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## Medical Assistance Letter (MAL) No. 535

**TO:** All Providers of Pharmacy Services and Prescribers  
Directors, County Departments of Job and Family Services  
Medical Assistance Coordinators

**FROM:** Helen E. Jones-Kelley, Director

**SUBJECT:** Changes to the Pharmacy Program Effective October 1, 2007

This letter provides information regarding three changes to the Ohio Medicaid Pharmacy Program that will be effective October 1, 2007:

1. Changes to the Preferred Drug List (PDL)
2. Step edit for Long-Acting Beta Agonist (LABA) and LABA-corticosteroid combination products
3. Federal requirement for use of tamper-resistant prescription pads

### **1. Changes to the Preferred Drug List (PDL)**

The newest phase of the Ohio Medicaid Preferred Drug List will be effective in October 2007.

The drug classes were reviewed to determine those products that the Department considers "preferred" for Ohio Medicaid consumers. A "preferred" status in these classes indicates that the product does not require prior authorization (PA) in most situations. Products in these classes that are "non-preferred" are subject to prior authorization.

Beginning in September, messages are sent back to pharmacies when a drug that will become "non-preferred" is dispensed. This gives the pharmacy an opportunity to suggest to prescribers that they consider the use of an alternative "preferred" medication in the future, if appropriate. **Prescribers may request prior authorization prior to October.**

Please note that while most of these categories have been part of the PDL in the past, the preferred drugs in each class may have changed. The table below gives a summary of changes. This table is not all-inclusive.

**Drugs which will require a Prior Authorization as of 10/3/2007. These are either new PDL classes or drugs which were previously preferred and will now require a Prior Authorization.**

Drug class	Drug Name
Analgesic: Opioids-Long Acting Oral	Avinza®
Cardiovascular: Lipotropics-Fibric Acid Derivative	Fenofibrate (use Tricor® brand)
CNS: Sedative-Hypnotics: Non-Barbiturate	Ambien CR®
CNS: Smoking Deterrents	Nicotine Patches (use Nicoderm CQ® brand)
Genitourinary: Benign Prostatic Hypertrophy	Uroxatral®
Infectious Disease: Cephalosporins	Cefdinir tablets and suspension (use Omnicef® brand)
Infectious Disease: Onychomycosis	Grifulvin V®
Infectious Disease: Hepatitis C Ribavirins	Ribavirin (use Rebetol® brand)
Ophthalmic: Antihistamines & Mast Cell Stabilizers	Alamast®
Ophthalmic: Glaucoma	Betoptic S®
	Lumigan™
	Iopidine®
Respiratory: Beta-Adrenergic, Long Acting	Brovana™
Respiratory: Leukotriene Receptor Modifiers and Inhibitors	Zyflo®
Respiratory: Nasal Preparations	Veramyst™

**Drugs which will no longer require a Prior Authorization effective 10/1/2007. These are either new PDL classes or drugs which previously required a Prior Authorization.**

Drug class	Drug Name
Analgesic: NSAIDs	Piroxicam
Cardiovascular: Angiotensin II Receptor Blocker	Benicar®
Cardiovascular: Angiotensin II Receptor Blocker/Diuretic	Benicar HCT®
Cardiovascular: Beta Blocker	Toprol XL®
Cardiovascular: Lipotropics-Statin	Pravastatin
	Simvastatin
CNS: Sedative-Hypnotics: Non-Barbiturate	Zolpidem
CNS: Smoking Deterrents	Nicotrol Nasal Spray®
Endocrine: Osteoporosis-Bisphosphonate	Actonel®
Infectious Disease: Onychomycosis	Griseofulvin Suspension
Infectious Disease: Anti-Fungal Topical	Vusion®
Ophthalmic: Antihistamines & Mast Cell Stabilizers	Alaway®
	Pataday™

A "quick list" of preferred drugs is available online at <http://jfs.ohio.gov/ohp/bhpp/meddrug.stm>. This site also includes other information about the Ohio Medicaid pharmacy program, including the approved drug list, Provider Manual, PA request fax form, and P & T Committee information. Providers may call ACS to request a pocket-sized copy of the PDL.

Pharmacies may contact the Technical Help Desk at ACS for assistance:

Phone: 1-877-518-1545

Prescribers may request prior authorization through ACS:

Phone: 1-877-518-1546 Fax: 1-800-396-4111

## **2. Step edit for Long-Acting Beta Agonist (LABA) and LABA-corticosteroid combination products**

To promote prescribing of asthma controller medications according to published clinical guidelines, a step edit will be implemented for LABA-containing products. LABAs are indicated for treatment of asthma when two controller medications are necessary. Products affected by this edit are arformoterol (Brovana<sup>®</sup>), formoterol (Foradil<sup>®</sup>), salmeterol (Serevent<sup>®</sup>), formoterol-budesonide (Symbicort<sup>®</sup>), and salmeterol-fluticasone (Advair<sup>®</sup>).

Patients who have previously used other controller therapy, such as inhaled corticosteroids, are systematically approved for a LABA-containing product by the Department's automated prior authorization system. The majority (75%) of patients who are prescribed a LABA-containing product have used prior controller therapy, so will be automatically approved for the LABA-containing product without the prescriber needing to request prior authorization.

