



Pharmacy News & Views

April 2013

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

Emergency Supply of Medications

When a “**non-preferred medication**” denial message is received on a submitted fee-for-service claim, the pharmacy should contact the prescriber to either change the medication, or have the prescriber obtain the necessary Prior Authorization (PA). It would be beneficial for the pharmacist to advise the prescriber of alternative drug(s) that do not require a PA. Normally the prescriber can obtain a PA with a phone call to **1-800-932-3918**.

When the prescriber is not available to obtain a PA, and the pharmacist in their professional judgment determined that the prescription is needed on an emergency basis, they should contact the Xerox call center at 1-800-932-3918 and request authorization to dispense a 72-hour emergency supply.

The pharmacist should use professional judgment in determining whether an emergency supply is needed. Please take 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 or expensive.

During the 72-hour window, the pharmacist is to contact the prescriber who must obtain prior authorization before the remainder of the prescription can be dispensed. After prior authorization has been established, the pharmacist can dispense the remainder of the prescription.

In the case of sprays, inhalers, eye or ear drops, creams, ointments, antibiotics, etc., it may be necessary to dispense the entire prescription as an emergency supply due to the way the drug is packaged or administered.

A 30-day supply is allowed for atypical antipsychotic medications while awaiting prior authorization for a non-preferred or Tier 2 drug.

For HealthChoice MCO and PAC members requiring an emergency supply of non-mental health and non-antiretroviral drugs, the pharmacist must contact the appropriate MCO Pharmacy Benefit Manager and follow their procedures before dispensing an emergency supply.

If at all possible 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.

Tier 2 and Non-Preferred Antipsychotics for Patients Age 10 Years and Older

The following clinical criteria must be met to obtain prior authorization (PA) for non-preferred and Tier 2 antipsychotics. All other existing policies such as those regarding generic substitution and quantity limit (including dose optimization) continue to apply to these drugs as well.

Note: Patient will be grandfathered if patient has been on the prescribed drug for greater than 30 days in the previous 120 days.

Criteria for immediate approval upon review:

- The medication was started on an inpatient unit/other acute care setting; **OR**

Tier 2 & Non-Preferred Antipsychotics (continued on Page 2)

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Tier 2 & Non-Preferred Antipsychotics (continued from Page 1)

- All preferred antipsychotics are medically contraindicated for the patient.

Other requests will be evaluated based on the following criteria:

- The patient has had an adequate trial (at least 6 weeks at recommended dose) of at least one preferred antipsychotic drug where FDA indicated;
AND
- The patient has a FDA indicated diagnosis for the requested medication;
AND
- The requested medication complies with the FDA package insert for dosage and frequency.

The use of pharmaceutical samples will not be considered when evaluating the patient's medical condition or prior prescription history for drugs that require prior authorization.

All requests are reviewed by a psychiatric clinical pharmacist at the Maryland Medicaid Pharmacy Program or its designee.

Requests for specific drugs/dosage forms

When a drug is available in an oral tablet or capsule dosage form, all other dosage forms (excluding injectable) will only be approved if the patient has medical justification(s) or condition(s) that prevents him/her from taking an oral tablet or capsule.

Invega® oral tablet: Authorization will only be approved if the patient has medical justification for not being able to take risperidone, or if the patient is being prepared for the Invega Sustenna®, then up to a 30 day supply of the tablets will be approved.

More information can be found at the MMPP website at:
<http://mmcp.dhmf.maryland.gov/pap/SitePages/paphome.aspx>

Peer Review Program for Antipsychotic Use in Children

There is increased public scrutiny, controversy and debate regarding the use of the antipsychotic agents in children and the lack of data on long-term effects. Many children receive these medications for non-FDA approved indications for which efficacy has not been demonstrated. Furthermore, studies have indicated that children and adolescents receiving these agents do not always receive appropriate side effect monitoring. These issues are complicated by the fact that almost half of those prescribing antipsychotics for children are primary care practitioners who may have less familiarity with these agents.

