Maryland Medicaid Pharmacy Program

# Pharmacy News & Views

February 2011

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

## Antipsychotics on Maryland Medicaid PDL and Coverage of a 30-day Emergency Supply of Atypical Antipsychotics

The Pharmacy Program's Preferred Drug List (PDL) was updated on October 1, 2010 *(http://www.dhmh.state.md.us/mma/mpap/druglist.html).* Some of the atypical antipsychotics are now subject to Step Therapy and/or Prior Authorization (PA).

When a "prior authorization required" denial message on a submitted claim is received, the pharmacy should contact the prescriber to either change the medication or have the prescriber obtain the necessary PA. It would be beneficial if the pharmacist would advise the prescriber of the alternative drugs that are Tier 1. Tier 1 drugs do not require a PA. Normally, the prescriber can obtain a PA with a phone call.

When the prescriber is not available to obtain a PA for an atypical antipsychotic medication that is non-preferred or subject to Step Therapy, a one-time-only authorization can be obtained to dispense up to a 30-day emergency supply. This policy was previously communicated in Advisories #65 on April 7, 2009 and #71 on September 30, 2009 *(http://www.dhmh.state.md.us/mma/mpap/provadv.html)* and remains in place. The pharmacist should use his or her professional judgment in determining whether the prescription is needed on an emergency basis, taking into account the patient's diagnostic and drug history, information about what medications the patient has on hand, and possible recent hospitalization, as well as any mobility, transportation or communication issues that make returning to the pharmacy difficult. ***The patient should not leave your pharmacy without medication if you believe that they will not return or will have difficulty returning to the pharmacy later that same day.***

In order to process a paid claim for an emergency supply of an atypical antipsychotic requiring a PA, the pharmacy must call 1-800-932-3918 for authorization. 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 the pharmacist contacted at the prescriber's office.

## Response to Corrective Managed Care (CMC) Program Intervention Letters

The Corrective Managed Care (CMC) Program is an ongoing effort conducted by the Maryland Medicaid Pharmacy Program (MMPP) to monitor and promote appropriate use of controlled substances. Maryland Medicaid recipients are identified who appear to be receiving duplicate controlled drug therapy, visiting

*(continued on Page 5)*

## Removal of Active Pharmaceutical Ingredients (API's) and Excipients as Covered Outpatient Drugs

In early 2011, several compounding ingredients, including bulk powders and excipients will no longer be covered by the Maryland Medicaid Pharmacy Program (MMPP) as a result of guidance received from the Centers for Medicare and Medicaid Services (CMS). This includes active pharmaceutical ingredients (API's) and excipients.

An API is a bulk drug substance, which is defined by the Food and Drug Administration (FDA) as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. According to

*(continued on Page 4)*

## In This Issue

## Tamper-Resistant Prescriptions Required for Prescriptions Reimbursed by the Maryland Medicaid Pharmacy Program

This is a reminder that prescriptions reimbursed by the Maryland Medicaid Pharmacy Program are required to be written on Tamper-Resistant Prescription Pads. This includes all prescriptions for fee-for-service recipients and those prescriptions for HealthChoice recipients for mental health drugs and antiretroviral agents. The exceptions to the Tamper-Resistant requirements are:

- if a prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax (please note that Schedule II controlled substances require a written prescription)
- or if a managed care organization pays for the prescription

Compliance with these COMAR regulations are mandatory 10.09.03.01 (26) and 10.09.03.05 (G). Any claims submitted for payment to the Medicaid Pharmacy Program which are not in compliance with the tamper resistant requirements will be subject to recovery of all funds paid by the State. Please review and ensure that your pharmacy is in compliance with the Maryland Medicaid Tamper-Resistant Prescription Pad regulations.

The link below provides more detailed information regarding the requirements for Tamper-Resistant Prescription Pads for Medicaid prescriptions. *http://www.dhmh.state.md.us/mma/mpap/prescrip_pads.htm*

## Dose Optimization Limitations for Mental Health Medications

For a complete listing of Dose Optimization Limitations for Mental Health Medications, go to *http://www.dhmh.state.md.us/mma/mpap/policies.htm.* Only the limits on the table at that site are subject to the dose optimization criteria. Those doses of the products that do not have any quantity limitations are also listed. These limits are based on the manufacturers' recommended dosing found in the product labeling. A patient is limited to the quantities for the specific time period as noted on the table.

