Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.713	**Effective Date: 01/01/2020** **Revision Date: 01/2021**
Policy Name: Antihemophilia Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021 annual review: no changes.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Antihemophilia Agents

Reference Number: PHW.PDL.713
Effective Date: 01/01/2020
Last Review Date: 01/2021

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 health plans affiliated with PA Health and 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 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);

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);

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;

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);

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.

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.

D. **Approval Duration: 6 months**

E. References

1. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. MASAC Document #253. April 2018.
2. National Hemophilia Foundation. MASAC recommendations concerning prophylaxis (regular administration of clotting factor concentrate to prevent bleeding). MASAC Document #214. February 2016.
3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. 2013;19:e1-e47.
4. Hoots WK, Shapiro AD. Hemophilia A and B: routine management including prophylaxis. Mahoney DH, Leung LLK, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated February 11, 2019. Accessed May 14, 2019.
5. Richards M, Williams M, Chalmers E, et al. A United Kingdom Haemophilia Centre Doctors' Organization guideline approved by the British Committee for Standards in Haematology: guideline on the use of prophylactic factor VIII concentrate in children and adults with severe haemophilia A. Br J Haematol. 2010;149(4):498-507.
6. Quon DV, Klamroth R, Kulkarni R, et al. Low bleeding rates with increase or maintenance of physical activity in patients treated with recombinant factor VIII Fc fusion protein (rFVIIIFc) in the A-LONG and Kids A-LONG studies. Haemophilia. 2016;23(1):e39-342.
7. Oldenburg J, Kulkarni R, Srivastava A, et al. Improved joint health in subjects with severe haemophilia A treated prophylactically with recombinant factor VIII Fc fusion protein. Haemophilia. 2018;24(1):77-84.
8. Blanchette VS, Key NS, Ljung LR, et al. Definitions in hemophilia: communication from the SSC of the ISTH. J Thromb Haemost. 2014;12:1935-9.
9. National Hemophilia Foundation. MASAC recommendation on the use and management of emicizumab-kxwh (Hemlibra) for hemophilia A with and without inhibitors. MASAC Document #255. December 2018.
10. Hoots WK, Shapiro AD. Inhibitors in hemophilia: mechanisms, prevalence, diagnosis, and eradication. Leung LLK, Mahoney DH, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated February 20, 2019, Accessed May 14, 2019.
11. Dimichelle DM, Hoots WK, Pipe SW, Rivards GE, Santagostino E. International workshop on immune tolerance induction: consensus recommendations. Haemophilia. 2007;13(Suppl. 1):1-22.
12. Collins PW, Chalmers E, Hart DP, et al. Diagnosis and treatment of factor VIII and IX inhibitors in congenital haemophilia (4th edition). Br J Haemotol. 2013;160(2):153-170.
13. Valentino LA, Kemptom CL, Kruse-Jarres R, Mathew P, Meeks SL. US guidelines for immune tolerance induction in patients with haemophilia A and inhibitors. Haemophilia. 2015;21:559-567.

14. Collins P, Chalmers E, Chowdary P, et al. The use of enhanced half-life coagulation concentrates in routine clinical practice: guidance from UKHCDO. Haemophilia. 2016;22:487-498.
15. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von Willebrand disease. MASAC Document #244. November 2016.
16. National Hemophilia Foundation. MASAC recommendations regarding girls and women with inherited bleeding disorders. MASAC Document #245. November 2016.
17. Rick ML. Treatment of von Willebrand disease. Leung LLK, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated October 30, 2018. Accessed May 14, 2019.

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