Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

ANTIHEMOPHILIA AGENTS

I. Requirements for Prior Authorization of Antihemophilia Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antihemophilia Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihemophilia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being prescribed the Antihemophilia Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; **AND**

5. Does not have a history of a contraindication to the requested medication; **AND**

6. For a non-preferred extended half-life factor VIII replacement agent, **one** of the following:

   a. Has documentation of failure to achieve clinical goals with the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   b. Has a documented history of a contraindication to or intolerance of the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   c. **Both** of the following:

      i. Has a current history (within the past 90 days) of being prescribed the same non-preferred extended half-life factor VIII replacement agent
      ii. Has documentation from the prescriber of a medical reason why the beneficiary should continue to use the non-preferred extended half-life factor VIII replacement agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent);

See the Preferred Drug List (PDL) for the list of preferred Antihemophilia Agents at: https://papdl.com/preferred-drug-list;

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AND

7. For a non-preferred extended half-life factor IX replacement agent, **one** of the following:

   a. Has documentation of failure to achieve clinical goals with the preferred extended half-life factor IX replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   b. Has a documented history of a contraindication to or intolerance of the preferred extended half-life factor IX replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   c. **Both** of the following:

      i. Has a current history (within the past 90 days) of being prescribed the same non-preferred extended half-life factor IX replacement agent
      ii. Has documentation from the prescriber of a medical reason why the beneficiary should continue to use the non-preferred extended half-life factor IX replacement agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent);

   See the PDL for the list of preferred Antihemophilia Agents at: https://papdl.com/preferred-drug-list;

   AND

8. For a bypassing agent (e.g., FEIBA, NovoSeven RT), **one** of the following:

   a. For use for routine prophylaxis, **one** of the following:

      i. **Both** of the following:

         a) Has a diagnosis of hemophilia A with inhibitors

         b) **One** of the following:

            (i) Has documentation of failure to achieve clinical goals with Hemlibra (emicizumab),
            (ii) Has documentation from the prescriber of a medical reason why Hemlibra (emicizumab) cannot be used,
            (iii) Has a current history (within the past 90 days) of being prescribed the same bypassing agent for routine prophylaxis,

      ii. Has a diagnosis of hemophilia B with inhibitors

   b. For uses other than for routine prophylaxis (e.g., episodic/on-demand treatment, intermittent/periodic prophylaxis), **one** of the following:

      i. Has a diagnosis of hemophilia A with inhibitors
      ii. Has a diagnosis of hemophilia B with inhibitors;

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AND

9. For all other non-preferred Antihemophilia Agents, **one** of the following:

   a. Has documentation of failure to achieve clinical goals with the preferred Antihemophilia Agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   b. Has a documented history of a contraindication to or intolerance of the preferred Antihemophilia Agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

   c. **Both** of the following:

      i. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antihemophilia Agent
      ii. Has documentation from the prescriber of a clinical reason why the beneficiary should continue to use the non-preferred agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent);

   See the PDL for the list of preferred Antihemophilia Agents at: https://papdl.com/preferred-drug-list;

   AND

10. For Hemlibra (emicizumab), **one** of the following:

   a. Has a diagnosis of hemophilia A with inhibitors

   b. **Both** of the following:

      i. Has a diagnosis of severe hemophilia A

      ii. **One** of the following:

         a) Has documentation of failure to achieve clinical goals using routine prophylaxis with factor VIII replacement,
         b) Has a documented history of a contraindication to or intolerance of routine prophylaxis with factor VIII replacement (e.g., vascular access issues, previous history of inhibitors, etc.),
         c) Has a current history (within the past 90 days) of being prescribed Hemlibra (emicizumab).

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

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FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTIHEMOPHILIA AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Antihemophilia Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the requested Antihemophilia Agent; **AND**

2. Is being prescribed the Antihemophilia Agent for an indication that is included in FDA-approved package labeling OR a medically accepted indication; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; **AND**

5. Does not have a history of a contraindication to the requested medication.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihemophilia Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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ANTIHEMOPHILIA AGENTS PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	Total # of pgs: _____	Prescriber name:
Name of office contact:		Specialty:
Contact's phone number:		NPI: / State license #:
LTC facility contact/phone:		Street address:
Beneficiary name:		Suite #: / City/State/Zip:
Beneficiary ID#:	DOB:	Phone: / Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other

CLINICAL INFORMATION.

Drug #1 requested:	Strength & package size:	
Directions:	Quantity:	Duration:
Drug #2 requested:	Strength & package size:	
Directions:	Quantity:	Duration:
Diagnosis *(submit documentation)*:	Dx code (*required*):	
Is the medication being prescribed by a hematologist or hemophilia treatment center practitioner?	☐Yes	☐No

Complete the section(s) below applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

INITIAL REQUESTS

- ☐For HEMLIBRA (emicizumab):
  - ☐Has a diagnosis of severe hemophilia A AND
    - ☐Failed to achieve clinical goals with or has a contraindication or intolerance to routine FVIII replacement prophylaxis
      - ☐Has been using Hemlibra in the past 90 days
  - ☐Has a diagnosis of severe hemophilia A with inhibitors
- ☐For a BYPASSING AGENT (eg, FEIBA NF, Novoseven):
  - ☐For routine prophylaxis:
    - ☐Has hemophilia A with inhibitors AND *(check all that apply)*:
      - ☐Failed to achieve clinical goals with Hemlibra
      - ☐Has a medical reason why Hemlibra cannot be used
      - ☐Has been using the requested bypassing agent for routine prophylaxis within the past 90 days
    - ☐Has hemophilia B with inhibitors
  - ☐For use other than routine prophylaxis (e.g., episodic/on-demand treatment, intermittent/periodic prophylaxis):
    - ☐Has hemophilia A with inhibitors OR has hemophilia B with inhibitors
- ☐For a non-preferred FACTOR VIII, FACTOR IX, or VWF:
  - ☐Has been using the requested product within the past 90 days AND has a medical reason to continue using the requested product
  - ☐Failed to achieve clinical goals with or has a contraindication or intolerance to the preferred FVIII, FIX, or FVIII/VWF products *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*

RENEWAL REQUESTS

- ☐Experienced a positive clinical response since starting the requested medication

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: