MEDICAL MUTUAL®

Drug Policy

Policy:	**Noctiva (desmopressin acetate) nasal spray** **Nocdurna (desmopressin acetate) sublingual tablet**	**Annual Review Date:** **07/16/2020** **Last Revised Date:** **07/16/2020**

OVERVIEW

Noctiva and Nocdurna, a vasopressin analog, is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Nocturnal polyuria was defined in the Noctiva and Nocdurna clinical studies as nighttime urine production exceeding one-third of the 24-hour urine production. Before initiating Noctiva or Nocdurna, evaluate the patient for possible causes of nocturia, which include excessive fluid intake prior to bedtime. Also optimize the treatment of underlying conditions that may lead to nocturia. Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection if one has not been previously obtained.

POLICY STATEMENT

This policy involves the use of Noctiva and Nocdurna. Prior authorization is recommended for pharmacy benefit coverage of Noctiva and Nocdurna. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Noctiva and Nocdurna as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Noctiva and Nocdurna be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Noctiva and Nocdurna is recommended in those who meet the following criteria:

1. <u>Nocturia due to Nocturnal Polyuria- initial therapy</u>
Criteria. *Patient must meet the following criteria*

- **A.** Patient is awakening at least two times per night to void prior to desmopressin therapy; AND
- **B.** Patient is 50 years of age or older if requesting Noctiva or 18 years of age or older if requesting Nocdurna; AND
- **C.** Diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection and the nocturnal urine volume exceeds 33% of total 24-hour urine volume in patients 65 years of age or older OR the nocturnal urine volume exceeds 20% of total 24-hour urine volume in patients younger than 65 years; AND
- **D.** Patient does not have renal impairment below 50 mL/min/1.73 m^2; AND

E. Patient does not have any of the following: current or history of hyponatremia, syndrome of inappropriate antidiuretic hormone (SIADH), congestive heart failure (class II to IV for Noctiva, all classes for Nocdurna), polydipsia, or uncontrolled hypertension; AND
F. Patient is not using the requested medication along with a loop diuretic (e.g. furosemide) or systemic/inhaled corticosteroid; AND
G. Provider has ruled out all possible resolvable underlying causes of nocturia and identified the correct underlying pathophysiological cause of nocturia (such as bladder dysfunction, excessive nocturnal urine production including but not limited to obstructive sleep apnea, neurodegenerative disease, diabetes mellitus and insipidus, electrolyte deficiencies or excess, current medications, chronic kidney disease, etc.); AND
H. The medication is prescribed by or in consultation with a urologist, geriatrician, or endocrinologist; AND
I. The patient has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia (e.g. nighttime fluid restriction, avoidance of caffeine and alcohol, earlier timing of medications, leg elevation and/or use of compression stockings, etc.); AND
J. The patient has previously tried generic oral desmopressin acetate tablets and had an inadequate response, contraindication, or intolerance

2. <u>Nocturia due to Nocturnal Polyuria- continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient does not have renal impairment below 50 mL/min/1.73 m^2; AND
B. The patient does not have any of the following: current or history of hyponatremia, syndrome of inappropriate antidiuretic hormone (SIADH), congestive heart failure (class II to IV for Noctiva, all classes for Nocdurna), polydipsia, or uncontrolled hypertension; AND
C. Patient is not using the requested medication along with a loop diuretic (e.g. furosemide) or systemic/inhaled corticosteroids; AND
D. Patient's serum sodium has been monitored since desmopressin initiation and patient is not at risk for hyponatremia or currently has hyponatremia; AND
E. Prescriber states that the patient's nocturnal voids have been reduced in frequency since beginning on desmopressin therapy

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Noctiva and Nocdurna have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Use of Noctiva for Primary Nocturnal Enuresis.** Use of Noctiva is contraindicated for the treatment of patients with primary nocturnal enuresis. Reports of hyponatremia-related seizures have occurred in pediatric patients treated with other intranasal formulations of desmopressin. Use of Noctiva has not been studied in pediatric patients. Desmopressin tablets (DDAVP tablets) are indicated for the management of primary nocturnal enuresis in pediatric patients.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Weiss JP, Blaivas JG, Bliwise DL, et al. The evaluation and treatment of nocturia: a consensus statement. *BJU Int*. 2011;108:6-21. .
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5. Van Kerrebroeck P, Andersson KE. Terminology, epidemiology, etiology, and pathophysiology of nocturia. Neurourol Urodyn. 2014 Apr;33 Suppl 1:S2-5. doi: 10.1002/nau.22595.
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8. Desmopressin. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 8 July 2019. Accessed on 18 July 2019.