

MEDICAL POLICY STATEMENT		
Effective Date	Next Annual Review Date	Last Review / Revision Date
6/24/2013	7/18/2015	7/18/2014
Author		
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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

desmopressin acetate (Stimate) nasal spray

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the desmopressin acetate medication (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. POLICY

CareSource will approve the use of desmopressin acetate (Stimate) nasal spray and consider its use as medically necessary when the following criteria have been met for:

- Hemophilia A
- von Willebrand's Disease (Type I)

All other uses of desmopressin acetate (Stimate) nasal spray are considered experimental/investigational and therefore, will follow CareSource's off label policy.

Hemophilia A

Stimate® Nasal Spray is indicated for patients with hemophilia A with Factor VIII coagulant activity levels greater than 5%. Desmopressin acetate will also stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.

Prior Authorization Criteria:

- Documented diagnosis of hemophilia A (factor VIII deficiency)

Factor VIII coagulant activity levels must be greater than 5%

AND

- Appropriate change in coagulation profile following a test dose of intranasal administration of desmopressin acetate (Stimate).
 - Bleeding time
 - Factor VIII coagulant activity

AND

- 11 months of age or older

AND

- Prescribed by a hematologist or under the direction of a hematologist

von Willebrand's Disease

Stimate® Nasal Spray is indicated for patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%. Desmopressin acetate will also stop bleeding in mild to moderate von Willebrand's disease patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia.

Prior Authorization Criteria:

- Documented diagnosis of mild to moderate von Willebrand's disease (Type 1).

Lab values: Von Willebrand factor antigen (VWF:Ag), VWF ristocetin cofactor activity (VWF:RCo), bleeding time.

AND

- Appropriate change in coagulation profile following a test dose of intranasal administration of desmopressin acetate (Stimate).
 - Bleeding time
 - Factor VIII coagulant activity
 - Ristocetin cofactor activity
 - Von Willebrand factor antigen

AND

- 11 months of age or older

AND

- Prescribed by a hematologist or under the direction of a hematologist

NOTE: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

For Medicare

Please refer to the CareSource policy

National and Local Coverage Determinations

Conditions of Coverage

J-Code	J-3490 (NDC code required)
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Place Of Service	Office, Outpatient, Home **Preferred place of service is in the home. Note: The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Coverage may be approved for up to 1 year. Coverage for re-treatment requires meeting current initial diagnosis criteria only and evidence of a beneficial response.

D. REVIEW / REVISION HISTORY

6/24/2013
7/2014

E. REFERENCES

Stimate Nasal Spray [package insert]. King of Prussia, PA: CSL Behring LLC.; D.

American Society of Health System Pharmacists. AHFS Drug Information. Bethesda, MD. Electronic Version 2009. <http://www.medicinescomplete.com/mc/ahfs/current>. (September 27, 2012).

National Heart, Lung, and Blood Institute (2007). The Diagnosis, Evaluation, and Management of von Willebrand Disease. (NIH Publication No. 08-5832). Available online: <http://www.nhlbi.nih.gov/guidelines/vwd>. (September 27, 2012)

Chittur M, Kulkarni R (2009). Hemophilia and related bleeding disorders. In RE Rakel, ET Bope, eds., Conn's Current Therapy, pp. 419-425. Philadelphia: Saunders Elsevier.

Friedman KD, Rodgers GM (2014). Inherited coagulation disorders. In JP Greer et al., eds., Wintrobe's Clinical Hematology, 13th ed., vol. 2, pp. 1379-1424. Philadelphia: Lippincott Williams and Wilkins.

Hillman RS, et al. (2011). Hemophilia and other intrinsic pathway defects. In RS Hillman, et al. eds., Hematology in Clinical Practice, 5th ed., chap. 32, pp. 368-379. New York: McGraw-Hill.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.



7/20/2014

Chief Medical Officer

Date



6/26/2014

Director of Specialty Pharmacy

Date