For these reasons, the State of Maryland Medicaid Pharmacy Program (MMPP) launched a new program in 2011 – The Peer Review Program for Mental Health Drugs. The program expanded on July 31st, 2012 and now addresses the use of antipsychotics in Medicaid patients under ten years of age. It is expected that the program will expand again in 2013 and include patients up to 17 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 peer review will inform clinicians of relevant clinical information for decision-making and ensure the appropriate use while monitoring for adverse outcomes in Medicaid's vulnerable pediatric patients. Claims for antipsychotic medications that are for children up to 17 years of age will require a Prior Authorization (PA) based on the peer-review assessment.

The Peer Review Program works as follows:

1. Unless the prescriber has contacted the Peer Review Call Center and provided a faxed application form or the necessary verbal information, the claim will be denied at the Point of Sale.
2. The denial message will be "PA Required" and "Prescriber or their designee must call Antipsychotic Peer Review Center at 1-855-283-0876 for PA"
3. The denial will require the pharmacy provider to contact the prescriber to obtain the PA.
4. The prescriber must contact the Peer Review call center and proceed with consultation
5. 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. In some instances, the Peer Review call center will notify the pharmacy provider.

6. After the initial PA is approved (usually for six months), the prescriber will need to complete a request to renew authorization to continue the therapy.

More information can be found at the MMPP website at: <http://mmcp.dhmf.maryland.gov/pap/SitePages/paphome.aspx>

Late Refill Alerts of HIV/AIDS Medications

This is to serve as a reminder that the Medicaid Pharmacy Program has in place a "Late Refill" edit which denies claims for any antiretroviral drug that is refilled later than 16.7% of the last days supply (e.g. on day 36 after a 30 day supply, or on day 17 after a 14 day supply).

When such a claim for an antiretroviral
(continued on Page 5)



Recent FDA Safety Warnings and Label Changes for Zolpidem (Ambien®)

On January 10, 2013 the Food and Drug Administration (FDA) issued a Drug Safety Communication concerning the dosing of immediate release and extended release zolpidem products in non-elderly women. New data has demonstrated that in some patients blood levels of the drug may still be high enough the next morning to impair activities that require alertness, such as driving. The data also suggests that women eliminate the drug more slowly than men and for that reason may be more susceptible to next day drowsiness. The FDA recommendations to health care professionals regarding dosing of zolpidem are listed below, along with the revised labeling for zolpidem products. The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not being updated since the current labeling already recommends a lower dose for women than men.

Additional Information for Health Care Professionals

- **Immediate-release products:** FDA is requiring the manufacturers of certain immediate-release zolpidem products (Ambien, Edluar, and Zolpimist) to lower the recommended dose. FDA has informed manufacturers that:
 - o The recommended initial dose for women should be lowered from 10 mg to 5 mg, immediately before bedtime.
 - o The drug labeling should recommend that health care professionals consider prescribing a lower dose of 5 mg for men. In many men, the 5 mg dose provides sufficient efficacy.
 - o The drug labeling should include a statement that, for both men and women, the 5 mg dose could be increased to 10 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.
- **Extended-release products:** FDA is also requiring the manufacturer of extended-release zolpidem (Ambien CR) to lower the recommended dose. FDA has informed the manufacturer that:
 - o The recommended initial dose for women should be lowered from 12.5 mg to 6.25 mg, immediately before bedtime.
 - o The drug labeling should recommend that health care professionals consider prescribing a lower dose of 6.25 mg in men. In many men, the 6.25 mg dose provides sufficient efficacy.
 - o The drug labeling should include a statement that, for both men and women, the 6.25 mg dose can be increased to 12.5 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.

