

ISSUE DATE December 6, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Antimigraine Agents, Other – 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: <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 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:

The Department of Human Services’ (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

*01-19-106	09-19-102	27-19-101	33-19-103
02-19-100	11-19-99	30-19-98	
03-19-99	14-19-98	31-19-106	
08-19-109	24-19-101	32-19-98	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p>

through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 13, 2019, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of Antimigraine Agents, Other:

- Clarification that the existing guidelines for calcitonin gene-related peptide (CGRP) antagonists/inhibitors apply to CGRP antagonists/inhibitors prescribed for a diagnosis of migraine;
- Addition of guidelines that address the expanded U.S. Food and Drug Administration approval of CGRP antagonists/inhibitors for the treatment of episodic cluster headache;
- Addition of a guideline that the requested CGRP antagonist/inhibitor is not used with another CGRP antagonist/inhibitor;
- Removal of the guideline that the prescribed CGRP antagonist/inhibitor not be used concomitantly with botulinum toxin;
- Addition of guidelines for non-preferred CGRP antagonists/inhibitors; and
- Revisions to the Dose and Duration of Therapy section.

The revisions to the guidelines to determine medical necessity of Antimigraine Agents, Other, as recommended by the DUR Board, 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 Antimigraine Agents, Other 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 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 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. Does not have a history of contraindication to the prescribed medication; **AND**
5. For a calcitonin gene-related peptide (CGRP) antagonist/inhibitor prescribed for the prevention of migraine, **all** of the following:
 - a. Is prescribed the CGRP antagonist/inhibitor by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS),
 - 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 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),

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- b) Antidepressants (e.g. amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g. topiramate, valproic acid, divalproex),
- ii. Has a 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 requested CGRP antagonist/inhibitor with another CGRP antagonist/inhibitor;

AND

6. For a CGRP antagonist/inhibitor prescribed for a diagnosis of episodic cluster headache, **all** of the following:
- a. Is prescribed the CGRP antagonist/inhibitor by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
 - b. Has a diagnosis of episodic cluster headache confirmed according to the current International Headache Society Classification of Headache Disorders,
 - c. Has a documented history of therapeutic failure, contraindication, or intolerance of at least one other preventive medication recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society),
 - d. Will not be using the requested CGRP antagonist/inhibitor with another CGRP antagonist/inhibitor;

AND

7. For a non-preferred CGRP antagonist/inhibitor, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred CGRP antagonists/inhibitors approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred CGRP antagonists/inhibitors at: <https://papdl.com/preferred-drug-list>; **AND**
8. For ergot alkaloids, **both** of the following:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a. Has a diagnosis of headache according to the current International Headache Society Classification of Headache Disorders
- b. Has a 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, American Academy of Family Physicians, American Headache Society);

AND

9. 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: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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. Does not have a history of contraindication to the prescribed medication; **AND**
2. For a CGRP antagonist/inhibitor prescribed for the prevention of migraine, **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. Experienced a decrease in severity or duration of migraines from baseline,
 - b. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is prescribed the CGRP antagonist/inhibitor by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS;

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

3. For a CGRP antagonist/inhibitor prescribed for a diagnosis of episodic cluster headache, **all** of the following:
 - a. Has documentation of a positive clinical response to the requested medication as evidenced by a reduction in cluster headache frequency from baseline,
 - b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is prescribed the CGRP antagonist/inhibitor by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS;

AND

4. For ergot alkaloids, **all** of the following:
 - a. Has documentation of 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,

AND

5. 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: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 prescribed for the prevention of migraine will be approved for up to 6 months.
2. Renewals of requests for prior authorization of CGRP antagonists/inhibitors prescribed for the prevention of migraine will be approved for up to 12 months.
3. Initial requests for prior authorization of CGRP antagonists/inhibitors prescribed for a diagnosis of episodic cluster headache will be approved for up to 4 months.
4. Renewals of requests for prior authorization of CGRP antagonists/inhibitors prescribed for a diagnosis of episodic cluster headache will be approved for up to 6 months.

E. References

1. Aimovig Package Insert. Thousand Oaks, CA: Amgen Inc.; March 2019.
2. Ajovy Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2018.
3. American Headache Society. The American Headache Society position statement on integrating the new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
4. Bajwa Z, Smith J. Acute treatment of migraine in adults. Waltham, MA: UpToDate Inc. Updated July 31, 2019. Accessed August 2, 2019.
5. Bajwa Z, Smith J. Preventive treatment of migraine in adults. Waltham MA: UpToDate Inc. Updated May 21, 2019. Accessed August 2, 2019.
6. Beck E, Sieber, WJ, Trejo R. Management of cluster headache. *American Family Physician*. 2005;71(4):717-724.
7. Botox Package Insert. Madison, NJ: Allergan. June 2019.
8. ClinicalTrials.gov. A study to evaluate the efficacy and safety of erenumab (AMG 334) in chronic migraine prevention. <https://clinicaltrials.gov/ct2/show/NCT02066415>. Accessed July 30, 2018.
9. ClinicalTrials.gov. Study to evaluate the efficacy and safety of erenumab (AMG 334) compared to placebo in migraine prevention (ARISE). <https://clinicaltrials.gov/ct2/show/NCT02483585>. Accessed July 30, 2018.
10. ClinicalTrials.gov. Study to evaluate the efficacy and safety of erenumab (AMG 334) in migraine prevention (STRIVE). <https://clinicaltrials.gov/ct2/show/NCT02456740>. Accessed July 30, 2018.
11. D.H.E. 45 Package Insert. Novartis. East Hanover, New Jersey. July 2002.
12. Emgality Package Insert. Indianapolis, IN: Eli Lilly and Company; June 2019.
13. Garza I, Schwedt T. Chronic migraine. UpToDate. Accessed August 6, 2018.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

14. Goadsby PJ, Dodick DW, et al. Trial of galcanezumab in prevention of episodic cluster headache. *N Engl J Med* 2019; 381:132-141. DOI: 10.1056/NEJMoa1813440.
15. Institute for Clinical Systems Improvement. Diagnosis and treatment of headache. eleventh edition. January 2013.
16. International Headache Society. Headache Classification Committee of the International Headache Society (IHS): the international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018; Vol. 38(1):1-211.
17. May A. Cluster headache: Epidemiology, clinical features, and diagnosis. Waltham MA: UpToDate Inc. Updated October 12, 2018. Accessed July 26, 2019.
18. May A. Cluster Headache: Treatment and Prognosis. Waltham MA: UpToDate Inc. Updated March 11, 2019. Accessed July 26, 2019.
19. Mayans L, Walling A. Acute migraine headache: treatment strategies. *American Family Physician*. 2018;97(4):243-251.
20. Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(Suppl 2):S1-S59.
21. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78:1337-45. Erratum in *Neurology* 2013;80:871.