


ISSUE DATE December 16, 2021	EFFECTIVE DATE January 3, 2022	NUMBER *See below
SUBJECT Prior Authorization of Anticonvulsants – 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 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 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 Anticonvulsants to the appropriate MCO.

BACKGROUND:

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

*01-21-56	09-21-55	27-21-44	33-21-54
02-21-40	11-21-44	30-21-49	
03-21-40	14-21-43	31-21-58	
08-21-58	24-21-52	32-21-41	

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

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Therapeutic classes of drugs and products 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 a revision to the guidelines to determine medical necessity of Anxiolytics to include catatonia as a diagnosis for a beneficiary under 21 years of age to be consistent with the 2020 American Academy of Pediatrics guidelines regarding the use of benzodiazepines in children with autism spectrum disorder. The Department is making the same revision to the corresponding language related to the benzodiazepine clonazepam in the guidelines to determine medical necessity of Anticonvulsants.

The Department is also revising the guidelines to determine medical necessity of a non-preferred Anticonvulsant to clarify that a current history 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.

The revisions to the guidelines to determine medical necessity of prescriptions for Anticonvulsants 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.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>

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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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A prescription for a gabapentinoid (e.g., gabapentin, pregabalin) when there is a record of a recent paid claim for another gabapentinoid in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
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 [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
6. A prescription for a clonazepam when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) 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. Has a documented history of therapeutic failure, contraindication, or intolerance of 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 prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- iv. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. 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,
 - c) Cerebral palsy,
 - d) Spastic disorder,
 - e) Dystonia,
 - f) Catatonia
- ii. Is receiving palliative care,

b. 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,

c. For therapeutic duplication of clonazepam with another benzodiazepine, **one** of the following:

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- i. Is being titrated to or tapered from another benzodiazepine
 - ii. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines,
- d. When there is a record of 2 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),
- e. **One** of the following:
- i. Meets the guidelines in B.2.a.
 - ii. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history;

AND

3. For therapeutic duplication of a gabapentinoid, **one** of the following:
- a. Is being titrated to or tapered from another gabapentinoid
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

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 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

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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.