

October 2011

Maryland Department of Health and Mental Hygiene /Office of Systems, Operations and Pharmacy

Peer Review Program for Mental Health Medications in Children and Adolescents

The use of antipsychotic agents in children and adolescents has increased substantially over the past decade. There is increased public scrutiny, controversy, and debate regarding the increasing use of the antipsychotic agents in children and the lack of data on long-term effects. The long-term efficacy and safety of these agents in the pediatric population has not been well established for any given clinical indication.

For these reasons, the State of Maryland Medicaid Pharmacy Program (MMPP) is launching a new program – The Peer Review Program for Mental Health Drugs. The program will start on October 19, 2011 and will initially address the use of antipsychotics in Medicaid patients under five years of age. In partnership with the Mental Hygiene Administration (MHA) and the University of Maryland (UMD) Division of Child and Adolescent Psychiatry and School of Pharmacy, the program's goal is to ensure that members of this vulnerable population receive optimal treatment in concert with appropriate non-pharmacologic measures in the safest manner possible.

The MMPP will implement a "hard edit" which will prevent a claim for an antipsychotic drug from processing. Claims for antipsychotic medications that are for children younger than the FDA approved age, will require a Prior Authorization (PA) based on the peer-review assessment. Child psychiatrists and clinical pharmacists will perform the reviews and pre-authorizations.

The Peer Review Program will work as follows:

- 1. The claim for a child less than 5 years old will be denied at the Point of Sale.
- 2. The denial message will be "PA Required" and "Prescriber must call Antipsychotic Peer Review Center @ 1-855-283-0876 for PA."
- 3. The denial will require pharmacy provider to contact the prescriber to obtain the PA.
- 4. The prescriber must contact the Peer Review call center and proceed with consultation and decision related to PA (approve/deny).

The Peer Review Program will notify the prescriber of the approval or denial of the prescription. The prescriber will in turn notify the pharmacy provider.

Additional information about the pre-authorization process, including the required pre-authorization form and clinical criteria is available at http://www.dhmh.state.md.us/mma/mpap/peerreview.htm.

Generic vs. Brand Status on Maryland Medicaid's Preferred Drug List

Maryland Medicaid's Preferred Drug List (PDL) covers most of the generic versions of preferred multisource brand drugs without any type of prior authorization. In order for the State to enhance the benefit of the PDL, in some instances the brand name drug is preferred over its generic equivalents, because the branded drug is less costly than its generic counterpart. This happens most often in cases of newly released generics. When manufacturer rebates are taken into consideration, the brand name drug has a lower net cost to the State.

When the brand name drug is Preferred, no Medwatch form nor authorization is needed. Enter a DAW code of 6 on the claim to have it correctly priced. If the brand name drug is required, and is not preferred, the prescriber must complete a Medwatch form (http://www.dhmh.state.md.us/mma/mpap/medwatch.htm) and submit it to the State. The State's clinical

Generic vs. Brand Status (continued on Page 2)

In This Issue

Peer Review Program for Mental Health Medications in Children and Adolescents
Generic vs. Brand Status on Maryland Medicaid's Preferred Drug List
Generic vs. Brand Status on Maryland Medicaid's Preferred Drug List
Dispensing Fee Changes
30-day Emergency Supply of Atypical Antipsychotic Agents Available
Quantity Limits and Dose Optimization
Corrective Managed Care Program and Misuse of Controlled Substances
Clinical Corner 4
Dispensing Maintenance Medications 5 Maryland Medicaid Pharmacy & Therapeutics Committee
Continuing Medical Education and Pharmacy
Continuing Education (CE) Seminar
Sign up to Receive the MMPP Newsletter and Advisories via e-mail
Advisory Keeps You in the Know6

Generic vs. Brand Status (continued from Page1)

pharmacy team will review the Medwatch form and notify the prescriber whether the request for the brand name drug was approved or denied. The State will forward the Medwatch form to the FDA.

The PDL is reviewed twice a year; however changes to the PDL can occur throughout the year as new generics become available or due to other significant changes. For the latest PDL, please visit the following link: http://www.dhmh.state.md.us/mma/mpap/prefdruglist.html

If any problems are encountered during the on-line claim adjudication of Preferred Brands, contact ACS 24-hour Help Desk at 800-932-3918 for additional system overrides related to the use of the correct DAW code.

