CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Antihemophilic agents: Advate, Adynovate, Afstyla, Alphanate and Alphanate/VWF Complex/Human, AlphaNine SD, Alprolix, Bebulin and Bebulin VH, BeneFIX, Coagadex, Corifact, Eloctate, Esperoct, 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-Alpolix; J7202-Idelvion; J7205-Eloctate; J7207-Adynovate; J7209-Nuwiq; J7210-Afstyla; J7211-Kovaltry; J3590-Kcentra; J7199-Jivi; J7203 and J7199-Rebinyn; J7199-Esperoct
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/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 FACTOR REPLACEMENT

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; AND
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.

HEMLIBRA

For **initial** authorization:
4. Member has diagnosis of Hemophilia A; AND
5. Congenital factor VIII deficiency confirmed by blood coagulation testing; AND
6. Member's weight in kilograms, measured within the last 180 days, is documented on medication prior authorization request; AND
7. If request is for Hemlibra for member with factor VIII inhibitors, member must meet the following:
   a) Chart notes with documented positive test for inhibitors (titer >/= 0.6 BU/mL [Bethesda unit per milliliter]); OR
8. If request is for Hemlibra for member without factor VIII inhibitors, member must meet the following:
   a) Member has history of frequent bleeds (≥ 5 bleeds in the previous 24 weeks) documented in chart notes while on prophylactic factor therapy; AND
9. Prophylactic use of bypassing agents (e.g., Feiba, NovoSeven RT, Obizur, etc.) are discontinued the day before starting Hemlibra; AND
10. Prophylactic use of factor replacements are discontinued after loading dose period is finished. (Note: Members on extended half-life products (e.g. Eloctate) for prophylactic AND/OR on-demand therapy prior to Hemlibra induction will be transitioned to short half-life products (e.g. Advate) after loading dose period is finished.)
11. **Dosage allowed:** Per package insert.

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**:
3. Member's updated measurement of weight in kilograms is documented on medication prior authorization request; AND
4. 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.
08/06/2019	New drug Esperoct added to the list of antihemophilic agents.

10/19/2019	Policy updated to include Hemlibra criteria.

References:

1. National Institutes of Health. National Heart, lung, and Blood Institute. “What is Hemophilia?” Available at: https://www.nhlbi.nih.gov/health-topics/hemophilia.
2. Advate [package insert]. Westlake Village, CA: Baxalta US Inc; Nov 2016.
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.
15. Feiba® VH [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; Apr 2005
16. Helixate® FS [package insert]. Kankakee, IL: CSL Behring LLC.; May 2014.
17. Hemlibra® [package insert]. South San Francisco, CA: Genentech, Inc.; Nov 2017
18. Hemofil® M [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; April 2012.
19. Humate-P® [package insert]. Kankakee, IL: CSL Behring LLC.; Aug 2013.
20. Idelvion® [package insert]. Kankakee, IL: CSL Behring LLC.; March 2016.
21. Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC; April 2018.
22. Kcentra® [package insert]. Kankakee, IL: CSL Behring LLC.; Dec 2013.
23. Koate-DVI® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2012.
24. Kogenate™ FS [package insert]. Tarrytown, NY: Bayer Healthcare; May 2014.
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.
42. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February, 2019.
43. ClinicalTrials.gov Identifier: NCT02847637. A Clinical Trial to Evaluate Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Participants Without Inhibitors (HAVEN 3). Available at: https://clinicaltrials.gov/ct2/show/NCT02847637.
44. Malcom E. Bypassing Agents. Hemophilia news today. Available at: https://hemophilianewstoday.com/bypassing-agents/.
45. Ng HJ, Lee LH. Recombinant activated clotting factor VII (rFVIIa) in the treatment of surgical and spontaneous bleeding episodes in hemophilic patients. *Vasc Health Risk Manag*. 2006;2(4):433–440. doi:10.2147/vhrm.2006.2.4.433.
46. Mahlangu J, Oldenburg J, Paz-Patel I, et al. Emicizumab prophylaxis in patients who have hemophilia A without inhibitors [supplementary appendix appears online]. N Engl J Med 2018;379:811-822. https://www.nejm.org/doi/pdf/10.1056/NEJMoa1803550.

47. Pipe S. Emicizumab subcutaneous dosing every 4 weeks is safe and efficacious in the control of bleeding in persons with haemophilia A with and without inhibitors – Results from the phase 3 HAVEN 4 study. Presented at the World Federation of Hemophila World Congress in Glasgow, Scotland; May 20–24, 2018. WFH Oral Presentation.
48. Protocol for Haven 3 Trial: Emicizumab prophylaxis in patients who have hemophilia A without inhibitors. 2018. Available at https://www.nejm.org/doi/suppl/10.1056/NEJMoa1803550/suppl_file/nejmoa1803550_protocol.pdf.

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