Zolpidem Dosing Recommendations for Adults (Non-Elderly)

	Dosing recommendations in current drug label for zolpidem	FDA's proposed new dosing recommendations for zolpidem
Ambien, Edluar, Zolpimist	Men and Women: 10 mg once daily, immediately before bedtime	Women: 5 mg once daily, immediately before bedtime
Ambien CR	Men and Women: 12.5 mg once daily, immediately before bedtime	Women: 6.25 mg once daily, immediately before bedtime Men: 6.25 or 12.5 mg once daily, immediately before bedtime

Physician Rubber Stamped Signatures on Prescriptions

COMAR 10.09.03.01 defines a prescription as “An original order signed by the prescriber.” Furthermore, the Maryland Board of Pharmacy does not recognize a prescription or prescription order with a rubber stamped signature of the prescriber as valid.

Therefore, the Maryland Medicaid Pharmacy Program (MMPP) considers any prescription claim submitted for payment with a rubber stamped signature of the prescriber as invalid and not reimbursable under current State regulations. MMPP and the Office of Inspector General will be auditing prescriptions to verify that they are not signed using a rubber stamp. Those prescriptions found to have been signed using a rubber stamp,

will be reversed and all funds paid to the pharmacy provider will be recovered.

In the event that the recipient presents to you a prescription with a rubber stamped signature of the prescriber, you should contact the prescriber to verify the prescription. Note this on the prescription where it can be viewed for an audit, front or back, as your system allows. As always, you can dispense a 72-hour emergency supply, if necessary.

MMPP Rules for Refills

The chart below indicates the rules associated with refills for prescription, filled under the MMPP program.

Type of Prescription	Number of Refills Allowed	Requirements		When Refill Allowed
Schedule II Controlled drugs	No refills	Date filled must be written within 30 days of date prescription order was written*		Requires new prescription order
Schedule III, IV and V Controlled drugs	Maximum 5 refills	Date first filled must be within 30 days of date prescription order was written Refills not allowed > 180 days after date prescription order was written	85% used	26 days after a 30 day supply was dispensed; or 29 days after a 34 day supply dispensed
Non-controlled, non-maintenance drugs	Maximum 11 refills	Date first filled must be within 120 days of date prescription order was written. Refills not allowed more than 360 days from date prescription order was written	85% used	26 days after a 30 day supply was dispensed, or 29 days after a 34 day supply was dispensed
Maintenance drugs	Maximum 3 refills (after initial prescription, which is limited to 34 day supply)	Refills not allowed more than 360 days from date prescription order written	90% used	90 days after a 100 day supply was dispensed; or 76 days after an 84 day supply dispensed

All requests for an override of an early refill denial at point of service are handled by Xerox in accordance with the Maryland Medicaid Program’s guidelines. Contact the call center at **1-800-932-3918**.

* See other article in this newsletter discussing post dated prescriptions for CII drugs.

Early Refill Edit Rejections

When processing claims, entering the appropriate days supply information is critical to the edit functions of the ProDUR system. Submitting incorrect days supply information in the days supply field can cause false ProDUR messages or claim denial for that particular claim or for drug claims that are submitted in the future. Refills that are submitted prior to 85% of the quantity dispensed being utilized will reject for an early refill. For early refill alerts for non-controlled medications, please use your professional judgment and contact the prescriber if needed. Then contact ***the call center at 800-932-3918*** to obtain an override.

For controlled drugs it is best to always contact the prescriber first unless you are well aware of the reason why the patient requires an early refill. Early refill overrides for controlled drugs can also be requested by calling the call center. However, overrides for early refills for controlled drugs are less likely to be approved without some indication that the prescriber has been contacted and informed of the issue.

