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 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 Antimigraine Agents, Other 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 Antimigraine Agents, Other to the appropriate managed care organization.

BACKGROUND:

| 02-19-32 | 11-19-31 | 30-19-31 |
| 03-19-31 | 14-19-31 | 31-19-37 |
| 08-19-40 | 24-19-33 | 32-19-31 |

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' (DHS) 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 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 requests for prior authorization of prescriptions for medical necessity.

**DISCUSSION:**

During the May 15, 2019, meeting, the P&T Committee recommended revising the Antimigraine Agents, Other medical necessity guidelines for calcitonin gene-related peptide (CGRP) antagonists/inhibitors to require a history of therapeutic failure of at least one preventive medication from two of the following three classes: beta-blockers, antidepressants, and anticonvulsants or a history of contraindication or intolerance to all preventive medications from all three classes. The medical necessity guidelines previously required a history of therapeutic failure of at least one preventive medication from each class (beta-blockers, antidepressants, anticonvulsants) or a history of contraindication or intolerance to all preventive medications from all three classes.

The revisions to the guidelines to determine medical necessity of Antimigraine Agents, Other, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by DHS.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Antimigraine Agents, Other are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Antimigraine Agents, Other) 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/pharmacieservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacieservices/drugsrequiringclinicalpriorauthorization/index.htm
I. Requirements for Prior Authorization of Antimigraine Agents, Other

A. Prescriptions That Require Prior Authorization

All prescriptions for Antimigraine Agents, Other must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA) approved package insert 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. Does not have a history of contraindication to the prescribed medication; AND

5. For calcitonin gene-related peptide (CGRP) antagonists/inhibitors, all of the following:
   a. Is prescribed the CGRP antagonist/inhibitor by or in consultation with a neurologist or headache specialist,
   b. Has documentation of baseline average number of migraine days and headache days per month,
   c. Has averaged four or more migraine days per month over the previous three months,
   d. Has a diagnosis of migraine with or without aura confirmed according to the current International Headache Society Classification of Headache Disorders,
   e. One of the following:
      i. Has a documented history of therapeutic failure of at least one preventive medication from two of the following three classes:
         a) Beta-blockers (e.g. metoprolol, propranolol, timolol),
         b) Antidepressants (e.g. amitriptyline, venlafaxine),
c) Anticonvulsants (e.g. topiramate, valproic acid, divalproex),

ii. Has a documented history of contraindication or intolerance to all preventive medications from all of the following three classes:

a) Beta-blockers (e.g. metoprolol, propranolol, timolol),
b) Antidepressants (e.g. amitriptyline, venlafaxine),
c) Anticonvulsants (e.g. topiramate, valproic acid, divalproex),

f. Will not be using the prescribed CGRP antagonist/inhibitor concomitantly with botulinum toxin,

g. For non-preferred CGRP antagonists/inhibitors, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred CGRP antagonists/inhibitors. See the Preferred Drug List (PDL) for the list of preferred Antimigraine Agents, Other at: https://papdl.com/preferred-drug-list.

AND

6. For ergot alkaloids, both of the following:

a. Has a diagnosis of headache based on the current International Headache Society Classification of Headache Disorders

b. Has a documented history of trial and failure, contraindication, or intolerance to standard first-line abortive medications based on headache classification as recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology or American Academy of Family Physicians);

AND

7. If a prescription for an Antimigraine Agent, Other is in 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: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 AN ANTIMIGRAINE AGENT, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for an
Antimigraine Agent, Other that was previously approved will take into account whether the beneficiary:

1. For CGRP antagonists/inhibitors, all of the following:
   
   a. **One** of the following:
      
      i. Has a reduction in the average number of migraine days or headache days per month from baseline
      ii. Has experienced a decrease in severity or duration of migraines,
   
   b. Is prescribed the CGRP antagonist/inhibitor by or in consultation with a neurologist or headache specialist,
   
   c. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   
   d. Does not have a history of contraindication to the prescribed medication;

   AND

2. For ergot alkaloids, all of the following:
   
   a. Has experienced an improvement in headache pain control or duration,
   
   b. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   
   c. Does not have a history of contraindication to the prescribed medication;

   AND

3. If a prescription for an Antimigraine Agent, Other is in 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: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

**NOTE:** If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 Antimigraine Agent, Other. 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. Dose and Duration of Therapy

Requests for prior authorization of Antimigraine Agents, Other will be approved as follows:

1. Initial requests for prior authorization of CGRP antagonists/inhibitors will be approved for up to 4 months of therapy.

2. Renewals of requests for prior authorization of CGRP antagonists/inhibitors will be approved for up to 6 months.

E. References