The current generic non-preferred exceptions as of July 1, 2011 are as follows:

Non-Preferred Generics and Status of Equivalent Brands

Differin (Preferred) adapalene amphetamine salt combo ER Adderall XR (Preferred) bromonidine Alphagan P (preferred) Miacalcin (Preferred) calcitonin salmon calcium acetate PhosLo (Preferred) carbamazepine ER capsules Carbatrol ER (Preferred) clindamycin-benzoyl peroxide Benzaclin (Preferred) cyclosporine Sandimmune (Preferred) dorzolomide/timolol Cosopt (Preferred) dorzolamide Trusopt (preferred) Marinol (Preferred) dronabinol enoxaparin Lovenox (Preferred) malathion crème rinse Ovide (Preferred) methylphenidate controlled release Concerta ER (Preferred) tacrolimus Prograf (Preferred) tinidazole Tindamax (Preferred) tranylcypromine Parnate (Preferred) valacyclovir Valtrex (Preferred)

In the following instances, both the multisource brand and the generic are preferred.

Preferred generics (Brand also Preferred- no MedWatch form required)

dexmethylphenidate Focalin

divalproex sprinkles Depakote sprinkles venlafaxine XR tablets Venlafaxine XR tablets

Please maintain this for a reference, together with any updates that follow. This information is available at http://www.epocrates.com/ on your desktop computer or PDA/Smartphone. Epocrates is updated weekly.

Dispensing Fee Changes

As required by the 2012 budget passed by the Maryland General Assembly, since July 1, 2011, the Maryland Medicaid Pharmacy Program has changed the pharmacy dispensing fees paid for fee-forservice prescriptions. The dispensing fee for retail prescriptions is \$3.51 for generic drugs and brand name drugs on the Preferred Drug List, and \$2.56 for brand name drugs not on the Preferred Drug List. The dispensing fee for prescriptions for recipients residing in nursing facilities is now \$4.46 for generic drugs and brand name drugs on the Preferred Drug List, and \$3.51 for brand name drugs not on the Preferred Drug List.

For prescriptions for individuals in the Maryland Kidney Disease Program (KDP), Maryland Breast and Cervical Cancer Diagnosis and Treatment Program (BCCDT) and Maryland AIDS Drug Assistance Program (MADAP), the dispensing fee is \$3.51 for generic drugs and \$2.56 for brand name drugs.

The above changes do not apply to prescriptions paid by managed care organizations.

30-day Emergency Supply of Atypical Antipsychotic Agents Available

When the prescriber is not available to obtain prior authorization for an antipsychotic medication that is non-preferred or second tier, the pharmacist can obtain a one-time-only authorization to dispense up to a 30-day emergency supply.

Do not let patients leave the pharmacy without medication if there is concern that the patient will be unwilling or unable to return at a later time that day after prior authorization is approved.

(continued on Page3)

30-day Emergency Supply (continued from Page 2)

To obtain authorization for an *emergency supply* of an antipsychotic agent, call Affiliated Computer Services (ACS) at 800-932-3918. During the 30-day window, the pharmacist must notify the prescriber of the need to obtain a PA before the prescription can be filled a second time and make a note for his or her records of the date, time and person contacted at the prescriber's office.

Quantity Limits and Dose Optimization

The Maryland Medicaid Pharmacy Program has consolidated all quantity and dose optimization limits on drugs such as opioids, antipsychotics, antimigraine agents, anti-emetics, etc. A comprehensive list of these limits is located on the Maryland Medicaid Pharmacy Program webpage http://www.dhmh.state.md.us/mma/mpap/. Look for Quantity Limits on the "Information for Providers" menu. As quantity limits and dose optimization for other drugs are developed, they will be added to this list.

Now there is a single form which should be used to request an override for excess quantity for both Maryland Medicaid fee-for-service patients and the MCO carve-out drugs. Prescribers must complete this form (Quantity Limit Override Request Form) for any drug that incurs a denial for the following exception codes:

4126 - Plan limitations exceeded

4165 - Plan limitations exceeded

4560 - Maximum quantity exceeded

4656 – PA Required. Max quantity allowed is exceeded.

4703 - PA required. Patient does not meet criteria.

This new form is available online at: http://www.dhmh.state.md.us/mma/mpap/forms.htm or by calling 1-800-932-3918.

Corrective Managed Care Program and Misuse of Controlled Substances

The Corrective Managed Care (CMC) Program is an ongoing effort by the Maryland Medicaid Pharmacy Program (MMPP) to monitor and promote appropriate use of controlled substances. The CMC Program is particularly concerned with appropriate utilization of opioids and benzodiazepines. Through a monthly review of individual recipient drug and diagnosis history profiles the MMPP identifies Maryland Medicaid recipients who appear to be receiving duplicate controlled drug therapy, visiting multiple prescribers and/or patronizing multiple pharmacies to obtain controlled substances.

