CareSource

PHARMACY POLICY STATEMENT **Georgia 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 (emicizumab)

For **initial** authorization:
1. Member has diagnosis of Hemophilia A, with congenital factor VIII deficiency confirmed by blood coagulation testing; AND
2. Medication is being prescribed by or in consultation with a hematologist; AND
3. Member's weight in kilograms, measured within the last 180 days, is documented on medication prior authorization request; AND
4. 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
5. For member without factor VIII inhibitors, member must have severe hemophilia A (Factor VIII level <1%) AND meet **one** of the following:
   a) Poor and/or frequent venous access AND risk outweighs benefit for obtaining a port or an alternative route of administration;
   b) Clinical documentation that prior prophylaxis with factor VIII (e.g., Advate, Adynovate, Eloctate, etc.) was ineffective for the prevention of bleeding episodes;
   c) Prescriber attested that member is not a candidate for factor VIII and the clinical rationale is strongly supported by chart notes; AND
6. Bypassing agents (e.g., Feiba, NovoSeven RT, Obizur, etc.) are discontinued the day before starting Hemlibra (if applicable); AND
7. Prophylactic use of factor replacements are discontinued after loading dose period is finished. Note: Factor VIII may be used as on-demand therapy for breakthrough bleeding.
8. **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**:
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.
08/06/2019	New drug Esperoct added to the list of antihemophilic agents.
10/19/2019	Policy updated to include Hemlibra criteria.
08/01/2020	Hemlibra criteria updated to include hematologist. Requirement changed for members without Factor VIII inhibitors to align better with current practice and clinical trials.

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