Desmopressin nasal and oral
Policy Number: C17861-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
09/01/2019	08/15/2019	08/15/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q4 2019 20191030C17861A

PRODUCTS AFFECTED:
DDAVP (oral and nasal) (generic) (desmopressin), Noctiva SUBL and EMUL (desmopressin)

*** STIMATE (desmopressin) - See Hemostatic Agents PA Criteria***

DRUG CLASS:
Vasopressin

ROUTE OF ADMINISTRATION:
Oral, intranasal

PLACE OF SERVICE:
Specialty Pharmacy

AVAILABLE DOSAGE FORMS:
Nasal:
Noctiva: 0.83 mcg/0.1 mL (3.8 g [DSC]); 1.66 mcg/0.1 mL (3.8 g), DDAVP: 0.01% (5 mL)
DDAVP Rhinal Tube: 0.01% (2.5 mL), Generic: 0.01% (5 mL)

Tablet: DDAVP: 0.1 mg, DDAVP: 0.2 mg [scored], Generic: 0.1 mg, 0.2 mg. Sublingual: Nocdurna: 27.7 mcg, 55.3 mcg

FDA-APPROVED USES: Antidiuretic replacement therapy in the management of central diabetes insipidus in adults and children ≥4 years, management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region, Management of primary nocturnal enuresis, either alone or as an adjunct to behavioral conditioning or other non-pharmacologic intervention

Nocturia (Noctiva): Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. Limitations of use: Has not been studied in patients <50 years of age.

Nocturia (Nocdurna): Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: central diabetes insipidus, nocturia, primary nocturnal enuresis

REQUIRED MEDICAL INFORMATION:

A. NOCTURIA OR PRIMARY NOCTURNAL ENURESIS:

1. Prescriber attests to a documented diagnosis for primary nocturnal enuresis
   AND
2. The patient does not have any of the following: hyponatremia or a history of uncorrected hyponatremia, moderate to severe renal impairment (creatinine clearance below 50 mL per min) or nephrogenic diabetes insipidus
   AND
3. Prescriber attests that primary underlying medical conditions of nocturia are managed such as: Psychogenic Polydipsia , Congestive heart failure or peripheral edema, diabetes mellitus, Gastroesophageal reflux disease (GERD) or nighttime cough, Obstructive sleep apnea (OSA), or Periodic limb movements/restless leg syndrome
   AND
4. Prescriber attests that ALL of the following non-pharmacologic interventions have been attempted or are contraindications for the patient: Reduction of overall fluid intake, reduction of evening consumption of diuretic fluids, including caffeine and alcohol, Avoiding use of nighttime diuretics, Treatment of peripheral edema by use of compression stockings or afternoon elevation of the legs, Avoidance of nocturnal hyperglycemia in patients with diabetes, Double-voiding prior to bedtime and pelvic floor muscle exercises.
   AND
5. Documentation patient has tried (4 week trial), failed or FDA labeled contraindication to ONE formulary antimuscarinic (ie oxybutynin) AND for women formulary vaginal estrogen product
   AND
6. Prescriber attests that patient does NOT have an underlying disease that would be made worse by fluid retention (eg, congestive heart failure, uncontrolled hypertension, increased intracranial pressure) OR a history of urinary retention
   AND
7. (a) FOR NOCTIVA, NOCDURNA AND DDVAP RHINAL TUBE: Documentation of a trial (of at least 2 weeks) and failure or labeled contraindication to DDVAP (desmopressin)-GENERIC tablets (ref. 7-12 to support off-label use)
   AND
   (b) Prescriber attests that patient's sodium concentration is normal before starting therapy and will be monitored as recommended within FDA label
   AND
   (c) intranasal formulations will not be used for nocturnal enuresis treatment in patients < 18 years of age

B. CENTRAL DIABETES INSIPIDUS:

1. Prescriber attests to a documented diagnosis of central diabetes insipidus
   AND
2. FOR DDVAP RHINAL TUBE REQUESTS: Documentation of a trial (of at least 2 weeks) and failure or labeled contraindication to DDVAP (desmopressin)-GENERIC tablets or nasal spray (0.01%)

DURATION OF APPROVAL: Initial Authorization 6 months , Continuation of Therapy: 12 months

QUANTITY:
Primary Nocturnal Enuresis/Nocturia: Dose does not exceed 0.6 mg/day. Noctiva: Not at risk for hyponatremia: 1.66 mcg in either nostril, At risk for hyponatremia: Initial: 0.83 mcg in either nostril Sublingual: Nocdurna: Females: 27.7 mcg once daily one hour before bedtime, Males: 55.3 mcg once daily one hour before bedtime

Central Cranial Diabetes Insipidus: Dose does not exceed: Tablet – 1.2 mg/day; Nasal spray/rhinal tube – 40 mcg/day

PRESCRIBER REQUIREMENTS: No requirement

AGE RESTRICTIONS:
Oral: ≥4 years of age
Rhinal tube (100 mcg/mL nasal solution) : ≥ 3 months of age
DDAVP nasal spray: ≥ 4 years of age
Noctiva: adults 50 to 64 years of age
Nocdurna: ≥ 18 years of age

GENDER:
Male and Female

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Documentation that the member has demonstrated a beneficial response to desmopressin, per the prescribing physician
AND
2. The member continues to have no contraindications to desmopressin

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of desmopressin oral and nasal are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Other contraindications include: Moderate to severe renal impairment (CrCl <50 mL/minute), concomitant use with loop diuretics or glucocorticoids, syndrome of inappropriate antidiuretic hormone (SIADH) secretion (known or suspected); illnesses that may cause fluid or electrolyte imbalance (eg, gastroenteritis, salt-wasting nephropathies, systemic infection); heart failure (Noctiva labeling specifies NYHA Class II to IV); uncontrolled hypertension

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND: None

APPENDIX: None

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