The CMC Program shares this information about potential drug misuse with prescribers and pharmacy providers. Physicians and pharmacies are sent educational intervention letters along with a response form to indicate any action taken. If, despite the best efforts of the prescriber and pharmacist, there still continues to be overutilization or perceived misuse of a controlled substance by a recipient, a recipient can be "locked-in" or restricted to one pharmacy for coverage of medications paid fee-for-service by the MMPP. Under a lock-in pharmacy agreement, the recipient will be required to fill prescriptions for all medications paid fee-for-service at one predetermined pharmacy.

Medicaid recipients may ask to pay cash for prescriptions of controlled substances when Medicaid has denied the claim because a recipient is locked into a specific pharmacy, the refill is too soon, and/or a therapeutic duplication exists.

Medicaid patients should not be paying cash for any prescriptions under normal circumstances, especially prescriptions for controlled substances. Recipients insisting to pay cash for prescriptions for controlled substances should be referred to the Medicaid recipient fraud and abuse department.

Report Concerns:

CMC Lock-In Referral 410-767-5945 Office of the Inspector General Recipient Fraud/Abuse Hotline 1-866-770-7175 www.dhmh.state.md.us/oig



Risk Evaluation and Mitigation Strategies (REMS)

In 2007 the Food and Drug Administration Amendments Act went into effect giving the FDA the legal authority to begin to require that specific medications include what is known as Risk Evaluation and Mitigation Strategies (REMS) to be required for their approval and continued use. These comprehensive REMS have been developed for a number of drugs which may pose significant risk for adverse effects to patients if not used exactly as intended in the product literature.

REMS include the following:

- Goals of the REMS
- Medication use guidelines
- Elements to assure safe use of the drug
- Communication plan for manufacturers to communicate with prescribers
- Monitoring parameters
- Implementation requirements
- Timetable for submission of materials from manufacturer to FDA

The major component of REMS is a comprehensive medication use guide that is developed by the manufacturer. The detailed medication use guide is more comprehensive than a typical patient package insert set of instructions included with many medications. In many cases the medication use guide must be distributed to patients by the dispensing pharmacy every time the prescription is filled, this includes every refill and not just for the initial filling of a new prescription. The primary role of the pharmacist, with regard to REMS, is to be sure that the medication use guides are made available to patients and that they are adequately explained to patients.

Many controlled drugs have comprehensive REMS programs because of the risk associated with their misuse. Some REMS have very specific requirements for prescribers and pharmacy providers that must be met as well. The REMS for oral fentanyl products require that all prescribers and pharmacies be first registered with the manufacturer prior to prescribing or dispensing these medications. The REMS for buprenorphine/naloxone (Suboxone®) requires that prescribers be certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 and have a specific prescriber number which begins with the letter "X". The pharmacist is then required to be sure that the special "X" prescriber number appears on the prescription.

Some REMS programs require a communication plan which defines what information must be provided from the manufacturer to prescribers to ensure the safe use of the drug. These include communications such as "Dear Doctor" letters to review potential adverse effects of the drugs if not used properly or to warn for specific adverse effects that may be rare but still should be monitored. A few examples of drugs with required communication plans are inhaled long acting beta agonists, erythropoietin stimulating agents and drugs which are blockers of tumor necrosis factor.

A complete list of drugs with REMS can be found by going to the FDA website www.fda.gov and then searching on the keyword "REMS."

Dispensing Maintenance Medications

COMAR: 10.09.03.01(19-1) defines Maintenance medication as medication in chronic therapeutic categories corresponding to certain American Hospital Formulary Service (AHFS) classifications numbers. A few of these classifications include Cardiac drugs, Hypotensive agents, Alpha/Betaadrenergic blocking agents, Diuretics, Lipotropic agents, Antidiabetic and Antihypoglycemic agents and Contraceptives. Various sections of COMAR 10.09.03.05 states that initial prescriptions for maintenance drugs shall be limited to a 34-day supply, with subsequent fillings of maintenance medications can be dispensed up to a 100 days supply at one time. The regulations also state that birth control pills (Oral Contraceptives) may be dispensed up to a 6 months supply at one time. Adhering to these regulations when dispensing a new or different maintenance medication will help to decrease waste of medications if recipients experience unwanted side effects of the new agent. When refilling a Maintenance medication prescription for a Medicaid Fee-For-Service recipient, you are encouraged dispense the maximum days supply allowed by the prescription.

