




Medical Assistance BULLETIN

ISSUE DATE November 8, 2024	EFFECTIVE DATE January 6, 2025	NUMBER *See below
SUBJECT Prior Authorization of Anticonvulsants – Pharmacy Services		BY  Sally 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.pa.gov/en/agencies/dhs/resources/providers/provider-enrollment-information/provider-enrollment-documents.html>.

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 Anticonvulsants 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 Anticonvulsants will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Anticonvulsants to the appropriate managed care organization.

BACKGROUND:

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 and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-04	09-25-04	27-25-04	33-25-04
02-25-04	11-25-04	30-25-04	
03-25-04	14-25-04	31-25-04	
08-25-05	24-25-04	32-25-04	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
<https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html>

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Anticonvulsants:

- Addition of a requirement for prior authorization of and corresponding medical necessity guidelines for Epidiolex (cannabidiol).
- Deletion of the guidelines related to documentation that the prescriber or prescriber's delegate conducted a search of the Prescription Drug Monitoring Program.
- Addition of an Automated Prior Authorization section.

The revisions to the guidelines to determine medical necessity of prescriptions for Anticonvulsants 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 Anticonvulsants 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 Anticonvulsants) 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 and products 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html>

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

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Anticonvulsants

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticonvulsants that meet any of the following conditions must be prior authorized:

1. A non-preferred Anticonvulsant. See the Preferred Drug List (PDL) for the list of preferred Anticonvulsants at: <https://papdl.com/preferred-drug-list>.
2. An Anticonvulsant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for Epidiolex (cannabidiol).
4. A prescription for clonazepam when prescribed for a beneficiary under 21 years of age.
5. A prescription for clonazepam when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity) in the point-of-sale online claims adjudication system (therapeutic duplication).
6. A prescription for a clonazepam when there is a record of two or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity) in the point-of-sale online claims adjudication system within the past 30 days.
7. A prescription for clonazepam when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

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

1. For a non-preferred Anticonvulsant, **one** of the following:
 - a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Anticonvulsant (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

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b. **All** of the following:

i. **One** of the following:

- a) For a diagnosis of a seizure disorder, has a history of therapeutic failure of or a contraindication or an intolerance to two preferred Anticonvulsants approved or medically accepted for the beneficiary's diagnosis (therapeutic failure of preferred Anticonvulsants must include the generic equivalent when the generic equivalent is designated as preferred)
 - b) For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Anticonvulsants approved or medically accepted for the beneficiary's diagnosis (therapeutic failure of preferred Anticonvulsants must include the generic equivalent when the generic equivalent is designated as preferred),
- ii. 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,
- iii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- iv. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. For Epidiolex (cannabidiol), **one** of the following:

- a. Has a history of therapeutic failure of or a contraindication or an intolerance to two preferred Anticonvulsants approved or medically accepted for the beneficiary's diagnosis
- b. Has a history of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex;

AND

3. For clonazepam, **all** of the following:

- a. For a beneficiary under 21 years of age, **one** of the following:
 - i. Has a diagnosis of **one** of the following:
 - a) Seizure disorder,
 - b) Chemotherapy induced nausea and vomiting,

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- c) Cerebral palsy,
 - d) Spastic disorder,
 - e) Dystonia,
 - f) Catatonia
- ii. Is receiving palliative care,
- b. For therapeutic duplication of clonazepam with another benzodiazepine, **one** of the following:
- i. Is being titrated to or tapered from another benzodiazepine
 - ii. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines,
- c. When there is a record of two or more paid claims for any benzodiazepine, **both** of the following:
- i. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines
 - ii. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s),
- d. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
- i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - ii. Has an acute need for therapy with clonazepam;

AND

4. If a prescription for an Anticonvulsant is for 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.

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

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clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anticonvulsant. 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. Automated Prior Authorization

Prior authorization of a prescription for Epidiolex (cannabidiol) will be automatically approved when the point-of-sale on-line claims adjudication system verifies a record of a diagnosis code for Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex or paid claims within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

E. References

1. Epidiolex (cannabidiol) Prescribing Information. Jazz Pharmaceuticals, Inc. March 2024.