Exceptions to these limits for clinical reasons, if in the best interest of the patient, can be obtained. A prior authorization form for obtaining quantities in excess of those listed can be found at *http://www.dhmh.state.md.us/mma/mpap/forms.htm* or by calling 1-800-932-3918.

## Coverage for Over-The-Counter (OTC) Pharmacy Products

The Maryland Medicaid Pharmacy Program will cover a number of OTC products when a recipient presents a prescription written by an authorized prescriber. For a listing of those products covered, see *http://www.dhmh.state.md.us/mma/mpap/policies.htm.*

## Revised MMPP Pharmacy and Therapeutics (P&T) Schedule

The Maryland Medicaid P&T Committee meets twice a year to make recommendations for updates to the Maryland Medicaid Preferred Drug List (PDL). The schedule of meetings and subsequent changes to the PDL has been revised for 2011. The next P&T Committee meeting is scheduled for May 24, 2011. The current PDL will be in place until July 1, 2011, at which time changes to the PDL discussed at the May 24th meeting will be implemented. The second meeting of the P&T Committee will take place in November 2011.

Clinical Corner

# Variation in Opioid Effects Due to Altered Drug Metabolism

"Clinical Corner" is a new feature of the Pharmacy News and Views Newsletters. Each issue will contain a brief article discussing relevant clinical considerations such as drug-interactions, issues pertaining to drug metabolism and potential adverse events.

Some patients taking what would be considered relatively high doses of specific opioids may have a poor or less than desired analgesic response. These poor responses can be due to genetic factors with respect to drug metabolism. Some commonly prescribed opioids are metabolized to their active forms before they exert an analgesic effect. Hydrocodone is metabolized to hydromorphone and the active form of codeine is morphine. The Cytochrome P450 system is responsible for these processes and specifically the CYP2D6 is a key enzyme.

Variants in the CYP2D6 enzyme function can result in changes in opioid metabolism and differences in opioid analgesic effects. Poor metabolizers of codeine and hydrocodone have a reduced ability to convert these drugs to their active forms, morphine and hydromorphone respectively. These patients may experience a reduced analgesic effect from what would be considered therapeutic doses for most patients. They may require higher doses of specific opioids to achieve a similar analgesic effect. It may appear that some of these patients are abusing opioids when in fact they may require higher doses than most other patients. Rapid metabolizers experience an enhanced opioid analgesic effect, as well as potential adverse effects, since they quickly and efficiently convert these drugs to an active form. Using opioids that are not impacted by the CYP2D6 enzyme (for example morphine or hydromorphone) may be an alternate means of treating these particular patients.

Genetic testing of variants in the CYP2D6 enzyme can be very useful in identifying rapid and poor metabolizers and explaining why some patients respond poorly to specific opioids or for those who experience adverse effects to relatively low doses.

Many other factors can influence opioid metabolism and response, such as drug interactions that influence CYP2D6 and other enzymes. Other medical conditions, mainly renal or hepatic impairment, also can have a significant impact on opioid metabolism. Listed below are two comprehensive references that may be useful in discussing this topic in much greater detail.

H.S. Smith, MD. Opioid Metabolism Mayo Clin Proc. July 2009;84(7):613- 624
*http://www.mayoclinicproceedings.com/content/84/7/613.full*

S.C. Armstrong, M.D., G.H. Wynn, M.D., and N.B. Sandson, M.D. Pharmacokinetic Drug Interactions of Synthetic Opiate Analgesics. Psychosomatics 50:169-176, March-April 2009

## Generic vs. Brand Status on Maryland's Preferred Drug List (Note New Fax Number)

Medicaid's Preferred Drug List, encompassing about 1000 drugs, covers most of the generic versions of preferred multisource brand drugs without any type of prior authorization. **If the brand name drug is required, the prescriber must complete a MedWatch form** *(http://www.dhmh.state.md.us/mma/mpap/medwatch.htm)* **and fax it to ACS at 866-440-9345 for review. Please note that as of March 1, 2011 this is a new fax number.** The State's clinical pharmacists will review the MedWatch form and will notify the prescriber whether the request for the brand name drug was approved or denied. The State will then forward the MedWatch form to the FDA.

