

Nocdurna (desmopressin acetate) Sublingual Tablets

Override(s)	Approval Duration
Prior Authorization	Initial requests: 3 months
Quantity Limit	Continuation requests: 1 year

Medications	Quantity Limit
Nocdurna (desmopressin acetate) sublingual tablets	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Nocdurna (desmopressin acetate) sublingual tablets may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has been diagnosed with nocturia due to nocturnal polyuria; **AND**
- III. Diagnosis has been confirmed by a 24-hour urine collection which notes the presence of greater than 1/3 (one-third) of 24 hour urine production occurring at night; **AND**
- IV. Individual awakens at least two (2) times per night to void; **AND**
- V. Individual has been evaluated for causes of nocturia, such as but not limited to overactive bladder, obstructive sleep apnea, diabetes mellitus, benign prostatic hyperplasia, congestive heart failure, and excessive evening fluid intake and treatment has been optimized for these conditions; **AND**
- VI. Individual has confirmed normal serum sodium level based on laboratory reference range within the previous 60 days.

Continuation requests for Nocdurna (desmopressin acetate) sublingual tablet may be approved if the following criteria are met:

- I. Individual has confirmed normal serum sodium level based on laboratory reference range since initiation of therapy; **AND**
- II. Individual has experienced a decrease in average number of nocturia episodes per night from baseline.

Requests for Nocdurna (desmopressin acetate) sublingual tablets may not be approved for the following:

- I. Individual is using during illnesses that can cause fluid or electrolyte imbalance; **OR**
- II. Individual has any of the following conditions:

- A. Hyponatremia or history of hyponatremia; **OR**
- B. Polydipsia; **OR**
- C. Concomitant use with loop diuretics or systemic or inhaled glucocorticoids; **OR**
- D. Estimated glomerular filtration rate (GFR) below 50 mL/min/1.73m²; **OR**
- E. Syndrome of inappropriate antidiuretic hormone secretion (SIADH) ; **OR**
- F. New York Heart Association (NYHA) Class II-IV congestive heart failure (CHF);
OR
- G. Uncontrolled hypertension; **OR**
- H. Primary nocturnal enuresis.

NOTE:

Nocdurna (desmopressin acetate) has a black box warning regarding the potential for hyponatremia, which may be life-threatening if severe. Nocdurna (desmopressin acetate) is contraindicated in those at risk for severe hyponatremia. Serum sodium should be normal before starting or resuming Nocdurna (desmopressin acetate). Serum sodium should be measured within seven days and one month after starting Nocdurna (desmopressin acetate), and periodically during treatment. Those 65 years of age and older should be more frequently monitored. Nocdurna (desmopressin acetate) may need to be temporarily or permanently discontinued if hyponatremia occurs.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 7, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.