

PHARMACY POLICY STATEMENT

Kentucky Medicaid

DRUG NAME	<u>Antihemophilic agents</u> : Advate, Adynovate, Afstyla, Alphanate and Alphanate/VWF Complex/Human, AlphaNine SD, Alprolix, Bebulin and Bebulin VH, BeneFIX, Coagadex, Corifact, Eloctate, Factor VIII SD (Human), Feiba, Feiba NF, and Feiba VH Immuno, Fibryga, Helixate and Helixate FS, Hemlibra, Hemofil M, Humate-P and Humate-P Human, Idelvion, Ixinity, Jivi, Kcentra, Koate, Koate-DVI, and Koate-HP, Kogenate, Kogenate FS, and Kogenate FS Bio-Set, Kovaltry, Monoclate-P, Mononine, Novoeight, NovoSeven and NovoSeven RT, Nuwiq, Obizur, Profilnine and Profilnine SD, Rebinyn, Recombinate, RiaSTAP, Rixubis, Tretten, Vonvendi, Wilate, Xyntha and Xyntha Solofuse
BILLING CODE	J7170-Hemlibra; J7192-Advate, Helixate, Kogenate, Recombinate; J7190-Hemofil M, Koate, Monoclate-P; J7193-Alphanate, Mononine; J7194-Bebulin, Profilnine; J7195-BeneFIX, Ixinity; J7175-Coagadex; J7177-Fibryga; J7178-RiaSTAP; J7179-Vonvendi; J7180-Corifact; J7181-Tretten; J7182-Novoeight; J7183-Wilate; J7185-Xyntha; J7186-Alphanate; J7187-Humate-P; J7188-Obizur; J7189-NovoSeven; J7198-Feiba; J7200-Rixubis; J7201-Alprolix; J7202-Idelvion; J7205-Eloctate; J7207-Adynovate; J7209-Nuwiq; J7210-Afstyla; J7211-Kovaltry; J3590-Kcentra; J7199-Jivi; J7203 and J7199-Rebinyn
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient/Home
COVERAGE REQUIREMENTS	Prior Authorization Required QUANTITY LIMIT— see package insert for each individual drug
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

All antihemophilic agents will only be considered for coverage under the medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEMOPHILIA

For **initial** authorization:

1. Member has diagnosis of Hemophilia A or Hemophilia B; AND
2. Member's weight in kilograms, measured within the last 180 days, is documented on medication prior authorization request.
3. **Dosage allowed:** Per package insert of individual drug.

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. Refer to the product package insert for dosing, administration and safety guidelines.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member’s updated measurement of weight in kilograms is documented on medication prior authorization request; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers antihemophilic agents not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
12/15/2016	Policy issued.
06/12/2018	Policy placed in a new format. Initial authorization length increased to 6 months.
10/05/2018	New drug Jivi added to the list of antihemophilic agents.

References:

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3. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc; March 2017.
4. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; Sept 2017.
5. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; June 2014.
6. Alphanine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; March 2017.
7. Alprolix [package insert]. Cambridge, MA: Biogen Inc.; November 2017.
8. Bebulin VH [package insert]. Westlake Village, CA: Baxalta US Inc; July 2012.
9. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; June 2017.
10. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; No date.
11. Corifact [package insert]. Kankakee, IL: CSL Behring LLC; Sept 2017.
12. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; Dec 2017.
13. Feiba® [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Nov 2013.
14. Feiba® NF [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Feb 2011.
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16. Helixate® FS [package insert]. Kankakee, IL: CSL Behring LLC.; May 2014.
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19. Humate-P® [package insert]. Kankakee, IL: CSL Behring LLC.; Aug 2013.
20. Idelvion® [package insert]. Kankakee, IL: CSL Behring LLC.; March 2016.
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22. Kcentra® [package insert]. Kankakee, IL: CSL Behring LLC.; Dec 2013.
23. Koate-DVI® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2012.
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25. Kovaltry [package insert]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
26. Monoclate-P® [package insert] Kankakee, IL: ZLB Behring LLC.; Aug 2004
27. Mononine® [package insert]. Kankakee, IL: CSL Behring LLC.; Feb 2013.
28. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2018.



29. Novoseven® RT [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; May 2014.
30. NuwiQ® [package insert]. Hoboken, NJ: Octapharma USA Inc.; Sept 2015.
31. Obizur® [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Oct 2014
32. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2010.
33. Rebinyn [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; May 2017.
34. Recombinate® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Dec 2010.
35. RiaSTAP® [package insert] Kankakee, IL: CSL Behring LLC.; Dec 2011.
36. Rixubis [package insert]. Westlake Village, CA: Baxalta US Inc.; Sept 2014.
37. Tretten® [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; Apr 2014.
38. VonVendi® [package insert]. Westlake Village, CA: Baxalta US Inc.; Dec 2015.
39. Wilate® [package insert]. Hoboken, NJ: Octapharma USA Inc.; Aug 2010.
40. Xyntha® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; Oct 2014.
41. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.

Effective date: 12/13/2018

Revised date: 10/05/2018