Patients whose Ohio Medicaid claims history meets any one of the following criteria will be automatically approved for the LABA-containing product:

<b>Criteria</b>	<b>Approval Length</b>
>= 3 claims for LABA-containing product in previous 6 months	6 months
>= 1 claim for inhaled anticholinergic in previous 6 months	12 months
>= 3 claims for inhaled corticosteroid in previous 12 months	6 months
>= 3 claims for leukotriene modifier in previous 12 months	6 months
>= 3 claims for theophylline in previous 12 months	6 months
>= 3 claims for oral corticosteroid in previous 4 months	6 months

If the patient's claims history does not meet any of the above criteria, the claim will be denied at the pharmacy and the prescriber may request prior authorization. Approvable criteria for prescriber-initiated prior authorization include diagnosis of chronic obstructive pulmonary disease (COPD); diagnosis of moderate persistent or severe persistent asthma, or uncontrolled or partly controlled asthma; or patient score of less than or equal to 19 on the Asthma Control Test<sup>™</sup>.

Compliance and persistence with asthma controller medications is an important tool in management of asthma. Patients who refill their LABA-containing product at least three times in each rolling six months will be automatically approved to receive their LABA-containing product for an additional six months. If the patient fails to refill their prescription three times per six months, and does not meet any of the criteria in the table above, the claim will be denied at the pharmacy and the prescriber will need to request prior authorization. At the time of prior authorization request, the prescriber will be educated about the patient's refill history and encouraged to speak with their patient about the importance of compliance with controller medications.

### **3. Federal requirement for use of tamper-resistant prescription blanks**

Congress passed HR2206, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Public Law 110-28, which amends the Medicaid statute to prevent payment of prescriptions "for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad." This federal law is effective October 1, 2007. In accordance with Ohio Administrative Code (OAC) rule 5101:3-9-06, "all records of prescriptions must comply with federal and state regulations." In addition, OAC rule 5101:3-1-17.2, Provider Agreement for Providers, reads "by signing this agreement the provider agrees to comply with the terms of the provider agreement, Revised Code, Administrative Code, and federal statutes and rules..."

The federal Centers for Medicare and Medicaid Services (CMS) released guidance on August 17, 2007, to clarify this provision.

To be considered tamper resistant on October 1, 2007, a prescription pad must contain at least one of the following three characteristics:

- 1) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- 2) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
- 3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

No later than October 1, 2008, to be considered tamper resistant, a prescription pad must contain all of the foregoing three characteristics. At this time, CMS has not released specific information to clarify the exact nature of these "industry-recognized features." Information will be provided as it becomes available. Please watch the Department's web site at <http://jfs.ohio.gov/ohp/bhpp/omdp/POS.stm> for updated information.

This requirement applies to:

- all written prescriptions presented at the pharmacy on or after October 1, 2007, regardless of the date the prescription was written;
- written prescriptions for all outpatient drugs, including controlled, non-controlled, and over-the-counter drugs;
- written prescriptions for drugs provided in a long-term care facility (LTCF), including nursing facility or intermediate care facility for the mentally retarded (ICF-MR), if the prescription is billed separately from the facility's charge (most prescriptions for LTCF residents are billed separately);
- written prescriptions when Medicaid pays any part of the claim, including when Medicaid is not the primary payer; and
- written prescriptions billed to Medicaid after the date of service due to retroactive eligibility.

This requirement does not apply to:

- refills of written prescriptions presented at a pharmacy before October 1, 2007;

- e-prescriptions transmitted to the pharmacy in accordance with state law;
- prescriptions faxed to the pharmacy in accordance with state law;
- prescriptions communicated to the pharmacy by telephone by a prescriber in accordance with state law;
- prescriptions for which payment will be made by a Medicaid managed care entity (i.e., this requirement applies only to prescriptions written for patients who receive a monthly paper Ohio Medicaid card, not to prescriptions written for patients enrolled in a Medicaid managed health care organization); and
- orders for medications administered in a provider setting (e.g., physician office or hospital outpatient or emergency department) and billed by the administering provider.

If a patient presents a non-compliant written prescription, the pharmacy may provide an emergency fill of the drug if the prescriber provides the pharmacy with a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.

#### **Web Page and Paper Distribution:**

The Ohio Department of Job and Family Services maintains an "electronic manuals" web page for the department's rules, manuals, letters, forms and handbooks. The URL is <http://emanuals.odjfs.state.oh.us/emanuals/>.

Providers may view documents online by:

- (1) Selecting "Ohio Health Plans – Provider"
- (2) Selecting "Pharmacy Services"; and
- (3) Selecting the desired item from the "Table of Contents" pull-down menu

The Legal/Policy Central Calendar (<http://www.odjfs.state.oh.us/lpc/calendar>) site is a quick reference of documents recently published. The Legal/Policy Center Calendar site also provides a link to a listing of ODJFS Letters (<http://www.odjfs.state.oh.us/lpc/ml>). The listing is categorized by letter number and subject and a link is provided to the easy print (PDF) document.

#### **Questions:**

Questions pertaining to this letter should be addressed to:

Office of Ohio Health Plans  
Provider Services Section  
P.O. Box 1461  
Columbus, OH 43216-1461  
Toll Free Telephone Number 1-800-686-1516