

## **Clinical Policy: Desmopressin Acetate (DDAVP)**

**Reference Number: LA.PHAR.214**

**Effective Date:**

**Last Review Date: 06.21**

**Line of Business: Medicaid**

**Coding Implications**

**Revision Log**

**See [Important Reminder](#) at the end of this policy for important regulatory and legal information.**

### **Description**

**Desmopressin acetate (DDAVP®) is a synthetic vasopressin analog.**

### **FDA Approved Indication(s)**

**DDAVP is von Willebrand's disease (VWD; type I) with factor VIII levels greater than 5%**

- **Hemophilia A with factor VIII coagulant activity levels greater than 5%**

**DDAVP is also indicated for the management of central (cranial) diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.**

### **Limitation(s) of use:**

- **DDAVP is not indicated for the treatment of hemophilia A with factor VIII coagulant activity levels equal to or less than 5%, or for the treatment of hemophilia B, or in patients who have factor VIII antibodies.**
- **DDAVP is not indicated for the treatment of severe classic VWD (type I) and when there is evidence of an abnormal molecular form of factor VIII antigen.**
- **DDAVP is ineffective for the treatment of nephrogenic diabetes insipidus.**

### **Policy/Criteria**

**Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.**

**It is the policy of Louisiana Healthcare Connections that DDAVP injection is medically necessary when the following criteria are met:**

#### **I. Initial Approval Criteria**

##### **A. Polyuria and Central Diabetes Insipidus (must meet all):**

1. **Diagnosis of one of the following (a or b):**
  - a. **Central (cranial) diabetes insipidus;**
  - b. **Temporary polyuria and polydipsia following head trauma or surgery in the pituitary region;**
2. **Prescribed by or in consultation with an endocrinologist;**
3. **Age ≥ 12 years;**
4. **Request is for DDAVP injection;**

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5. Failure of desmopressin tablets, unless contraindicated, clinically significant adverse effects are experienced, or documentation supports inability to swallow tablets;

6. Dose does not exceed 4 mcg per day.

Approval duration:

Medicaid – 6 months

#### B. Congenital Hemophilia A (must meet all):

1. Diagnosis of congenital hemophilia A (factor VIII deficiency);
2. Prescribed by or in consultation with a hematologist;
3. Age  $\geq$  3 months;
4. Request is for DDAVP injection for one of the following uses (a, b, or c):
  - a. Control and prevention of bleeding episodes;
  - b. Perioperative management;
  - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
5. Factor VIII coagulant activity levels are  $> 5\%$ ;
6. Member does not have factor VIII antibodies;
7. Dose does not exceed (a or b):
  - a. DDAVP injection: 0.3 mcg/kg per dose;

Approval duration:

Medicaid – 6 months

#### C. Von Willebrand Disease (must meet all):

1. Diagnosis of VWD type 1 or type 2;
2. Prescribed by or in consultation with a hematologist;
3. Age  $\geq$  3 months;
4. Request is for DDAVP injection for one of the following uses (a, b, or c):
  - a. Control and prevention of bleeding episodes;
  - b. Perioperative management;
  - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
5. Factor VIII coagulant activity levels are  $> 5\%$ ;
6. Dose does not exceed (a or b):
  - a. DDAVP injection: 0.3 mcg/kg per dose;

Approval duration:

Medicaid – 6 months

#### D. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

## II. Continued Therapy

### A. All Indications in Section I (must meet all):

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1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a, b, c, or d):
  - a. DDAVP injection: 4 mcg per day for polyuria or diabetes insipidus and 0.3 mcg/kg per dose for hemophilia A or VWD;

Approval duration:  
Medicaid – 12 months

#### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized):  
LA.PMN.53 for Medicaid.

#### III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents;

#### IV. Appendices/General Information

##### Appendix A: Abbreviation/Acronym Key

DDAVP: 1-deamino-8-D-arginine vasopressin

FDA: Food and Drug Administration

VWD: von Willebrand disease

##### Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>desmopressin acetate oral tablets (DDAVP®)</u>	<u>0.05 mg PO BID, titrated to a maintenance dose in the range of 0.1-1.2 mg divided into 2- 3 daily doses as needed to obtain adequate antidiuresis</u>	<u>1.2 mg/day</u>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

##### Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - DDAVP injection: moderate to severe renal impairment (creatinine clearance < 50 mL/min), hyponatremia or a history of hyponatremia

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- **Boxed warning(s):**
  - **DDAVP injection**

#### Appendix D: General Information

#### V. Dosage and Administration

<u>Drug Name</u>	<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<b><u>Desmopressin injection (DDAVP)</u></b>	<b><u>Central diabetes insipidus</u></b>	<b><u>2 to 4 mcg IV or SC daily, usually in 2 divided doses</u></b>	<b><u>4 mcg/day</u></b>
	<b><u>Hemophilia A, VWD</u></b>	<b><u>0.3 mcg/kg IV or SC as needed</u></b>	<b><u>0.3 mcg/kg/dose</u></b>

#### VI. Product Availability

<u>Drug Name</u>	<u>Availability</u>
<b><u>Desmopressin injection (DDAVP)</u></b>	<b><u>Ampules: 4 mcg/mL (1 mL)</u></b> <b><u>Vials: 4 mcg/mL (10 mL)</u></b>

#### VII. References

1. **DDAVP Injection Prescribing Information**. Parsippany, NJ: Ferring Pharmaceuticals; September 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=651f6fee-a2c7-431b-8d5d-58b156c72244>. Accessed November 4, 2020.
2. **Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia*. Jan 2013; 19(1): e1-47.**
3. **Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations>. Accessed November 4, 2020.**
4. **Van Kerrebroeck P, Abrams P, Chaikin D et al. The standardisation of terminology in nocturia: Report from the standardization sub-committee of the International Continence Society. *Neurourol Urodyn* 2002; 21: 179.**
5. **MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders (Revised August 2020). MASC Document #263. Available at:**

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[https://www.hemophilia.org/sites/default/files/document/files/263\\_treatment.pdf](https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf).  
Accessed November 4, 2020.

#### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J2597</u>	<u>Injection, desmopressin acetate, per 1 mcg</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>
<u>Converted corporate to local policy</u>	<u>06.2021</u>

#### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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