&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
 Call 866-325-1794 to check the status of a request.
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
 Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> No There is absence of ALL contraindications.	

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:	Date:
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Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.