pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 2, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Antihemophilia Agents – Pharmacy Services

BY

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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: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated 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. The guidelines to determine the medical necessity of Antihemophilia Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Antihemophilia Agents to the appropriate MCO.

BACKGROUND:

*01-21-17	09-21-16	27-21-07	33-21-16
02-21-04	11-21-06	30-21-11	
03-21-04	14-21-07	31-21-19	
08-21-18	24-21-14	32-21-04	

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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (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 September 14, 2021, meeting, the P&T Committee recommended revising the guidelines specific to Hemlibra (emicizumab) to address recent peer-reviewed medical literature and specialist input regarding the clinical efficacy and cost effectiveness of Hemlibra (emicizumab) prophylaxis compared to FVIII prophylaxis for people with hemophilia A and the removal of the guideline that the beneficiary is age-appropriate according to package labeling or medical literature.

The revisions to the guidelines to determine medical necessity of prescriptions for Antihemophilia Agents submitted for prior authorization, 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
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 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 history of 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 beneficiary's diagnosis or indication,

    b. Has a documented history of 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

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 beneficiary's diagnosis or indication,

   b. Has a documented history of 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:

      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

7. For a bypassing agent (e.g., FEIBA, NovoSeven RT, Sevenfact), **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

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 beneficiary's diagnosis or indication,

   b. Has a documented history of a contraindication or an intolerance to 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

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 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

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