Maryland Medicaid Pharmacy & Therapeutics Committee

The next meeting of the Department of Health & Mental Hygiene Maryland Medicaid Preferred Drug List Pharmacy & Therapeutics Committee is scheduled for November 3, 2011 from 9:00AM to 1:00 PM. This public meeting is held at the Conference Center at Sheppard Pratt, 6501 N. Charles Street, Baltimore, Md. 21285. There will be 28 therapeutic classes reviewed and 6 single new drug reviews. Some of the classes being reviewed include Anticonvulsants, Antidepressants, Antipsychotics, Bronchodilators and COPD Agents, NSAIDS, Ophthalmics, Sedatives/Hypnotics and Stimulants and Related Agents. The complete list of the classes being reviewed at this meeting can be found at http://www.dhmh. state.md.us/mma/mpap/mtgnotice.html. Results of the Committee recommendations will be reviewed by the Department, and if necessary by the Drug Utilization Board. Once approved, the new Preferred Drug List (PDL) will take effect January 1, 2012.

Continuing Medical Education and Pharmacy Continuing Education (CE) Seminar

Join us for a Live CME/CE Seminar. We are offering a Continuing Medical Education (CME) and Pharmacy Continuing Education (CE) seminar. The program is being sponsored by the Department of Health and Mental Hygiene (DHMH). The topic of the program is "The Current State of HIV/AIDS Infection" and it will be held Saturday November 5, 2011 at St. Agnes Hospital. The seminar and CE credits are free of charge. Both pharmacy and medical education credits are being offered. Pharmacy CE credits are provided by the Maryland Board of Pharmacy and medical CE credits are provided by St. Agnes Hospital. A registration form is online at www.marylandmedicaidpharmacyinformation.com.

Registration will begin at 8:00 am and breakfast will be provided. The Seminar will begin at 8:30 am and it is anticipated to end at 1:30 pm.

Objectives of the seminar are noted below.

- · Provide an overview of the prevalence of HIV/AIDS in Maryland
- Discuss current HIV/AIDS treatment recommendations
- · Identify barriers to success of HIV treatment
- · Discuss the prevalence of cancer in HIV infected patients
- · Discuss Hepatitis Co-infection

Go Green!!!! Sign up to Receive the MMPP News & Views and Advisories via e-mail.

Look for information coming soon on the MMPP website http://www.dhmh.state.md.us/mma/mpap/ that will allow you to sign up to receive future copies of the MMPP News & Views and important Advisories via e-mail. Past issues of the newsletter can be viewed at:

www.marylandmedicaidpharmacyinformation. com and there you can also sign up to receive future copies of the News & Views and Advisories via e-mail.





Maryland Medicaid Pharmacy Program

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Martin O'Malley, *Governor* Anthony G. Brown, *Lt. Governor* Joshua M. Sharfstein, M.D, *Secretary, DHMH* PRSRT STANDARD U.S. POSTAGE PAID PERMIT #273 ANNAPOLIS, MD

Advisory Keeps You in the Know

Get the latest updates regarding pharmacy issues through the Maryland Medicaid Pharmacy Program (MMPP) e-mail notification service. Called the *Advisory*, these communications provide the pharmacy community with the most up-to-date information. *Advisories* can be found at this link http://www.dhmh.state.md.us/mma/mpap/provadv.html

Please contact the MMPP representative at 410-767-1455 if you are currently not receiving e-mail *Advisories* through a pharmacy organization to which you belong. You can sign up to receive Advisories and the MMPP News & Views via e-mail by going to the website:

www.marylandmedicaidpharmacyinformation.com and follow the links to enter your e-mail address. See page 5 of this newsletter for more information.

TELEPHONE NUMBERS

ACS Technical Assistance and Preauthorizations

1-800-932-3918 24 hours a day, 7 days a week

Maryland Medicaid Pharmacy Access Hotline

1-800-492-5231 (select option three) Monday-Friday, 8:00 am to 5:00 pm

Kidney Disease Program

1-410-767-5000 or 5002

Monday-Friday, 8:00 am to 5:00 pm

Breast & Cervical Cancer Diagnosis and Treatment

1-410-767-6787 Monday-Friday, 8:00 am to 4:30 pm

Maryland AIDS Drug Assistance Program

1-410-767-6535 Monday-Friday, 8:30 am to 4:30 pm