PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
11/23/2016	11/24/2017	12/15/2016
Policy Name		**Policy Number**
Hemophilic Agents		SRx-0053
Policy Type		
Medical	Administrative	**PHARMACY** Reimbursement

Pharmacy Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that 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. Medically necessary services also include those services defined in any Evidence of Coverage documents, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Pharmacy Policy Statement. If there is a conflict between the Pharmacy Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination

Contents of Policy

A. INTRODUCTION

Hemophilia is a rare, hereditary, bleeding disorder in which blood does not clot normally. People born with hemophilia have little or no clotting factor, which is a protein needed for normal blood clotting.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient, Home	**Preferred place of service is in the home.** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

2. Coverage Criteria

CareSource will approve the use of the agents listed below and consider use medically necessary when the criteria have been met for each condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

- Advate [Antihemophilic Factor (Recombinant), Plasma/Albumin Free Method]
- Adynovate [Antihemophilic Factor (Recombinant), PEGylated]

- Afstyla [Antihemophilic Factor (Recombinant), Single Chain]
- Alphanate [Antihemophilic Factor/von Willebrand Factor Complex (Human)]
- Alprolix[Coagulation Factor IX (Recombinant), Fc Fusion Protein]
- Benefix [Coagulation Factor IX (Recombinant)]
- Eloctate [Antihemophilic Factor (Recombinant), Fc Fusion Protein]
- Helixate FS [Antihemophilic Factor (Recombinant), Formulated with Sucrose]
- Hemofil M [Antihemophilic Factor (Human) (AHF), Method M, Monoclonal Purified]
- Idelvion [Coagulation Factor IX (Recombinant), Albumin Fusion Protein (rIX-FP)]
- Ixinity [coagulation factor IX (recombinant)]
- Kogenate FS [Antihemophilic Factor [Recombinant], Formulated with Sucrose]
- Kogenate FS Bio-Set [Antihemophilic Factor [Recombinant], Formulated with Sucrose]
- Kovaltry [Antihemophilic Factor (Recombinant)]
- Monoclate-P [Factor VIII:C Pasteurized Monoclonal Antibody Purified]
- Mononine [Coagulation Factor IX (Human)]
- Novoeight [Antihemophilic Factor (Recombinant)]
- NovoSeven [Coagulation Factor VIIa (Recombinant)]
- Nuwiq [Antihemophilic Factor (Recombinant)]
- Obizur [Antihemophilic Factor (Recombinant), Porcine Sequence]
- Recombinate [Antihemophilic Factor (Recombinant)]
- Rixubis [Coagulation Factor IX (Recombinant)]
- Xyntha [Antihemophilic Factor (Recombinant), Plasma/Albumin Free
- Xyntha Solofuse [Antihemophilic Factor (Recombinant), Plasma/Albumin Free]

Drug	Coverage criteria for Hemophilia A or Hemophilia B:
Advate, Adynovate, Afstyla, Alphanate, Alprolix, Benefix, Eloctate, Helixate FS, Hemofil M, Idelvion, Ixinity, Kogenate FS, Kogenate FS Bio-Set, Kovaltry, Monoclate-P, Mononine, Novoeight, NovoSeven, Nuwiq, Obizur, Recombinate, Rixubis, Xyntha, Xyntha Solofuse	1) Diagnosis of Hemophilia A or Hemophilia B 2) Member's weight in kilograms, measured within the last 90 days, must be documented on medication prior authorization request.

All other uses of the above agents are considered experimental/investigational; and therefore, will follow CareSource's off-label policy.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Condition	Dosage and Quantity Limit of Afstyla
Routine Hemophilic Prophylaxis	No more than 50 Units/Kg (+/- 10% for kg) 3 times weekly for maintenance treatment

Condition	Dosage and Quantity Limit of Adynovate
Routine Hemophilic Prophylaxis	No more than 50 units per kg (+/- 10% for kg) 2 times a week.

