GEORGIA DEPARTMENT OF COMMUNITY HEALTH

GEORGIA MEDICAID FEE-FOR-SERVICE
HEMOPHILIA TREATMENT PA SUMMARY

Preferred	Non-Preferred
Factor VIII Recombinant Products	
Advate (factor VIII albumin-free recombinant, hamster murine) Kogenate FS (factor VIII recombinant, hamster murine) Kovaltry (factor VIII recombinant, hamster murine) Novoeight (factor VIII, recombinant, hamster murine) Nuwiq (factor VIII recombinant, simoctocog alfa) Xyntha (factor VIII albumin-free recombinant, hamster murine)	Recombinate (factor VIII recombinant, bovine hamster murine)
Factor VIII Recombinant Long-Acting Products	
Afstyla (factor VIII recombinant, single chain)	Adynovate (factor VIII recombinant, pegylated) Altuviiio [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] Eloctate (factor VIII recombinant, Fc fusion protein) Esperoct (factor VIII recombinant, glycopegylated) Jivi (factor VIII recombinant, pegylated-aucl)
Factor IX Recombinant Products	
Benefix (factor IX, recombinant, hamster)	Ixinity (factor IX recombinant, hamster) Rixubis (factor IX, recombinant, hamster)
Factor IX Recombinant Long-Acting Products	
Rebinyn (factor IX recombinant, glycopegylated)	Alprolix (factor IX recombinant, Fc fusion protein) Idelvion (factor IX recombinant, albumin fusion protein)
Factor von Willebrand Products	
Alphanate (Antihemophilic Factor/von Willebrand Factor Complex [Human]) Wilate (von Willebrand Factor/Coagulation Factor VIII Complex [Human])	Humate-P (Antihemophilic Factor/von Willebrand Factor Complex [Human]) Vonvendi (von Willebrand Factor [Recombinant])
Other Factor Products	

Corifact (factor XIII concentrate human) Hemlibra (emicizumab-kxwh)	FEIBA (anti-inhibitor coagulant complex) Novoseven RT (factor VIIa, recombinant) Sevenfact (factor VIIa, recombinant-jncw) Tretten (factor XIII A-subunit recombinant)

The drug names above include all available formulations under the same primary name.

LENGTH OF AUTHORIZATION: 1 year

NOTES:

- **The criteria details below are for the outpatient pharmacy program.** If a medication is being administered in a physician's office or clinic, then the medication must be billed through the DCH physician services program and not the outpatient pharmacy program. Information regarding the physician services program is located at www.mmis.georgia.gov.
- Dispensing amount for all factor recombinant products must be within *three percent aggregate* of the prescribed target dose.
- All current users of non-preferred products will be issued a prior authorization approval for continuation of therapy, as the Department of Community Health (DCH) coordinates with providers to optimize treatment.
- For patients receiving factor VIII or factor IX products for prophylaxis *and* breakthrough bleeding episodes, two separate prescriptions (one for prophylaxis and one for on-demand treatment) are required.

PA CRITERIA:

Adynovate, Altuviiio, Eloctate, Esperoct, Jivi and Recombinate

- For members with a diagnosis of hemophilia A (congenital factor VIII deficiency), prescriber must submit a written letter of medical necessity stating the reasons the preferred products, Advate, Afstyla, Alphanate, Hemlibra, Kogenate FS, Kovaltry, Novoeight, Nuwiq and Xyntha, are not appropriate for the member.
- Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Alprolix, Idelvion, Ixinity and Rixubis

- For members with a diagnosis of hemophilia B (congenital factor IX deficiency or Christmas disease), prescriber must submit a written letter of medical necessity stating the reasons the preferred products, Benefix and Rebinyn, are not appropriate for the member.
- Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Humate-P

- For members with a diagnosis of von Willebrand disease (vWD), prescriber must submit a written letter of medical necessity stating the reasons the preferred products, Alphanate and Wilate, are not appropriate for the member.
- For members with a diagnosis of hemophilia A (congenital factor VIII deficiency), prescriber must submit a written letter of medical necessity stating the reasons the preferred products, Advate, Afstyla, Alphanate, Kogenate FS, Hemlibra, Kovaltry, Novoeight, Nuwiq and Xyntha, are not appropriate for the member.

- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Vonvendi

- ❖ For members with a diagnosis of von Willebrand disease, prescriber must submit a written letter of medical necessity stating the reasons the preferred products, Alphanate and Wilate, are not appropriate for the member.
- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

FEIBA

- ❖ Approvable for members with a diagnosis of hemophilia A (congenital factor VIII deficiency) who have a documented factor VIII inhibitor titer of ≥5 Bethesda Units [BU]/mL, require routine prophylaxis to prevent or reduce the frequency of bleeding episodes and have had an inadequate response, developed inhibitors, allergy/hypersensitivity, contraindication, drug-drug interaction or intolerable side effect to the preferred product, Hemlibra.
- ❖ Approvable for members with a diagnosis of hemophilia B (congenital factor IX deficiency or Christmas disease) who have a documented factor IX inhibitor titer of ≥5 Bethesda Units [BU]/mL and require routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- ❖ Must be prescribed by or in consultation with a physician associated with a Hemophilia Treatment Center or a physician experienced in treating hemophilic patients with inhibitors.
- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Novoseven RT

- ❖ Approvable for members with a diagnosis of hemophilia A (congenital factor VIII deficiency) who have a documented factor VIII inhibitor titer of ≥5 Bethesda Units [BU]/mL, require routine prophylaxis to prevent or reduce the frequency of bleeding episodes and have had an inadequate response, developed inhibitors, allergy/hypersensitivity, contraindication, drug-drug interaction, or intolerable side effect to the preferred product, Hemlibra
- ❖ Approvable for members with a diagnosis of hemophilia B (congenital factor IX deficiency or Christmas disease) who have a documented factor IX inhibitor titer of ≥5 Bethesda Units [BU]/mL and require routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- ❖ For members with inhibitors, must be prescribed by or in consultation with a physician associated with a Hemophilia Treatment Center or a physician experienced in treating hemophilic patients with inhibitors.
- ❖ Approvable for members with a diagnosis of congenital factor VII deficiency or acquired hemophilia.
- ❖ Approvable for members with a diagnosis of Glanzmann's thrombasthenia who are refractory to or are not a candidate for platelet transfusions.
- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Sevenfact

- ❖ For members with a diagnosis of hemophilia A (congenital factor VIII deficiency) who have a documented factor VIII inhibitor titer of ≥5 Bethesda Units [BU]/mL, prescriber must submit a

written letter of medical necessity stating the reasons Hemlibra and Novoseven RT are not appropriate for the member.

- ❖ For members with a diagnosis of hemophilia B (congenital factor IX deficiency or Christmas disease) who have a documented factor IX inhibitor titer of ≥5 Bethesda Units [BU]/mL, prescriber must submit a written letter of medical necessity stating the reasons Novoseven RT is not appropriate for the member.
- ❖ Must be prescribed by or in consultation with a physician associated with a Hemophilia Treatment Center or a physician experienced in treating hemophilic patients with inhibitors.
- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

Tretten

- ❖ For members with a diagnosis of factor XIII A-subunit deficiency, prescriber must submit a written letter of medical necessity stating the reasons the preferred product, Corifact, is not appropriate for the member.
- ❖ Requests for reasons not cited above may be submitted with a letter of medical necessity, which will be reviewed on a case-by-case basis by a healthcare professional.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827.**

PREFERRED DRUG LIST:

- For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

PA AND APPEAL PROCESS:

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Pharmacy and click on Other Documents, then select the most recent quarters QLL list.