Noctiva (desmopressin acetate) Intranasal Spray

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

Medications	Quantity Limit
Noctiva (desmopressin acetate) Intranasal Spray	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Noctiva (desmopressin acetate) intranasal spray 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 Noctiva (desmopressin acetate) intranasal spray 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 Noctiva (desmopressin acetate) intranasal spray 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/1.73m^2; **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:
Noctiva (desmopressin acetate) has a black box warning regarding the potential for hyponatremia, which may be life-threatening if severe. Noctiva is contraindicated in those at risk for severe hyponatremia. Serum sodium should be normal before starting or resuming Noctiva. Serum sodium should be measured within seven days and one month after starting Noctiva, and periodically during treatment. Those 65 years of age and older should be more frequently monitored. Noctiva 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.