Peer to Peer Program for Antipsychotic Treatment of Youth <5

Webinar Presentation
9/15/11
Presentation Objectives

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

- Dr. Mary Mussman  
  Medicaid Administration

- Dr. Al Zachik  
  Mental Hygiene Association

- Dr. Ray Love  
  UM School of Pharmacy

- Dr. Gloria Reeves  
  UM Child Psychiatry
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

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<tr>
<th>Age</th>
<th># of Rxs</th>
<th># of Children</th>
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<tbody>
<tr>
<td>0 - 4</td>
<td>705</td>
<td>178</td>
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<td>5 - 9</td>
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<td>13 - 17</td>
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* 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

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

- Fax review form to 1-866-671-8084

- Should occur before sending patient to pharmacy with a prescription
Information for Pre-authorization

- Brief demographic information
- Diagnosis and indication for treatment
- Medications
- Psychosocial Services
- Weight, height
- Fasting labs
- 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

- Will occur every 90 days

- Will focus on:
  - medication monitoring
  - 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:

- Patient is < 3 years of age
- Diagnosis is other than autism or target symptom is other than irritability/aggression
- 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?

- There are currently no protocols in place to complete pre-authorization or review for children >4.

- Protocols for older youth will be phased in beginning July 2012

- Indications for treatment may be different

- We will update you when new protocols for older children are developed
Will treatment be approved for aggression?

- For youth without autism, aggression must be severe, as indicated by need for crisis services.

- 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?

- The prescriber will be asked if child has had a referral for psychosocial services.

- The prescriber will be asked if child has attended a single appointment.

- 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

- Medicaid Website
  - http://www.dhmh.state.md.us/mma/mpap/peerreview.htm

- Maryland Medicaid Pharmacy Program Recipient Hotline
  - 1-800-492-5231
Questions
References


