Clinical Policy: Antihemophilia Agents

Reference Number: PHW.PDL.713
Effective Date: 01/01/2020
Last Review Date: 10/2022

Revision Log

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 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 member'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 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

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 member'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 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

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 member'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 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 Hemlibra (emicizumab), **one** of the following:

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

   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 medication.

   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.

D. **Approval Duration: 6 months**

E. References

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21. Rind DM, Walton SM, Agboola F, et al. Valoctocogene roxaparvovec and emicizumab for hemophilia A: effectiveness and value; final report. Institute for Clinical and Economic Review, November 20, 2020. https://icer.org/wp-content/uploads/2020/10/ICER_Hemophila-A_Final-Report_112020.pdf.
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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