

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE

EFFECTIVE DATE

NUMBER

January 6, 2016

January 20, 2016

*See below

SUBJECT

Prior Authorization of Antipsychotics - Pharmacy Service

BY

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IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25**, **2011** must revalidate their enrollment information no later than **March 24**, **2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994 Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Antipsychotics, including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the thresholds for prior authorization of Antipsychotics to include Rexulti (brexiprazole), Saphris (asenapine), Symbyax (olanzapine/fluoxetine), and Versacloz (clozapine) when prescribed in a low-dose range. The recommended thresholds and low-dose ranges were subject to public review and comment, and subsequently approved for implementation by the Department. The revised thresholds and low dose ranges are included in the attached updated provider handbook pages.

*01-16-08	09-16-08	27-16-08	
02-16-08	11-16-08	30-16-08	
03-16-08	14-16-08	31-16-08	
08-16-08	24-16-08	32-16-08	33-16-08

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

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 chapters 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

SECTION II Antipsychotics

I. Requirements for Prior Authorization of Antipsychotics

A. <u>Prescriptions That Require Prior Authorization</u>

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

- A prescription for a non-preferred Antipsychotic, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Antipsychotics at: www.providersynergies.com/services/documents/PAM_PDL.pdf
- A prescription for a preferred Antipsychotic with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.state.pa.us/cs/groups/webcontent/documents/document/s 002077.pdf
- 3. A prescription for either a preferred or non-preferred Antipsychotic regardless of quantity limit when prescribed for a child under 18 years of age.
- 4. A prescription for a preferred or non-preferred Atypical Antipsychotic or a preferred or non-preferred Typical Antipsychotic when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in PROMISe, the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication)
- 5. A prescription for a preferred or non-preferred oral Atypical Antipsychotic for a recipient 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 mg
Saphris (asenapine)	≤ 5mg
Symbyax (olanzapine/fluoxetine)	≤ 3/25mg
Seroquel/Seroquel XR (quetiapine)	≤ 150
Versacloz (clozapine)	≤ 50mg
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 recipients 18 years of age and older to allow for titration to a therapeutic dose.

GRANDFATHER PROVISION – The Department will grandfather prescriptions for non-preferred Antipsychotics for those recipients age 18 years and older when the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies that the recipient has a record of a paid claim for a non-preferred Antipsychotic within the past 90 days from the date of service of the new claim. If the recipient has a record of a paid claim for a non-preferred Antipsychotic, a prescription or a refill for the same non-preferred Antipsychotic will be automatically approved.

Grandfathering does not apply to children under 18 years of age when prescribed either a preferred or non-preferred Antipsychotic, to prescriptions for Atypical or Typical Antipsychotics that are therapeutic duplications, or to prescriptions for a preferred or non-preferred oral Atypical Antipsychotic for recipients 18 years of age and older when prescribed in a low-dose range beyond the first 60 days of therapy.

B. <u>Clinical Review Guidelines and Review of Documentation for Medical Necessity</u>

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

1. For Invega - Whether the recipient has:

 A history of therapeutic failure of the preferred Antipsychotics;

OR

- Active liver disease with elevated LFTs or is at risk for active liver disease
- 2. For all other non-preferred Antipsychotics Whether the recipient:
 - a. Has a history of therapeutic failure, contraindication or intolerance (such as, but not limited to, diabetes, obesity, etc.) to the preferred Antipsychotics;

OR

- b. For Zyprexa Relprevv
 - i. Is being transitioned from oral Olanzapine to Zyprexa Relprevv

AND

II. Has a history of non-compliance with Oral Antipsychotics resulting in decompensation or is at high risk of decompensation.

OR

- c. For aripiprazole extended-release injectable suspension, for intramuscular use
 - i. Is being transitioned from Oral aripiprazole

AND

ii. Has a history of non-compliance with Oral Antipsychotics resulting in decompensation or is at high risk of decompensation

OR

- d. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic
- 3. For a preferred or non-preferred Antipsychotic for a child under the age of 18 years Whether the recipient
 - 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, OR
 - ii. Intellectual disability, OR
 - iii. Conduct Disorder, OR
 - iv. Bipolar disease, OR
 - v. Tic Disorder, including Tourette's Syndrome, **OR**
 - vi. Transient encephalopathy, OR
 - vii. Schizophrenia

AND

- b. If less than 14 years of age, is being prescribed the medication by, or in consultation with a:
 - i. Pediatric Neurologist, OR
 - ii. Child and Adolescent Psychiatrist, OR
 - iii. Child Development Pediatrician

OR

- c. If 14 years of age or older, is being prescribed the medication by, or in consultation with, a :
 - i. Pediatric Neurologist, OR
 - ii. Child and Adolescent Psychiatrist, **OR**
 - iii. Child Development Pediatrician, OR
 - iv. General Psychiatrist

AND

d. 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

AND

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January 20, 2016 (Replacing January 21, 2015)

- e. 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)
- 4. For therapeutic duplication of an Atypical or Typical Antipsychotic, whether:
 - a. The recipient is being titrated to, or tapered from, a drug in the same class

OR

- Supporting peer reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested
- 5. For a low dose oral Atypical Antipsychotic for a recipient 18 years of age and older, whether the recipient has a diagnosis that is:
 - a. Indicated in the package insert

OR

- Listed in nationally recognized compendia for the determination of medically-accepted indications for off-label uses
- 6. In addition, if a prescription for either a preferred or nonpreferred 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 quidelines set forth in the Quantity Limits Chapter.

OR

7. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR PREFERRED and NON-PREFERRED ANTIPSYCHOTICS FOR CHILDREN UNDER 18 YEARS

OF AGE: A request for prior authorization of a renewal of a prescription for an Antipsychotic for a child under 18 years of age that was previously approved will take into account whether the recipient:

1. Has documented improvement in target symptoms

AND

2. Has documented monitoring of weight or BMI quarterly

AND

3. Has documented monitoring of blood pressure, fasting glucose, fasting lipid panel, and EPS using AIMS after the first 3 months of therapy, and then annually

AND

4. Has a documented plan for taper/discontinuation of the Antipsychotic or rationale for continued use

OR

 Does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the recipient

C. Automated Prior Authorization Approvals

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 PROMISe 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 the request for 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

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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 recipient.

NOTE: Approved requests for prior authorization of prescriptions for Symbyax will require the use of two (2) separate prescriptions for Fluoxetine and Zyprexa.

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 when:

1. The guidelines in Section B. 3. are met,

OR

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

E.. <u>Dose and Duration of Therapy</u>

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

- 1. 3 months for an initial request
- 2. 12 months for a renewal of a previously approved request

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.

- 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.