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| ISSUE DATE November 8, 2024 | EFFECTIVE DATE January 6, 2025 | NUMBER *See below |
| SUBJECT Prior Authorization of Antipsychotics – 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/for-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 Antipsychotics 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 Antipsychotics 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 Antipsychotics to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Antipsychotics to add a guideline to the requests for renewal of the prior authorization section related to requests for a non-preferred Antipsychotic with a therapeutically equivalent brand or generic that is preferred on the Preferred Drug List and to specify that requests for renewal of the prior authorization of prescriptions

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| *01-25-10 | 09-25-10 | 27-25-10 | 33-25-10 |
| 02-25-10 | 11-25-10 | 30-25-10 | |
| 03-25-10 | 14-25-10 | 31-25-10 | |
| 08-25-11 | 24-25-10 | 32-25-10 | |

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>

that exceed the quantity limit require prior authorization. There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of prescriptions for Antipsychotics 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 Antipsychotics 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 Antipsychotics) 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>

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PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Antipsychotics

A. Prescriptions That Require Prior Authorization

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

1. A non-preferred Antipsychotic. See the Preferred Drug List (PDL) for the list of preferred Antipsychotics at: <https://papdl.com/preferred-drug-list>.
2. An Antipsychotic 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. An Antipsychotic when prescribed for a child under 18 years of age.
4. An atypical Antipsychotic when there is a record of a recent paid claim for another atypical Antipsychotic in the point-of-sale online claims adjudication system (therapeutic duplication).
5. A typical Antipsychotic when there is a record of a recent paid claim for another typical Antipsychotic in the point-of-sale online claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

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

1. For a non-preferred Antipsychotic, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance (such as, but not limited to, diabetes, obesity, etc.) to the preferred Antipsychotics approved or medically accepted for the beneficiary's diagnosis or indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic (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);

AND

2. For an Antipsychotic for a child under the age of 18 years, **all** of the following:

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- a. Has severe symptoms related to psychotic or neuro-developmental disorders such as seen in, but not limited to, the following diagnoses:
 - i. Autism spectrum disorder,
 - ii. Intellectual disability,
 - iii. Conduct disorder,
 - iv. Bipolar disorder,
 - v. Mood disorders with psychotic features,
 - vi. Tic disorder, including Tourette's syndrome,
 - vii. Transient encephalopathy,
 - viii. Schizophrenia and schizophrenia-related disorders,
- b. **One** of the following:
 - i. If under 14 years of age, is being prescribed the drug by or in consultation with **one** of the following:
 - a) Pediatric neurologist,
 - b) Child and adolescent psychiatrist,
 - c) Child development pediatrician
 - ii. If 14 years of age or older, is being prescribed the drug by or in consultation with **one** of the following:
 - a) Pediatric neurologist,
 - b) Child and adolescent psychiatrist,
 - c) Child development pediatrician,
 - d) General psychiatrist,
- c. Has chart documented evidence of a comprehensive evaluation,
- d. Has a documented plan of care that includes non-pharmacologic therapies (e.g., evidence-based behavioral, cognitive, and family based therapies) when indicated according to national treatment guidelines,
- e. Has documented baseline monitoring of weight or body mass index (BMI), blood pressure, fasting glucose or hemoglobin A1c, fasting lipid panel, and extrapyramidal symptoms (EPS) using the Abnormal Involuntary Movement Scale (AIMS);

AND

3. For therapeutic duplication, **one** of the following:
 - a. For an atypical Antipsychotic, is being titrated to or tapered from another atypical Antipsychotic,

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- b. For a typical Antipsychotic, is being titrated to or tapered from another typical Antipsychotic,
- c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 4. If a prescription for an Antipsychotic 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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PREFERRED AND NON-PREFERRED ANTIPSYCHOTICS FOR CHILDREN UNDER 18 YEARS OF AGE: The determination of medical necessity of a request for renewal of a prior authorization for an Antipsychotic for a child under 18 years of age that was previously approved will take into account whether the beneficiary:

- 1. Has **all** of the following:
 - a. Documented improvement in target symptoms,
 - b. Documented monitoring of weight or BMI quarterly,
 - c. Documented monitoring of blood pressure, fasting glucose or hemoglobin A1c, fasting lipid panel, and EPS using AIMS after the first 3 months of therapy and then annually,
 - d. Documented plan for taper/discontinuation of the Antipsychotic or rationale for continued use;

AND

- 2. For a non-preferred Antipsychotic with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
- 3. If a prescription for an Antipsychotic 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.

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C. Clinical Review Process

Except as noted below, 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 Antipsychotic. 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 (a psychiatrist) for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of an antipsychotic drug for a child under 18 years of age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical necessity determination. The physician reviewer (a psychiatrist) will prior authorize the prescription based on **one** of the following:

1. The guidelines in Section B. 2. are met.
2. In the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for an Antipsychotic for a child under 18 years of age will be approved as follows:

1. Up to three months for an initial request.
2. Up to 12 months for a renewal of a previously approved request.

E. References

1. Alexander GC, Gallagher SA, Mascola, et al. Increasing off-label use of antipsychotic medication in the United States, 1995-2008, *Pharmacoepidemiology and Drug Safety* (2011), doi: 10.1002/pds.2082.
2. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, *Diabetes Care*, 27:2, February 2004.
3. McKinney C, Renk K. Atypical antipsychotic medication in the management of disruptive behaviors in children: Safety guidelines and recommendations, *Clinical Psychology Review* (2010), doi:10.1016/j.cpr.2010.11.005.
4. Olfson M, Blanco C, Linxu L, et al. National Trends in the Outpatient Treatment of Children and Adolescents With Antipsychotic Drugs, *Arch Gen Psychiatry*. 2006;63:679-685.
5. Pappadopulos E, MacIntyre JC, Crismon ML. Treatment Recommendations for the Use of Antipsychotics for Aggressive Youth (TRAAY). Part II, *J Am Acad Child Adolesc Psychiatry*, 42:2, February 2003.

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6. Schur SB, Sikich L, Rindling RL. Treatment Recommendations for the Use of Antipsychotics for Aggressive Youth (TRAAY). Part I: A Review, J Am Acad Child Adolesc Psychiatry, 42:2, February 2003.