Original Effective Date: 09/01/2019
Current Effective Date: 09/01/2024
Last P&T Approval/Version: 07/31/2024
Next Review Due By: 07/2025
Policy Number: C17861-A

Desmopressin Nasal and Oral (DDAVP)

PRODUCTS AFFECTED

DDAVP (oral and nasal) (desmopressin), desmopressin (oral and nasal), Nocdurna SL (desmopressin)
*** STIMATE (desmopressin) - SEE HEMOSTATIC AGENTS MHI C14570-A***

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Central diabetes insipidus/Arginine vasopressin deficiency (AVP-D), Nocturia, Primary nocturnal enuresis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NOCTURIA OR PRIMARY NOCTURNAL ENURESIS:
1. (a) Documentation of diagnosis of primary nocturnal enuresis in a member 6 years of age or older
OR

(b) Documented diagnosis of nocturia
AND

2. Prescriber attests that member does not have 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 member: 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 members with diabetes, Double-voiding prior to bedtime and pelvic floor muscle exercises.
AND
5. Prescriber attests that member does NOT have an underlying disease that would be made worse by fluid retention (e.g., congestive heart failure, uncontrolled hypertension, increased intracranial pressure) OR a history of urinary retention
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to desmopressin acetate tablets or nasal spray include: moderate to severe renal impairment (CrCl below 50 mL/min), hypersensitivity to desmopressin, hyponatremia or a history of hyponatremia; Contraindications to Nocdurna include: Hyponatremia or a history of hyponatremia, polydipsia, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate below 50 mL/min/1.73 m2, Syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, heart failure, uncontrolled hypertension]
AND
7. FOR NOCDURNA AND NASAL SOLUTION REQUESTS:
   (a) Documentation of a trial (at least 2 weeks) and failure, or labeled contraindication, to desmopressin GENERIC tablets
   MOLINA REVIEWER NOTE: See references 8-13 to support off- label use.
   AND
   (b) Prescriber attests that member's sodium concentration is normal before starting therapy and will be monitored as recommended within FDA label

B. CENTRAL DIABETES INSIPIDUS/ARGININE VASOPRESSIN DEFICIENCY (AVP-D) (TABLETS, NASAL SOLUTION ONLY):
   1. Documentation of diagnosis of central diabetes insipidus/arginine vasopressin deficiency (AVP-D)
   AND
   2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to desmopressin acetate tablets, nasal spray include: moderate to severe renal impairment (CrCl below 50 mL/min), hypersensitivity to desmopressin, hyponatremia, or a history of hyponatremia]

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. Prescriber attests that the member continues to have no contraindications to desmopressin
   AND

3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

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

PRESCRIBER REQUIREMENTS:
No Requirement

AGE RESTRICTIONS:
Nasal Spray:
CENTRAL DIABETES INSIPIDUS/ARGININE VASOPRESSIN DEFICIENCY (AVP-D): 4 years of age and older
NOCTURIA/ENURESIS: 18 years of age and older

Nocdurna: 18 years of age and older

Tablets: No restriction

QUANTITY:
Primary Nocturnal Enuresis/Nocturia:
Tablet – Maximum 0.6 mg/day
Nasal spray – Maximum 40 mcg/day
Nocdurna: Females: 27.7 mcg once daily one hour before bedtime, Males: 55.3 mcg once daily one hour before bedtime

Central Diabetes Insipidus:
Tablet – Maximum 1.2 mg/day
Nasal spray– Maximum 40 mcg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral, sublingual, and intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, intranasal, sublingual

DRUG CLASS:
Vasopressin

FDA-APPROVED USES:
Desmopressin tablets: Indicated as antidiuretic replacement therapy in the management of central diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region; Indicated for the management of primary nocturnal enuresis, either alone or as an adjunct to behavioral conditioning or other non-pharmacologic intervention.
Limitation of use: Desmopressin is ineffective for the treatment of nephrogenic diabetes insipidus.

Desmopressin nasal spray (0.01%): Indicated as antidiuretic replacement therapy in the management of central diabetes insipidus in adults and pediatric patients 4 years of age and older.
Limitations of use: Desmopressin nasal spray is not indicated for treatment of nephrogenic diabetes insipidus, treatment of primary nocturnal enuresis, use in patients with conditions that compromise the intranasal route of administration (e.g., severe nasal congestion and blockage, nasal mucosa atrophy,

severe atrophic rhinitis, recent nasal surgery such as transsphenoidal hypophysectomy), use in patients with an impaired level of consciousness, use in patients requiring doses lass than 10mcg or doses that are not multiples of 10mcg.

Nocdurna*:* Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

COMPENDIAL APPROVED OFF-LABELED USES:
Desmopressin tablets for nocturia

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of desmopressin oral and nasal are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.
Contraindications to desmopressin oral and nasal include: Moderate to severe renal impairment (CrCl <50 mL/minute), hypersensitivity to desmopressin, hyponatremia or a history of hyponatremia.
Contraindications to Nocdurna include: Hyponatremia or a history of hyponatremia, renal impairment (eGFR <50 mL/minute/1.73 m2); polydipsia; concomitant use with loop diuretics or glucocorticoids (inhaled or systemic), syndrome of inappropriate antidiuretic hormone (SIADH) secretion (known or suspected); illnesses that may cause fluid or electrolyte imbalance (e.g., gastroenteritis, salt-wasting nephropathies, systemic infection); heart failure uncontrolled hypertension.

OTHER SPECIAL CONSIDERATIONS:
Nocdurna (desmopressin) sublingual tablets have a Black Boxed warning for Hyponatremia. Desmopressin can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death. Desmopressin is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids. Ensure serum sodium concentrations are normal before starting or resuming desmopressin. Measure serum sodium within 7 days and ~1 month after initiating therapy and periodically during treatment. More frequently monitor serum sodium in patients ≥65 years of age and in patients at increased risk of hyponatremia. If hyponatremia occurs, desmopressin may need to be temporarily or permanently discontinued.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
DDAVP SOLN 0.01%
DDAVP TABS 0.1MG
DDAVP TABS 0.2MG
Desmopressin Ace Spray Refrig SOLN 0.01%
Desmopressin Acetate Spray SOLN 0.01%
Desmopressin Acetate TABS 0.1MG
Desmopressin Acetate TABS 0.2MG
Nocdurna SUBL 27.7MCG
Nocdurna SUBL 55.3MCG

REFERENCES

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3. DDAVP Tablets (desmopressin) [prescribing information]. North York, Ontario: Ferring; July 2020.
4. Nocdurna (desmopressin acetate) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; November 2020.
5. Noctiva (desmopressin) [prescribing information]. Chesterfield, MO: Avadel Specialty Pharmaceuticals LLC; December 2017.
6. Desmopressin Nasal Spray [prescribing information]. Toronto, Ontario: Apotex Inc.; September 2022.
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15. Tomkins, M., Lawless, S., Martin-Grace, J., Sherlock, M., & Thompson, C. J. (2022). Diagnosis and Management of Central Diabetes Insipidus in Adults. The Journal of Clinical Endocrinology & Metabolism, 107(10). https://doi.org/10.1210/clinem/dgac381

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Age Restrictions Quantity Place of Administration Route of Administration References	Q3 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Age Restrictions References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file