

ISSUE DATE July 5, 2016	EFFECTIVE DATE July 11, 2016	NUMBER *See below
SUBJECT Prior Authorization of Hereditary Angioedema (HAE) Agents - Pharmacy Services		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISE to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Hereditary Angioedema (HAE) Agents for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is clarifying the reference to C1 esterase inhibitor in the guidelines to determine medical necessity of an HAE Agent to specify human C1 esterase inhibitor. There are no other changes to the medical necessity guidelines.

*01-16-22	09-16-20	27-16-20	
02-16-19	11-16-19	30-16-19	
03-16-19	14-16-20	31-16-24	
08-16-20	24-16-22	32-16-18	33-16-19

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>

PROCEDURE:

The procedures for prescribers to request prior authorization of HAE 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 HAE 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

SECTION II
Hereditary Angioedema (HAE) Agents

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Hereditary Angioedema (HAE) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hereditary Angioedema (HAE) Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a preferred or non-preferred HAE Agent. See Preferred Drug List (PDL) for the list of preferred HAE Agents at: www.papdl.com

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HAE Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Has a diagnosis of hereditary angioedema (HAE) by an allergist/immunologist that is confirmed by all of the following:
 - a. Low C4 complement level (mg/dL)
 - b. Low C1 esterase inhibitor antigenic level (mg/dL) OR functional level (<65%)

AND

2. Is not taking estrogen or an ACE inhibitor

AND

3. Is being prescribed the HAE agent by an allergist/immunologist

AND

4. If prescribed a human C1 esterase inhibitor:
 - a. Was tested for hepatitis B, hepatitis C and HIV

AND

- b. Received vaccination for hepatitis B

AND

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5. If prescribed a C1 esterase inhibitor for prophylaxis, has a documented history of more than one HAE attack per month requiring acute treatment in the hospital emergency department (ED) setting

AND

6. For a non-preferred HAE agent:
 - a. Has a documented history of therapeutic failure, contraindication or intolerance to the preferred HAE Agents

OR

- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred HAE Agent

OR

7. 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 recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR AN HAE AGENT:
Requests for prior authorization of renewals of prescriptions for an HAE agent that were previously approved will take into account whether the recipient:

1. Is being prescribed the HAE agent by an allergist/immunologist

AND

2. Had annual testing for hepatitis B, hepatitis C and HIV

AND

3. If prescribed a C1 esterase inhibitor for prophylaxis, has a documented reduction in the number and/or severity of HAE attacks

OR

4. 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 recipient.

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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 the request for a prescription for an HAE 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 recipient.