




ISSUE DATE August 21, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below	
SUBJECT Prior Authorization of Antipsychotics – 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:
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 Antipsychotics 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 Antipsychotics to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (DHS) is removing the guidelines to determine medical necessity that are specific to Zyprexa Relprevv and aripiprazole extended-release injectable suspension.

*01-19-43	09-19-41	27-19-39	33-19-41
02-19-38	11-19-37	30-19-37	
03-19-37	14-19-37	31-19-43	
08-19-46	24-19-39	32-19-37	

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 revisions to the guidelines to determine medical necessity of Antipsychotics were subject to public review and comment and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Antipsychotics 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 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 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/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

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

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK
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: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. An Antipsychotic when prescribed for a child under 18 years of age.
4. An Atypical Antipsychotic or Typical Antipsychotic when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in the Department of Human Services' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
5. An oral Atypical Antipsychotic for a beneficiary 18 years of age and older when prescribed in a low-dose range as listed in the following table:

Drug	Low Dose Range (mg/day)
Abilify (aripiprazole)	≤ 10
Clozaril (clozapine)	≤ 100
Fanapt (iloperidone)	≤ 2
Fazaclo (clozapine)	≤ 100
Geodon (ziprasidone)	≤ 40
Invega (paliperidone)	≤ 3
Latuda (luradisone)	≤ 20
Risperdal (risperidone)	≤ 1
Rexulti (brexiprazole)	≤ 0.5
Saphris (asenapine)	≤ 5
Symbyax (olanzapine/fluoxetine)	≤ 3/25
Seroquel/Seroquel XR (quetiapine)	≤ 150
Versacloz (clozapine)	≤ 50
Zyprexa (olanzapine)	≤ 5

EXEMPTION: Prior authorization is not required for the first 60 days of therapy with a prescription for a preferred oral Atypical Antipsychotic when prescribed in a low-dose range for beneficiaries 18 years of age and older to allow for titration to a therapeutic dose.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 Invega, **one** of the following:

- a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Antipsychotics,
- b. Has active liver disease with elevated LFTs or is at risk for active liver disease,
- c. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic;

OR

2. For all other non-preferred Antipsychotics, **one** of the following:

- a. Has a history of therapeutic failure, contraindication, or intolerance (such as, but not limited to, diabetes, obesity, etc.) to the preferred Antipsychotics
- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic;

AND

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

- a. Has severe behavioral problems 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 disease,
 - v. Tic disorder, including Tourette's syndrome,
 - vi. Transient encephalopathy,
 - vii. Schizophrenia,
- b. **One** of the following:
 - i. If less than 14 years of age, is being prescribed the medication by or in consultation with **one** of the following:
 - a) Pediatric neurologist,
 - b) Child and adolescent psychiatrist,
 - c) Child development pediatrician,

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- ii. If 14 years of age or older, is being prescribed the medication 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, including non-pharmacologic therapies such as, but not limited to, evidence-based behavioral, cognitive, and family based therapies,
- d. Has documented baseline monitoring of weight or body mass index (BMI), blood pressure, fasting glucose, fasting lipid panel, and extrapyramidal symptoms (EPS) using the Abnormal Involuntary Movement Scale (AIMS);

AND

- 4. For therapeutic duplication of an Atypical or Typical Antipsychotic, **one** of the following:
 - a. Is being titrated to, or tapered from, a drug in the same class
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

- 5. For a low dose oral Atypical Antipsychotic for a beneficiary 18 years of age and older, **one** of the following:
 - a. Has a diagnosis that is indicated in the package insert
 - b. Has a diagnosis that is listed in nationally recognized compendia for the determination of medically accepted indications for off-label uses;

AND

- 6. If a prescription for an Antipsychotic 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.

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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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, 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.

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. Automated Prior Authorization

Prior authorization of a preferred oral Atypical Antipsychotic prescribed in a low-dose range beyond the first 60 days of therapy will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim within 90 days prior to the date of service that documents a diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder, autism, or major depression with psychotic features.

D. 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 medication 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. 3. are met.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

2. In the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

E. 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 3 months for an initial request.
2. Up to 12 months for a renewal of a previously approved request.

F. 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.
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.