



Peer to Peer Program for Antipsychotic Treatment of Youth <5

Webinar Presentation

9/15/11

Presentation Objectives

- o To introduce a new pre-authorization program for antipsychotic tx of youth <5
- o To provide information on why this initiative was developed
- o To give prescribers an overview of the pre-authorization program
- o To discuss common questions and concerns about this program

Presenters

o **Dr. Mary Mussman**

Medicaid Administration

o **Dr. Al Zachik**

Mental Hygiene Association

o **Dr. Ray Love**

UM School of Pharmacy

o **Dr. Gloria Reeves**

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Background Information

- ☑ Use of antipsychotics ↑ over past decade^[1]
- ☑ Outpatient antipsychotic medication prescriptions in US for patients age < 21 ↑ 6-fold^[2]
- ☑ 1% of outpatient pediatric visits resulted in antipsychotic agent^[3]

Background (cont)

- ☑ Public scrutiny, controversy & debate regarding the increasing use of the antipsychotic agents in children ^[4]
- ☑ Limited long term safety/efficacy data in children
- ☑ Growing concerns by Medicaid Programs in the US

Maryland Medicaid Statistics

Age	# of Rxs	# of Children
0 - 4	705	178
5 - 9	12,992	2,065
10 - 12	11,699	1,824
13 - 17	19,349	2,875

* Review Period: 01/01/2010 – 12/31/2010

- 48% of antipsychotic medications prescribed to children below the FDA approved age were prescribed by providers that were not in the public mental health system (e.g., pediatricians and PCPs)

Mental Hygiene Administration

- Supports pre-authorization program to promote safe, cost effective, and evidence based pediatric treatment
- This program will help to better identify needs of young children and their families receiving mental health services

Program Development

UM &
JHU

MD
Coalition

Clinical
Providers

Pediatric
Experts

Medicaid
& MHA

Program Implementation Timeline

- Program will be rolled out in Phases
 - Phase I – Apply off-label use edit for children ages 0 – 4
 - Phase II – Apply off-label use edit for children ages 5 – 9
 - Phase III – Apply off-label use edit for children ages > 10
- Phase I will begin early October 2011

Overview

Antipsychotic prescription
for youth < 5 y/o



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graph TD; A[Antipsychotic prescription for youth < 5 y/o] --> B[Pre-authorization review]; B --> C[Re-authorization every 90 days];
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Pre-authorization review

Re-authorization every
90 days

Pre-authorization Review Process

- Prescriber completes pre-authorization form or call for information prior to writing a prescription
- Initial review is by a clinical pharmacist within one business day
- If approved, next review is 90 days
- Secondary review by child psychiatrist, as indicated
- If child psychiatrist denies approval, prescriber may request reconsideration by DHMH

The Review

- o Fax review form to **1-866-671-8084**
- o Should occur before sending patient to pharmacy with a prescription

Information for Pre-authorization

- o Brief demographic information
- o Diagnosis and indication for treatment
- o Medications
- o Psychosocial Services
- o Weight, height
- o Fasting labs
- o ECG for ziprasidone or quetiapine

What if child is already on antipsychotic medication?

- Prescriber will receive a letter concerning the child
- Existing cases of children <5 currently treated with antipsychotic medication will be reviewed
- Criteria will be similar to pre-authorization, but inquiries regarding medication response will be made
- Additional time will be allowed to obtain labs and ECG

Ongoing Review Process

- o Will occur every 90 days
- o Will focus on:
 - o medication monitoring
 - o treatment response

Indication for antipsychotic treatment

- Treatment under age 5 is “off label” use
- Current FDA approval for pediatric autism treatment is for irritability
- Pre-authorization review will assess target symptoms (irritability and aggression)
- Autism or severe aggression (evidenced by need for crisis services) may be approved

Criteria

A clinical pharmacist will perform the initial review. The prescriber will be offered the option for a child psychiatrist review if:

- o Patient is < 3 years of age
- o Diagnosis is other than autism or target symptom is other than irritability/aggression
- o Patient is receiving > 1 antipsychotic or high doses or an unusual drug regimen

Fasting labs

- Glucose, triglycerides, HDL, LDL
- Monitoring with fasting labs recommended by every antipsychotic treatment guideline
- Baseline labs may detect asymptomatic health issues
- Liver function tests and basic labs also collected at this time

Ongoing Labs

- Repeat labs at 3 months, then every 6 months
- Lab monitoring guidelines will be updated based on new information and expert consultation

ECG

- Required for ziprasidone or quetiapine treatment
- Recommendations based on FDA alerts for risk of QTc prolongation
- Required at baseline and repeat at 90 days

Psychosocial Services

- Non-medication treatments may be helpful to target behavioral problems
- Therapies may include parenting skills training, behavior management, PTSD treatment, and autism specific therapies
- Pre-authorization requires referral to psychosocial services if not currently receiving
- Contact information provided to prescriber for to seek referral



Common Questions

What if my patient turns 5?

- o There are currently no protocols in place to complete pre-authorization or review for children >4.
- o Protocols for older youth will be phased in beginning July 2012
- o Indications for treatment may be different
- o We will update you when new protocols for older children are developed

Will treatment be approved for aggression?

- o For youth without autism, aggression must be severe, as indicated by need for crisis services
- o We will provide contact number to seek psychosocial services to help manage aggressive behavior

What if the family does not cooperate with obtaining labs?

- Lab monitoring is based on safety concerns and current clinical guidelines
- The review process will support the provider in informing the family what type of monitoring is needed to safely continue treatment
- Collaboration with the pediatrician and/or a therapist to address needle phobia/anxiety may be beneficial to obtain labs

How quickly will the review of denied cases occur?

- A child psychiatrist review of unapproved prescriptions is available within one business day of the denial
- The patient's pharmacy can dispense 72 hours emergency supply of medication during that time
- The child psychiatrist will call the prescriber to discuss the case

What type of psychosocial services are required?

- o The prescriber will be asked if child has had a referral for psychosocial services
- o The prescriber will be asked if child has attended a single appointment
- o A specific type of psychosocial services will not be required

Why is there an ongoing review process?

- The risk:benefit ratio of treatment may change over time
- This program supports the provider in obtaining appropriate safety monitoring
- Provider can use this review process to provide ongoing informed consent to families about side effects and benefits

Where to go for additional information

- o Medicaid Website

- o <http://www.dhmf.state.md.us/mma/mpap/peerreview.htm>

- o Maryland Medicaid Pharmacy Program Recipient Hotline

- o 1-800-492-5231

Questions



References

1. Vitiello B, Correll C, van Zwieten-Boot B, Zuddas A, Parellada M, Arango C. Antipsychotics in children and adolescents: Increasing use, evidence for efficacy and safety concerns. Eur Neuropsychopharmacol. 2009 May 23, Epub.
2. Olfson M, Blanco C, Liu L, Moreno C, Laje G. National trends in the outpatient treatment of children and adolescents with antipsychotic drugs. Arch Gen Psychiatry. 2006;63:679-685. [Abstract](#)
3. Aparasu RR, Bhatara V. Patterns and determinants of antipsychotic prescribing in children and adolescents, 2003-2004. Curr Med Res Opin. 2007;23:49-56. [Abstract](#)
4. Parens E, Johnston J. Understanding the agreements and controversies surrounding childhood psychopharmacology. Child Adolesc Psychiatry Ment Health. 2008;2:5.