Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 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 prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; **AND**
4. Does not have a contraindication to the requested medication; **AND**
5. 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 contraindication or an intolerance to 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;

    AND
6. 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 contraindication or an intolerance to 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

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

a. Has a diagnosis of hemophilia A with inhibitors and at least **one** of the following:

i. **Both** of the following:

a) Is using the requested medication for routine prophylaxis

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. Is using the requested medication for episodic/on-demand treatment or intermittent/periodic prophylaxis

b. Has a diagnosis of **one** of the following:

i. Hemophilia B with inhibitors,
ii. Acquired hemophilia,
iii. Congenital factor VII deficiency,
iv. Glanzmann's thrombasthenia;

AND

8. 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 contraindication or an intolerance to the preferred Antihemophilia Agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,

c. Has a diagnosis for which no preferred Antihemophilia Agents are appropriate,

d. **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

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

   a. Has a diagnosis of congenital hemophilia A with inhibitors,
   b. Has a diagnosis of severe congenital hemophilia A,
   c. Has a diagnosis of congenital hemophilia A and a history of at least 1 spontaneous episode of bleeding into a joint or other serious bleeding event.

   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.

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 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 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 *(form effective 1/8/2024)*

☐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:		City/State/Zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION.

Drug #1 requested:	Strength & package size:	
Directions:	Quantity:	Refills:
Drug #2 requested:	Strength & package size:	
Directions:	Quantity:	Duration:
Diagnosis *(submit documentation)*:	Dx code (*required*):	
Is the medication 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

1. Request is for HEMLIBRA (emicizumab):
- ☐Has a diagnosis of severe congenital hemophilia A
- ☐Has a diagnosis of congenital hemophilia A with inhibitors
- ☐Has a diagnosis of congenital hemophilia A and a history of at least 1 spontaneous joint bleed or other serious bleeding event

2. Request is for a BYPASSING AGENT (eg, FEIBA NF, NovoSeven, Sevenfact):
- ☐Has hemophilia A with inhibitors AND:
  - ☐Is using the requested medication for episodic/on-demand treatment OR intermittent/periodic prophylaxis
  - ☐Is using the requested medication for routine prophylaxis AND:
    - ☐Failed to achieve clinical goals with Hemlibra (emicizumab)
    - ☐Has a medical reason why Hemlibra (emicizumab) cannot be used
    - ☐Has been using the requested bypassing agent for routine prophylaxis within the past 90 days
- ☐Has hemophilia B with inhibitors
- ☐Has acquired hemophilia
- ☐Has congenital factor VII deficiency
- ☐Has Glanzmann's thrombasthenia

3. Request is for a non-preferred FACTOR VIII, FACTOR IX, or VWF:
- ☐Both of the following:
  - ☐Has been using the requested medication within the past 90 days
  - ☐Has a medical reason to continue using the requested medication
- ☐Failed to achieve clinical goals with or has a contraindication or an intolerance to the preferred FVIII, FIX, or FVIII/VWF medications with the same half-life (standard v. extended half-life), if applicable. *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*
- ☐Has a diagnosis for which no preferred Antihemophilia Agents are appropriate.

RENEWAL REQUESTS

☐Experienced a positive clinical response since starting the requested medication

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: