Clinical Policy: Antihemophilia Agents

Reference Number: PHW.PDL.713
Effective Date: 01/01/2020
Last Review Date: 11/2025

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Antihemophilia Agents are **medically necessary** when the following criteria are met:

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 member:

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 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 drug; **AND**

5. 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 drug 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 drug 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;

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 member's diagnosis or indication,

   b. Has a contraindication or intolerance to the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the member'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 member 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);

   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 member's diagnosis or indication,

   b. Has a contraindication or intolerance to the preferred extended half-life factor IX replacement agent(s) approved or medically accepted for the member'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 member 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);

AND

AND

8. For all other non-preferred factor replacemnet 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 member's diagnosis or indication,

   b. Has a contraindication or intolerance to the preferred Antihemophilia Agent(s) approved or medically accepted for the member'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 member 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);

   AND

9. For a non-facor replacement Antihemophilia Agent, **both** of the following:

   a. **One** of the following:

      i. For hemophilia A, has **one** of the following diagnoses:

         a) Severe congenital hemophilia A,
         b) Congenital hemophilia A with inhibitors,
         c) Congenital hemophilia A and a history of at least one spontaneous episode of bleeding into a joint or other serious bleeding event,
         d) Acquired hemophilia A (emicizumab only)

ii. For hemophilia B, has **one** of the following diagnoses:

a) Severe congenital hemophilia B,
b) Congenital hemophilia B with inhibitors,
c) Congenital hemophilia B and a history of at least one spontaneous episode of bleeding into a joint or other serious bleeding event

b. For a non-preferred non-factor replacement Antihemophilia Agent, **one** of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-factor replacement Antihemophilia Agents approved or medically accepted for the beneficiary's diagnosis
ii. Has a current history (within the past 90 days) of being prescribed the same non-preferred non-factor replacement Antihemophilia Agent (does not apply to non-preferred biologics when a corresponding biosimilar/brand biologic/unbranded biologic is preferred)

10. If a prescription for an Antihemophilia Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 member:

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 drug,

6. If a prescription for an Antihemophilia Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.
   NOTE: If the member 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 member, 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 member.

Approval Duration: 6 months

D. References

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Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024.	11/2023
Q1 2025 annual review: no changes.	11/2024
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025