

Hemophilia and Blood Factor Products

Policy Number: C15607-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
02/2019	02/2019	02/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
See below	RxPA	Q2 2019

PRODUCTS AFFECTED:

Plasma Factor VIII concentrates: Hemofil M, Monoclate P, Koate DVI (J7190)

Recombinant Factor VIII concentrates: Advate (J7192), Helixate FS(J7192), Kogenate FS(J7192), Kovaltry (J7211), Novoeight (J7182), Nuwiq (J7209), Obizur(J7188), Recombinate(J7192), Xyntha (J7185) , Jivi (J7199)

Prolonged Half-Life Recombinant Factor VIII concentrates: Adynovate, Afstylia (J7210), Eloctate (J7205)

Human Plasma-Derived Factor VIII Concentrates that Contain Von Willebrand Factor: Alphanate (J7186), Humate P (J7187), Wilate (J7183)

Plasma Factor IX concentrates: Alphanine SD(J7193), Mononine(J7193), Profilnine SD J7194), Rixubis (J7200)

Recombinant Factor IX concentrates: Rixubis, Benefix, Ixinity (J7195)

Prolonged Half-life Recombinant Factor IX concentrates: Rebinyn (J7203), Alprolix (J7201), Idelvion (J7202)

Coagulation Factor X (Plasma-derived) agent: Coagadex (J7175)

Factor XIII Concentrate (Recombinant) agent: Tretten

Factor XIII Concentrate (Plasma-derived) agent: Corifact

Coagulation Factor VIIa (Recombinant) agent: NovoSeven RT (J7189)

Anti-inhibitor Coagulant Complex (Plasma-derived) agent: FEIBA NF

Von Willebrand factor (Recombinant) agent: Vonvendi

DRUG CLASS: Antihemophilic Products

ROUTE OF ADMINISTRATION:

Intravenous

PLACE OF SERVICE:

Specialty Pharmacy

AVAILABLE DOSAGE FORMS:

Advate SOLR 1000UNIT
 Advate SOLR 1500UNIT
 Advate SOLR 2000UNIT
 Advate SOLR 250UNIT

Advate SOLR 3000UNIT
 Advate SOLR 4000UNIT
 Advate SOLR 500UNIT
 Adynovate SOLR 1000UNIT

Adynovate SOLR 1500UNIT
 Adynovate SOLR 2000UNIT
 Adynovate SOLR 250UNIT
 Adynovate SOLR 3000UNIT

Adynovate SOLR 500UNIT
 Adynovate SOLR 750UNIT
 Afstylar KIT 1000UNIT
 Afstylar KIT 1500UNIT
 Afstylar KIT 2000UNIT
 Afstylar KIT 2500UNIT
 Afstylar KIT 250UNIT
 Afstylar KIT 3000UNIT
 Afstylar KIT 500UNIT
 Alphanate/VWF
 Complex/Human SOLR
 1000UNIT
 Alphanate/VWF
 Complex/Human SOLR
 1500UNIT
 Alphanate/VWF
 Complex/Human SOLR
 2000UNIT
 Alphanate/VWF
 Complex/Human SOLR
 250UNIT
 Alphanate/VWF
 Complex/Human SOLR
 500UNIT
 AlphaNine SD SOLR
 1000UNIT
 AlphaNine SD SOLR
 1500UNIT
 AlphaNine SD SOLR
 500UNIT
 Alprolix SOLR 1000UNIT
 Alprolix SOLR 2000UNIT
 Alprolix SOLR 250UNIT
 Alprolix SOLR 3000UNIT
 Alprolix SOLR 4000UNIT
 Alprolix SOLR 500UNIT
 BeneFIX KIT 1000UNIT
 BeneFIX KIT 2000UNIT
 BeneFIX KIT 250UNIT
 BeneFIX KIT 3000UNIT
 BeneFIX KIT 500UNIT
 Coagadex SOLR 250UNIT
 Coagadex SOLR 500UNIT
 Corifact KIT 1000-
 1600UNIT
 Eloctate SOLR 1000UNIT
 Eloctate SOLR 1500UNIT
 Eloctate SOLR 2000UNIT
 Eloctate SOLR 250UNIT
 Eloctate SOLR 3000UNIT
 Eloctate SOLR 4000UNIT
 Eloctate SOLR 5000UNIT

Eloctate SOLR 500UNIT
 Eloctate SOLR 6000UNIT
 Eloctate SOLR 750UNIT
 Feiba SOLR
 Fibryga SOLR
 Helixate FS KIT 1000UNIT
 Helixate FS KIT 2000UNIT
 Helixate FS KIT 250UNIT
 Helixate FS KIT 3000UNIT
 Helixate FS KIT 500UNIT
 Hemlibra SOLN 30MG/ML
 Hemlibra SOLN
 60MG/0.4ML
 Hemlibra SOLN
 105MG/0.7ML
 Hemlibra SOLN 150MG/ML
 Hemofil M SOLR 1000UNIT
 Hemofil M SOLR 1700UNIT
 Hemofil M SOLR 250UNIT
 Hemofil M SOLR 500UNIT
 Humate-P SOLR 1000-
 2400UNIT
 Humate-P SOLR 250-
 600UNIT
 Humate-P SOLR 500-
 1200UNIT
 Idelvion SOLR 1000UNIT
 Idelvion SOLR 2000UNIT
 Idelvion SOLR 250UNIT
 Idelvion SOLR 3500UNIT
 Idelvion SOLR 500UNIT
 Ixinity SOLR 1000UNIT
 Ixinity SOLR 1500UNIT
 Ixinity SOLR 2000UNIT
 Ixinity SOLR 250UNIT
 Ixinity SOLR 3000UNIT
 Ixinity SOLR 500UNIT
 Jivi SOLR 1000UNIT
 Jivi SOLR 2000UNIT
 Jivi SOLR 3000UNIT
 Jivi SOLR 500UNIT
 Kcentra KIT 1000UNIT
 Kcentra KIT 500UNIT
 Koate SOLR 1000UNIT
 Koate SOLR 250UNIT
 Koate SOLR 500UNIT
 Koate-DVI SOLR 1000UNIT
 Koate-DVI SOLR 250UNIT
 Koate-DVI SOLR 500UNIT
 Kogenate FS KIT 1000UNIT
 Kogenate FS KIT 2000UNIT
 Kogenate FS KIT 250UNIT

Kogenate FS KIT 3000UNIT
 Kogenate FS KIT 500UNIT
 Kovaltry SOLR 1000UNIT
 Kovaltry SOLR 2000UNIT
 Kovaltry SOLR 250UNIT
 Kovaltry SOLR 3000UNIT
 Kovaltry SOLR 500UNIT
 Monoclate-P KIT 1000UNIT
 Mononine SOLR 1000UNIT
 Novoeight SOLR 1000UNIT
 Novoeight SOLR 1500UNIT
 Novoeight SOLR 2000UNIT
 Novoeight SOLR 250UNIT
 Novoeight SOLR 3000UNIT
 Novoeight SOLR 500UNIT
 NovoSeven RT SOLR 1MG
 NovoSeven RT SOLR 2MG
 NovoSeven RT SOLR 5MG
 NovoSeven RT SOLR 8MG
 Nuwiq KIT 1000UNIT
 Nuwiq KIT 2000UNIT
 Nuwiq KIT 2500UNIT
 Nuwiq KIT 250UNIT
 Nuwiq KIT 3000UNIT
 Nuwiq KIT 4000UNIT
 Nuwiq KIT 500UNIT
 Nuwiq SOLR 1000UNIT
 Nuwiq SOLR 2000UNIT
 Nuwiq SOLR 2500UNIT
 Nuwiq SOLR 250UNIT
 Nuwiq SOLR 3000UNIT
 Nuwiq SOLR 4000UNIT
 Nuwiq SOLR 500UNIT
 Obizur SOLR 500UNIT
 Profilnine SD SOLR
 1000UNIT
 Profilnine SD SOLR
 1500UNIT
 Profilnine SD SOLR
 500UNIT
 Profilnine SOLR 1000UNIT
 Profilnine SOLR 1500UNIT
 Profilnine SOLR 500UNIT
 Rebinyn SOLR 1000UNIT
 Rebinyn SOLR 2000UNIT
 Rebinyn SOLR 500UNIT
 Recombinate SOLR 1241-
 1800UNIT
 Recombinate SOLR 1801-
 2400UNIT
 Recombinate SOLR 220-
 400UNIT

Recombinant SOLR 401-800UNIT	Tretten SOLR 2000-3125UNIT	Xyntha Solofuse KIT 1000UNIT
Recombinant SOLR 801-1240UNIT	Vonvendi SOLR 1300UNIT	Xyntha Solofuse KIT 2000UNIT
RiaSTAP SOLR	Vonvendi SOLR 650UNIT	Xyntha Solofuse KIT 250UNIT
Rixubis SOLR 1000UNIT	Wilate KIT 1000-1000UNIT	Xyntha Solofuse KIT 3000UNIT
Rixubis SOLR 2000UNIT	Wilate KIT 500-500UNIT	Xyntha Solofuse KIT 500UNIT
Rixubis SOLR 250UNIT	Xyntha KIT 1000UNIT	
Rixubis SOLR 3000UNIT	Xyntha KIT 2000UNIT	
Rixubis SOLR 500UNIT	Xyntha KIT 250UNIT	
	Xyntha KIT 500UNIT	

FDA-APPROVED USES: control and prevention of Hemophilia A hemorrhage, control and prevention of Hemophilia B hemorrhage, hemorrhage in von Willebrand disorder, treatment of hemorrhage in congenital fibrinogen deficiency, acquired factor VIII deficiency disease, congenital factor VII deficiency, Glanzmann's thrombasthenia, hemophilia, with inhibitors to Factor VIII or Factor IX

OBIZUR ONLY: routine prophylaxis in Hemophilia A, surgical procedure prophylaxis in Hemophilia A, control of hemorrhage in Hemophilia A

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency)

REQUIRED MEDICAL INFORMATION:

A. FOR ALL INDICATIONS:

1. Documentation of diagnosis and the requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
AND
2. Documentation of the prescription drug, dose and directions along with requested assay and quantity dated within the last 12 months
AND
3. Documentation prescriber has verified that the number of on-hand doses (prn doses) in members home doses not exceed three doses

DURATION OF APPROVAL: Initial authorization: 1 months, Continuation of therapy: 3 months

QUANTITY:

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a hematologist or specialist at a Hemophilia treatment center

(https://www2a.cdc.gov/ncbddd/htcweb/Dir_Report/Dir_Search.asp)- Directory

AGE RESTRICTIONS: None

GENDER:

Male and female

CONTINUATION OF THERAPY:**A. FOR ALL INDICATIONS:**

1. Documentation of the current number of on-hand doses and number of bleeding episodes since the previous authorization
AND
2. For prophylactic dosing, coverage will not be granted for additional doses if greater than a 7-day supply is on hand unless on-demand dosing is medically necessary
AND
3. If inhibitors are present, Bethesda assay titers are required
AND
4. For treatment with ITI, continued therapy is no longer considered medically necessary if either of the following criteria are met: Inhibitor levels become undetectable (negative Bethesda assay) or recovery of Factor VIII levels after infusion are normal (defined as at least 66% of expected level and a half-life of >6 hours are considered sufficient normal pharmacokinetic responses to characterize a complete tolerance)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Hemophilia and Blood Factor Products are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: Hemophilia and von Willebrand's disease are the most common congenital bleeding disorders. The two main types of hemophilia are A and B. Hemophilia A (classic hemophilia) has low levels of clotting factor VIII, or antihemophilic factor (AHF). Hemophilia B (Christmas disease) has low levels of clotting factor IX. AHF is an endogenous glycoprotein necessary for blood clotting and hemostasis. It is a cofactor that is necessary for factor IX to activate factor X in the intrinsic pathway.

The main treatment for hemophilia is replacement of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B). Administration of clotting factors is indicated for hemophilia when a bleeding episode arises (demand treatment) or when bleeding is anticipated or likely (prophylactic treatment).

Hemophilia A and B are classified as mild, moderate or severe, depending on the amount of clotting factor VIII or IX in the blood.

Mild hemophilia: 5 – 40 percent of normal clotting factor

Moderate hemophilia: 1 – 5 percent of normal clotting factor

Severe hemophilia: Less than 1 percent of normal clotting factor

APPENDIX: None

REFERENCES:

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3. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2016.
4. Eloctate [package insert]. Cambridge, MA: Biogen Idec Inc.; January 2017.
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6. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
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