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PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** desmopressin acetate (DDAVP®)
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PPA.02
EFFECTIVE DATE: 11/06	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 08/16, 07/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/08, 05/08, 02/10, 02/11, 02/12, 02/13, 02/14, 06/15

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Desmopressin is a synthetic analog of the natural pituitary hormone arginine vasopressin, an antidiuretic hormone affecting renal water conservation.

Brand: desmopressin acetate (generic): 0.1mg, 0.2mg tablets; 0.1mg/ml (0.01% solution, 10mcg/spray) nasal solution pump or Rhinal tube delivery 4mcg/ml injection

FDA Labeled Indications:

1. Central Diabetes Insipidus: The tablet form for antidiuretic therapy in the management of this condition and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
2. Primary nocturnal enuresis: The tablet form is indicated for the management of primary nocturnal enuresis used alone or as an adjunct to behavioral conditioning or other non-pharmacologic intervention.

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Criteria for Approval:

Tablets

A. Patient has documented diagnosis of Central Diabetes Insipidus.
B. Patients ≥ 6 years of age, with primary nocturnal enuresis require a trial of liquid management intake for at least 3 months prior to approval.

Spray

Patients with Central Diabetes Insipidus who are unable to swallow tablets or where oral therapy has shown to provide inadequate control and in the judgment of an endocrinologist, the spray is thought to be more effective for the patient.

Approval:

Central Diabetes Insipidus

Initial Approval: 12 months.
Continued Approval: 12 months. If documented response and no adverse events has been documented.

Primary Nocturnal Enuresis

Initial Approval: 6 months.
Continued Approval: 6 months. Requires another trial and failure of liquid management intake for at least 3 months.

Special Instructions

> DDAVP is not effective in the treatment of nephrogenic diabetes insipidus.
> Please see prescribing information for dosing, warnings, precautions.
> DDAVP intranasal formulations are no longer indicated for the treatment of primary nocturnal enuresis and should not be used in hyponatremic patients or patients with a history of hyponatremia.
> PNE treatment with desmopressin *tablets* should be interrupted during acute illnesses that may lead to fluid and/or electrolyte imbalance.
> Desmopressin IV indicated for Central Diabetes Insipidus, Hemophilia A,

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and von Willebrand's Disease (Type I)
☐ Stimate 1.5mg/ml nasal spray (>=11 months of age) Indicated for Hemophilia A and von Willebrand's Disease (Type 1) usually given prior to surgical procedures

References:

1. Removal of the indication for treatment of primary noctural enuresis for desmopressin nasal spray. December, 2007. http://products.sanofi-aventis.us/DDAVPTablet/DDAVP Dear HCP.pdf
2. DDAVP prescribing information. Accessed December 2012. http://products.sanofi.us/DDAVPTablet/DDAVP Tablets.pdf
3. American Family Physician, Nocturnal Enuresis, May, 2006. http://www.aafp.org/afp/2006/0501/p1611.html
4. Desmopressin acetate monograph. Facts and Comparisons. Accessed January 2014.

Revision Log	
Revision	**Date**
Under "FDA Indications" "Primary nocturnal enuresis:" specify tablets only, not nasal spray.	02/08
Under the "Criteria for Approval" "tablets" section (1) replace "one of the above conditions" with "Central Diabetes Insipidus." and (2) add "b. Patients with primary nocturnal enuresis require a trial of a wet alarm and management of liquid intake for at least 3 months prior to approval."	02/08
Add the following section under "Criteria for Approval": Spray: Patients with Central Diabetes Insipidus who are unable to swallow tablets.	02/08
Add "for Central Diabetes Insipidus, Hemophilia A and von	02/08

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Willebrand Disease." after "Authorization for 12 months" in the "Approval" section.	
Add the following in the "Approval" section: "Authorization for 6 months for primary nocturnal enuresis. Reauthorization for 6 months requires an annual trial of a wet alarm and management of liquid intake for at least 3 months."	02/08
Add the following two bullet points to "Special Instructions": "DDAVP intranasal formulations are no longer indicated for the treatment of primary nocturnal enuresis and should not be used in hyponatremic patients or patients with a history of hyponatremia." and "PNE treatment with desmopressin *tablets* should be interrupted during acute illnesses that may lead to fluid and/or electrolyte imbalance."	02/08
Add the following to the Spray Criteria of Approval: or where oral therapy has shown to provide inadequate control and in the judgment of an endocrinologist, the spray is thought to be more effective for the patient.	05/08
Updated the "Description" section.	02/10
Updated reference section to reflect current literature search.	02/10
No changes.	02/11
Add an age limit for patient use for primary nocturnal enuresis indication.	02/11
Updated reference section to reflect current literature search.	02/12
Add availability of IV formulation in the Brand section	02/13
Add the following in Special Instructions: "Desmopressin IV indicated for Central Diabetes Insipidus, Hemophilia A, and von Willebrand's Disease (Type I) and Stimate 1.5mg/ml nasal spray (>=11 months of age) Indicated for Hemophilia A and von Willebrand's Disease (Type 1) usually given prior to surgical procedures."	2/13
Updated reference section to reflect current literature search.	02/13
Updated reference section to reflect current literature search.	02/14

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Removed requirement of wet alarm	06/15
Annual Review. No Changes	08/16
Annual Review. No Changes	07/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file