

Clinical Policy: Desmopressin Acetate (DDAVP Injection)

Reference Number: CP.PHAR.214

Effective Date: 05/16

Last Review Date: 05/17

[Coding Implications](#)

[Revision Log](#)

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

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for desmopressin acetate (DDAVP Injection®).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that desmopressin acetate - 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. Prescribed by or in consultation with an endocrinologist;
2. Prescribed as antidiuretic replacement therapy for one of the following conditions:
 - a. Central (cranial) diabetes insipidus;
 - b. Temporary polyuria and polydipsia following head trauma or surgery in the pituitary region;
3. Creatinine clearance is ≥ 50 mL/min and serum sodium concentration is ≥ 35 meq/L.

Approval duration: 6 months

B. Congenital Hemophilia A (must meet all):

1. Prescribed by or in consultation with a hematologist;
2. Age ≥ 3 months;
3. Diagnosis of congenital hemophilia A (factor VIII deficiency);
4. Request is for one of the following:
 - a. Control and prevention of bleeding episodes;
 - b. Perioperative management;
 - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
5. Does not have factor VIII antibodies;
6. Factor VIII coagulant activity levels are $>5\%$;
7. Creatinine clearance is ≥ 50 mL/min and serum sodium concentration is ≥ 35 meq/L.

Approval duration: 6 months

C. Von Willebrand Disease (must meet all):

1. Prescribed by or in consultation with a hematologist;
2. Age ≥ 3 months;
3. Diagnosis of von Willebrand disease (VWD), Type 1 or Type 2 (*off-label*);
4. Factor VIII coagulant activity levels are $>5\%$;
5. Request is for one of the following:

- a. Control and prevention of bleeding episodes;
 - b. Perioperative management;
 - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
6. Creatinine clearance is ≥ 50 mL/min and serum sodium concentration is ≥ 35 meq/L.

Approval duration: 6 months

D. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. All indications listed in section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 6 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Desmopressin is a synthetic analogue of the antidiuretic hormone arginine vasopressin. In a dose dependent manner, desmopressin increases cyclic adenosine monophosphate in renal tubular cells which increases water permeability resulting in decreased urine volume and increased urine osmolality. Desmopressin also increases plasma levels of von Willebrand factor (VWF), factor VIII, and t-PA contributing to a shortened activated partial thromboplastin time and bleeding time.

Formulations:

- Solution, Intravenous, as acetate:
 - DDAVP: 4 mcg/mL (1 mL)
 - DDAVP: 4 mcg/mL (10 mL)
 - Generic: 4 mcg/mL (1 mL, 10 mL)
- Solution, Intravenous, as acetate [preservative free]:
 - Generic: 4 mcg/mL (1 mL)

FDA Approved Indications:

DDAVP (desmopressin acetate injection) is a synthetic vasopressin analogue/intravenous formulation indicated for:

- Central (cranial) diabetes insipidus:

Antidiuretic replacement therapy in the management of central (cranial) diabetes insipidus and for management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

Limitations of use: DDAVP is ineffective for the treatment of nephrogenic diabetes insipidus.

- **Hemophilia A:**

For patients with hemophilia A with factor VIII coagulant activity levels > 5%. DDAVP will often maintain hemostasis in patients with hemophilia A during surgical procedures and postoperatively when administered 30 minutes prior to scheduled procedure. DDAVP will also stop bleeding in hemophilia A patients with episodes of spontaneous or trauma induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.

Limitations of use: DDAVP is not indicated for the treatment of hemophilia A with factor VIII coagulant activity levels $\leq 5\%$, or for the treatment of hemophilia B, or in patients who have factor VIII antibodies. In certain clinical situations, it may be justified to try DDAVP in patients with factor VIII levels between 2% to 5%; however, these patients should be carefully monitored.

- **Von Willebrand disease (Type 1):**

For patients with mild to moderate classic VWD (Type 1) with factor VIII levels > 5%. DDAVP will often maintain hemostasis in patients with mild to moderate VWD during surgical procedures and postoperatively when administered 30 minutes prior to the scheduled procedure. DDAVP will usually stop bleeding in mild to moderate von Willebrand's patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.

Limitations of use: Those VWD patients who are least likely to respond are those with severe homozygous VWD with factor VIII coagulant activity and factor VIII von Willebrand factor antigen levels < 1%. Other patients may respond in a variable fashion depending on the type of molecular defect they have. Bleeding time and factor VIII coagulant activity, ristocetin cofactor activity, and VWF antigen should be checked during administration of DDAVP to ensure that adequate levels are being achieved. DDAVP is not indicated for the treatment of severe classic von Willebrand's disease (Type 1) and when there is evidence of an abnormal molecular form of factor VIII antigen.

Appendices

Appendix A: Abbreviation Key

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

t-PA: tissue plasminogen activator

VWD: von Willebrand disease

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.

CLINICAL POLICY
Desmopressin

HCPCS Codes	Description
J2597	Injection, desmopressin acetate, per 1 mcg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Specific approval periods are added: 6 months initial/renewal. Added type 2 vWD indication. Age restrictions added per PI. Stimite removed as it is no longer on PA. Specialist reviewed.	04/16	05/16
Trauma/surgery is separated from diabetes insipidus (DI). The nephrogenic DI restriction is removed. Age restriction is removed. The designation “mild to moderate” is removed from VWD. Safety information is removed with the exception of CrCl; current hyponatremia as a contraindication is added. Wording for uses and approval periods for all blood factor products made consistent across all policies. Efficacy statement added to renewal criteria. Hemophilias are specified as “congenital” versus “acquired” across blood factor policies where indicated. Reviewed by specialist- hematology/internal medicine	04/17	05/17

References

1. DDAVP Injection Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals; April 2015. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=651f6fee-a2c7-431b-8d5d-58b156c72244>. Accessed April 26, 2017.
2. Desmopressin: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 25, 2017.
3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia*. Jan 2013; 19(1): e1-47.
4. 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 April 28, 2017.

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or

CLINICAL POLICY

Desmopressin

administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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