

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ANTIHEMOPHILIA AGENTS

Proposed Effective Date: January 5, 2026

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Antihemophilia Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antihemophilia Agents must be prior authorized.

B. Revisions to 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 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 emicizumab,
 - (ii) Has documentation from the prescriber of a medical reason why 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

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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

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 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

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 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:

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- 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 all other non-preferred **factor replacement** 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.~~
- 10. **For a non-factor replacement Antihemophilia Agent, both of the following:**
 - a. **One of the following:**

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- 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).

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

AND

- 11. If a prescription for an Antihemophilia Agent is for 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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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

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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 drug; **AND**
6. **If a prescription for an Antihemophilia Agent is for 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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.**

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.

D. References

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