Condition	Dosage and Quantity Limit of Alprolix
Routine Hemophilic Prophylaxis	No more than 100 units per kg (+/- 10% for kg) once every 10 days

Condition	Dosage and Quantity Limit of Eloctate
Routine Hemophilic Prophylaxis	No more than 65 IU/kg (+/- 10% for kg) at 3 day intervals

Condition	Dosage and Quantity Limit of Helixate FS
Routine Hemophilic Prophylaxis	No more than 25 units per kg (+/- 10% for kg) 3 times a week.

Condition	Dosage and Quantity Limit of Kogenate
Routine Hemophilic Prophylaxis	No more than 25 units per kg (+/- 10% for kg) 3 times a week.

Condition	Dosage and Quantity Limit of Novoeight
Routine Hemophilic Prophylaxis	No more than 60 units per kg (+/- 10% for kg) 3 times a week.

Condition	Dosage and Quantity Limit of Nuwiq
Routine Hemophilic Prophylaxis	No more than 50 units per kg 4 times a week.

4. Authorization Period

Drug	Approval Period
All medications listed above	The initial authorization period is 3 month Continued treatment may be considered when updated request is submitted with an updated weight. A reauthorization after will be placed for a 3 month period **ALL** authorizations are subject to continued eligibility.

5. Coding

HCPCS	
J7199	Hemophilia clotting factor, not otherwise classified

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
12/15/2016	Policy issued

F. REFERENCES

1. National Institutes of Health. National Heart, lung, and Blood Institute. “What is Hemophilia?”July 13th 2013.
2. Prescribing information. Eloctate. Biogen. Cambridge, MA 02142. 08/2016
3. Prescribing Information. Helixate FS. CSL Behring 5/2016
4. Prescribing Information. Kogenate FS. Bayer HealthCare LLC. Whippany, NJ 07981. 05/2016
5. Prescribing Information. NovoEight. Novo Nordisk. 800 Scudders Mill Road, Plainsboro, NJ 08536. 11/2016
6. Prescribing Information. Nuwiq. Octapharma AB. Elersvagen 40 SE-112 75, Sweden. 09/2015.
7. Prescribing Information. Adynovate. Baxalta US Inc. Westlake Village, CA 91362. 07/2016.
8. Prescribing Information. Alprolix, Biogen Inc. Cambridge, MA 02142. 07/2016
9. Prescribing Information. Afstyla. CSL Behring LLC. Kankakee, IL 60901. 05/2016

10. Prescribing Information. Monoclate-P. CSL Behring LLC. Kankakee, IL 60901
11. Prescribing Information. Koate-DVI. Defrion Biopharma, Inc. 485 Massachusetts Avenue. Cambridge, MA 02139. 06/2011
12. Prescribing Information. Advate. Baxter Healthcare Corporation. Westlake Village, CA 91362.
13. Prescribing Information. NovoSeven RT. Novo Nordisk 2880 Bagsvaerd, Denmark. 03/2016.
14. Prescribing Information. Recombinate. Baxter Healthcare Corporation. Westlake Village, CA 91362.
15. Prescribing Information. Xyntha. Wyeth Pharmaceuticals Inc. Philadelphia, PA 19101. 03/2015.
16. Prescribing Information. Obizur. Baxter Healthcare Corporation. Westlake Village, CA 91362. 10/2014.
17. Prescribing Information. Benefix. Wyeth Pharmaceuticals Inc. Philadelphia, PA 19101.
18. Prescribing Information. Humate-P. CSL Behing LLC. Kankakee, IL 60901. 06/2014.
19. Prescribing Inormation. AlphaNine SD. Grifols Biologicals Inc. Los Angeles, CA 90032. 08/2010
20. Prescribing Information. Ixinity. Cangene biopharma, Inc. 111 South Paca St. Baltimore, MD 21230-2526.
21. Prescribing Information. Rixubis. Baxalta US Inc. Westlake Village, CA 91362
22. Prescribing Information. Mononine. CSL Behring LLC. Kankakee, IL 60901. 04/2016.
23. Prescribing Information. Idelvion. CSL Behring LLC. Kankakee, Il 60901. 03/2016.

The Pharmacy Policy detailed above has received due consideration and is approved.

Independent medical review – 12/13/2016