


ISSUE DATE September 3, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Antihemophilia Agents – Pharmacy Services	BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers of the addition of the Antihemophilia Agents class of drugs to the Preferred Drug List (PDL).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Antihemophilia Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Antihemophilia Agents to the appropriate managed care organization.

BACKGROUND:

*01-19-52	09-19-48	27-19-46	33-19-48
02-19-46	11-19-45	30-19-44	
03-19-45	14-19-44	31-19-51	
08-19-54	24-19-46	32-19-44	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the PDL;
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the June 21, 2019, meeting, the P&T Committee recommended that the Department add the Antihemophilia Agents class of drugs to the PDL and proposed guidelines to determine medical necessity of Antihemophilia Agents. The requirement for prior authorization and guidelines to determine medical necessity of Antihemophilia Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Antihemophilia Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Antihemophilia Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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);

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 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);

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

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,

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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);

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

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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. References

1. National Hemophilia Foundation. MASAC recommendations concerning products licensed

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 (rFVIII Fc) 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 Haematol*. 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.