Clinical Policy: Desmopressin acetate (DDAVP, Stimate)
Reference Number: HIM.PA.61
Effective Date: 12/14
Last Review Date: 08/17
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Desmopressin acetate (DDAVP®, Stimate®) is a synthetic analog of the natural pituitary hormone 8-arginine vasopressin (ADH), an antidiuretic hormone.

FDA approved indication
DDAVP injection is indicated:
- For the treatment of central (cranial) diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region
- For the treatment of patients with mild to moderate classic von Willebrand's disease (Type I) with factor VIII levels greater than 5%
- For the treatment of hemophilia A with factor VIII coagulant activity levels greater than 5%

Stimate nasal spray is indicated:
- For the treatment of hemophilia A with Factor VIII coagulant activity levels greater than 5%
- For the treatment of mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Central Diabetes Insipidus (must meet all)**:**
1. Diagnosis of central diabetes insipidus;
2. Prescribed by or in consultation with an endocrinologist;
3. Documentation that the member is unable to swallow tablets or oral therapy provides inadequate control;
4. Request is for DDAVP injection;
5. Dose does not exceed 4 mcg/day injection.

Approval duration: 12 months

B. Hemophilia A (must meet all)**:**
1. Diagnosis of hemophilia A;
2. Factor VIII coagulant level > 5% ;
3. Dose does not exceed the following (a or b):
   a. DDAVP injection: 0.3 mcg/kg per procedure;
   b. Stimate: 300 mcg/day.

Approval duration: 12 months

C. Von Willebrand's Disease (must meet all)**:**
1. Diagnosis of von Willebrand's disease (type 1);
2. Factor VIII coagulant level > 5%;
3. Dose does not exceed the following (a or b):
   a. DDAVP injection: 0.3 mcg/kg per procedure;
   b. Stimate: 300 mcg/day.

Approval duration: 12 months

D. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. Central Diabetes Insipidus (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 4 mcg/day injection;

Approval duration: 12 months

B. Hemophilia A (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. DDAVP injection: 0.3 mcg/kg per procedure;
   b. Stimate: 300 mcg/day.

Approval duration: 12 months

C. Von Willebrand's Disease (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. DDAVP injection: 0.3 mcg/kg per procedure;
   b. Stimate: 300 mcg/day.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key

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

FDA: Food and Drug Administration

V. References

1. Stimate Prescribing Information. King of Prussia, PA: CSL Behring LLC; June 2013. Available at: http://labeling.cslbehring.com/PI/US/Stimate/EN/Stimate-Prescribing-Information.pdf. Accessed April 13, 2017.
2. DDAVP injection Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; April 2015. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=651f6fee-a2c7-431b-8d5d-58b156c72244. Accessed January 31, 2017.
3. DDAVP tablet Prescribing information. Parsippany, NJ: Ferring Pharmaceuticals Inc.; December 2014. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6d55baa9-2b62-469c-93ae-3909ab249332. Accessed January 31, 2017.
4. Desmopressin acetate Drug Monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 31, 2017.
6. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format. Streamlined guideline. Removed PA requirement from desmopressin tablets.	08/16	08/16
Converted to new template Updated references Removed age limits as age is not an absolute contraindication	4/17	08/17

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

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 Health Plan-level administrative policies and procedures.

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.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.