Post Dated Prescriptions for CII Controlled Drugs

Federal law allows a prescriber to provide individual patients with multiple prescriptions for the same schedule II controlled substance to be filled sequentially. The combined effect of these multiple prescriptions is to allow the patient to receive, over time, up to a 90-day supply of that controlled substance. MMPP only allows prescriptions for controlled drugs to be filled within 30 days of the date they are ordered (COMAR 10.09.03.05). ***However, MMPP has a procedure to follow in which claims for CII prescriptions that are post dated can be filled as valid prescriptions. The prescriber must be contacted by the pharmacist and this must be documented on the prescription along with the date the prescriber was contacted and that the prescriber authorized the dispensing.***

Responsible Use of Intervention Codes

As the community pharmacist is well aware, MMPP performs a 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). If you have a question about a particular prospective DUR alert, contact the help desk at ***800-932-3918***.

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 overridden 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.

Late Refills Alerts (continued from Page 2)

drug rejects with the short message “DUR Reject Error”, the pharmacy will see a long message directing them to *“Counsel patient, Inform prescriber. Override with DUR code for pd claim.”* The pharmacist is expected to counsel the patient when dispensing the drug. While counseling patients, find out when they last took a dose or if they have missed any doses. Reinforce the importance of complying with the proper regimen. ***It is critically important that the patient does not leave the pharmacy without the medication.***

The pharmacist should alert prescriber about the late refill. To process the claim, the pharmacist should use the following DUR intervention codes:

“LR”(Underuse) in the Reason for Service field;

“MO or RO” (Prescriber Consulted or Pharmacist Consulted) in the Professional Service field; and
“1B” (Filled as is) in the Result of Service field.

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

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 prescription for a brand name drug is to be dispensed as written, the prescriber must complete and submit a DHMH Medwatch form (<http://mmcp.dhmh.maryland.gov/pap/SitePages/paphome.aspx>). The State's clinical pharmacy team will review the DHMH Medwatch form and notify the prescriber whether the request for the brand name drug was approved or denied. The State will forward the DHMH Medwatch form to the FDA.

The current non-preferred exceptions are as follows:

Non-Preferred Generics

adapalene
amphetamine salt combo ER
azelastine
brimonidine P 0.15%
budesonide respules
calcitonin salmon
calcium acetate
carbamazepine XR and ER capsules
clonidine patches
cyclosporine
dextroamphetamine
diazepam rectal
divalproex sprinkles
dronabinol
enoxaparin
morphine sulfate Er
tobramycin/dexamethasone
tranylcypromine
triamcinolone

Preferred Brands

Differin
Adderall XR
Astelin
Alphagan P 0.15%2
Pulmicort respules
Miacalcin
PhosLo
Carbatrol ER capsules
Catapres TTS patches
Sandimmune
Dexedrine spansules
Diastat
Depakote Sprinkles
Marinol
Lovenox
Kadian
Tobradex
Parnate
Nasocort AQ

Not All Generics are Preferred

In order for the State to enhance the benefit of the PDL, in some instances the multisource 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 DHMH Medwatch nor authorization is needed. Enter a **DAW code of 6** on the claim to have it correctly priced.

If any problems are encountered during the on-line claim adjudication of Preferred Brands, contact Xerox 24-hour Help Desk at **800-932-3918** for additional system overrides related to the use of the correct DAW code (for example, when there is other insurance primary).

The list of preferred brands may be updated July 1, 2013 based on a review of the PDL at the next P & T Committee meeting to be held May 2, 2013.

The PDL can be viewed at <https://mmcp.dhmh.maryland.gov/pap/SitePages/paphome.aspx>

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

Preferred generics

carbamazepine suspension
dexmethylphenidate
metipranolol
metronidazole
oxcarbazepine suspension
valacyclovir

Brand also Preferred - no DHMH MedWatch form required

Tegretol suspension
Focalin
Optipranolol
Metrogel-vaginal
Trileptal suspension
Valtrex

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.



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

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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://mmcp.dhmh.maryland.gov/pap/SitePages/paphome.aspx>

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.

TELEPHONE NUMBERS

Xerox 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

Peer Review Program

1-855-283-0876
Monday-Friday, 8:00 am to 6:00 pm
with exception of State Holidays