There are exceptions to this rule which change from time to time. Not all generics are preferred over the equivalent brand name drug. In order for the State to enhance the benefit of the PDL, in some instances the single source brand name drug is Preferred over its generic equivalents, because the branded drug is less costly to the Program 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 nor authorization is needed. Enter a DAW code of 6 on the claim to have it correctly paid.

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 (for example, if there is other primary insurance).

The entire PDL can be found at *http://www.dhmh.state.md.us/mma/mpap/druglist.html.*

Brand name preferred exceptions are noted throughout the document.

This PDL is also available at *http://www.epocrates.com/* on your desktop computer or PDA/Smartphone. Epocrates is updated weekly and is free to subscribe.

## Responsible Use of Intervention Codes

As the community pharmacist is well aware, the Maryland Medicaid Pharmacy Program (MMPP) performs prospective drug utilization review (ProDUR) on each submitted claim. ProDUR alerts are designed to prevent and reduce adverse drug effects. They do so by identifying conflicts in drug therapy, including therapeutic duplication, drug-drug interactions, and high doses. Claims can be overridden when the prescriber has been consulted (MO code), the pharmacist has reviewed the profile (RO code), or the pharmacist counsels the patient (PO code).

The MMPP relies on the pharmacist to use his or her best clinical judgment in determining when the prescriber should be consulted. The MMPP continues to evaluate therapeutic duplication alerts that are over-ridden by the pharmacist. ***The majority of override codes indicated that the prescriber was consulted (claims overridden with the MO code). The MO code should only be used when the prescriber is consulted.*** Be advised that the MMPP counts on the pharmacist to use the intervention codes responsibly and to monitor their use by the pharmacy technical staff.

---

*(***Removal of Active Pharm. Ingred.** *cont. from Page 1)*
definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, API's and excipients are not subject to the requirements of the Medicaid Drug Rebate (MDR) program and therefore will no longer be covered by the Maryland Medicaid Pharmacy Program.

A listing of these compounding powders, excipients and products can be found on the CMS website at the link below. Please note that this is not a definitive list. However, some of the compounding powders may be covered by the program. Currently MMPP is reviewing the list. Once the list is finalized it will be included in an Advisory.
*http://www.cms.gov/Reimbursement/02_Spotlight.asp*

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



# Pharmacy News & Views

**Maryland Medicaid Pharmacy Program**
201 West Preston Street, 4th Floor
Baltimore, Maryland 21201
410-767-1455

Martin O'Malley, *Governor*
Anthony G. Brown, *Lt. Governor*
Joshua M. Sharfstein, M.D, *Secretary, DHMH*

## DHMH E-mail "Advisory"

The MMPP utilizes an e-mail notification service called an "Advisory" to provide the pharmacy community with important timely information. Recent Advisories have discussed many of the topics that are included in this newsletter, along with other issues that that are of interest to the provider community. All of the current Advisories are listed on the MMPP website at the following link: http://www.dhmh.state.md.us/mma/mpap/provadv.html. If you are currently not receiving e-mail Advisories through a pharmacy organization you belong to, please contact the MMPP representative at 410-767-1455.

**Response to Corrective Managed Care** (*continued from Page1)* multiple prescribers and/or patronizing multiple pharmacies to obtain controlled substances. Physicians and pharmacies are sent educational intervention letters along with a response form to indicate any action taken. **It is critically important that completed response forms are returned so that the Program can be modified based on pharmacy and prescriber responses and action taken with regard to the intervention letters.** If overutilization of a controlled substance continues by a recipient, they can be "locked-in" or restricted to one pharmacy to obtain all of their medications.

Thank you for your cooperation in this manner and for helping the MMPP ensure the safe and effective use of controlled substances.

## 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