



MARYLAND PHARMACY PROGRAM

Medicaid - Pharmacy Assistance – Pharmacy Discount

No. 12
Friday, November 5, 2004

ADVISORY

*In an effort to give timely notice to the pharmacy community concerning important pharmacy topics, the Department of Health and Mental Hygiene's (DHMH) **Maryland Pharmacy Program (MPP)** has developed the **Maryland Pharmacy Program Advisory**. To expedite information timely to the pharmacy and prescriber communities, an email network has been established which incorporates the email lists of the Maryland Pharmacists Association, EPIC, CARE, Long Term Care Consultants, headquarters of all chain drugstores and prescriber associations and organizations. It is our hope that the information is disseminated to all interested parties. If you have not received this email through any of the previously noted parties or via DHMH, please contact the MPP representative at 410-767-5395.*

New Cost Containment Initiatives

- I. Step Therapy for Non-Steroidal Anti-Inflammatory/COX-II Inhibitors
- II. Actiq[®] Restrictions
- III. Quantity Limits for Anti-emetic Drugs
- IV. Ranitidine and Fluoxetine Dosage Form Restrictions
- V. Two Drug Classes Removed from the Preferred Drug List: **Intermittent Claudication Agents and Estrogen Agents, Oral and Transdermal**

I. Step Therapy Requirements for the Class-Non-Steroidal Anti-Inflammatory/COX-II Inhibitors

Effective November 15, 2004 the “Non-steroidal Anti-inflammatory (NSAID)/COX-II Inhibitor” class of drugs will become subject to a three-tier step therapy protocol. All New Pharmacy Program prescriptions in this class will be affected.

The three tiers of NSAID/COX-II Inhibitors are:

- *Tier One – Preferred NSAIDs;*
- *Tier Two – Preferred COX-II Inhibitors and Prevacid Naprapac; and,*
- *Tier Three – Non-Preferred NSAIDs.*

Tier One

All of the drugs in Tier One are generic NSAIDs. With few exceptions, it is required that drugs from Tier One must be tried first, before drugs in other Tiers may be prescribed without preauthorization.

Tier Two

If the therapeutic responses of Tier One drugs are not satisfactory, Tier Two drugs may be considered. When a recipient has had a prescription for a Tier One drug within the previous 45-day period, prior to a new prescription for a Tier Two drug, he or she will be eligible for a Tier Two agent. This step therapy will allow for prescriptions for Tier Two drugs to be automatically accepted without preauthorization, as they are adjudicated online. The preferred drugs in Tier Two are **Bextra[®]**, **Celebrex[®]**, and **Prevacid Naprapac[®]**.

In the event of such diagnoses as esophageal reflux disease, asthma, rhinitis, nasal polyps, NSAID hypersensitivity and GI ulceration, bleeding or perforation, a Preferred Tier Two agent may be prescribed with prior authorization, absent NSAID failure.

Tier Three

Finally, after a Tier Two Preferred agent has failed, a Tier Three non-preferred NSAIDs may be prescribed. However, pre-authorization will be necessary. The agents in Tier Three are Arthrotec[®], Mobic[®], and Ponstel[®].

II. Actiq[®] Restrictions

The current Food and Drug Administration labeling for Actiq[®] (transmucosal fentanyl), which has non-preferred status at this time, specifies that this dosage form of the drug has very limited use. The labeling reads as follows:

Actiq[®] (transmucosal fentanyl) is indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. The drug is not indicated in the management of acute or postoperative pain. This medication must not be used in opioid non-tolerant patients. Transmucosal fentanyl is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are experienced in the use of Schedule II opioids to treat cancer pain.

Based on the labeling criteria for this drug, the Program is implementing additional prior authorization criteria effective November 1, 2004. A copy of the prior authorization request form, which spells out the criteria for use of Actiq[®] is attached. Prescribers may **call 1-800-932-3918** for an authorization or **fax a completed copy of the Prior Authorization Request Form to 1-800-932-3921**.

The duration of the preauthorization is six months unless the prescriber requests a shorter period. The quantity limit for Actiq will be 120 units in a 34-day period regardless of dosage strength.

III. Quantity Limits for Anti-emetic Drugs

In an effort to avoid wastage in the anti-emetic class of drugs, the Maryland Pharmacy Program will implement quantity limitations that are explicit in the Food and Drug Administration labeling of these drugs. While the newer anti-emetics offer therapeutic advantages over their traditional counterparts, they are substantially more costly. Since they are indicated for only a few days post chemotherapy or radiation therapy, their use will be appropriately limited to quantities more reflective of anticipated treatment duration. Quantity limitations are as noted on the following table. When necessary, prior authorizations for quantities in excess of these limits will be available.

PRODUCT (Preferred in bold)	STRENGTHS/ DOSAGE FORMS	APPROVED ADJUNCT CHEMO REGIMENS	30-DAY QUANTITY LIMITS
Emend[®] (aprepitant)	<ul style="list-style-type: none"> • 80 & 125 mg caps • 125mg/80mg Tri-fold Pack (3's) 	Chemo: 125mg 1hr pre-Tx, then 80mg daily for 2-3 days in combination with dexamethasone	15 tabs
Marinol[®] (dronabinol)	<ul style="list-style-type: none"> • 2.5, 5, & 10mg caps 	Chemo: 2.5 to 40mg per day in divided doses every 4 to 6 hrs	60 caps
Zofran[®], Zofran ODT[®] (ondansetron)	Zofran: <ul style="list-style-type: none"> • 4 & 8 mg tabs – 30s, 100s, & 1x3 daily UD packs • 24 mg tabs – 1x1 daily UD packs • Oral soln. (4mg/5ml) – 50 ml bottles 	<ul style="list-style-type: none"> • Chemo: 8mg, 30 min. pre-Tx, and 8mg, 8 hrs later; then 8mg q 12 hrs for 1 to 2 days post Tx. • Radiation: 8mg, 1 to 2 hrs pre-Tx; then up to q 8 hrs for 1 to 2 days post-Tx 	<ul style="list-style-type: none"> • 15 tabs (4 or 8mg) • 10 tabs (24mg)
	Zofran ODT (orally disintegrating tabs): <ul style="list-style-type: none"> • 4mg - UD 30s • 8mg - UD 10s & 30s 		<ul style="list-style-type: none"> • 100ml • 15 tabs (4 or 8mg)
Anzemet[®] (dolasetron)	<ul style="list-style-type: none"> • 50mg tabs -5s, blister pack 5s, & UD 10s • 100mg tabs - 5s, blister pack 5s, and UD 10s 	Chemo: 100mg within 1 hr of chemo.	10 tabs
Kytril[®] (granisetron)	<ul style="list-style-type: none"> • 1mg tab - 2s and 20s • 1mg/5ml oral soln. - 30ml 	<ul style="list-style-type: none"> • Chemo: 2mg q d within 1 hr of Tx or 1mg (5ml) 1 hr prior to Tx and 1 mg (5ml) 12 hrs later. • Radiation: 2mg within 1 hr of TX 	<ul style="list-style-type: none"> • 15 tabs • 90ml

IV. Ranitidine and Fluoxetine Dosage Form Restrictions

Generic ranitidine and fluoxetine are both available as tablets and capsules. The literature reports no therapeutic differences between the two solid oral dosage forms for each of these agents. However, there is a substantial difference in the cost, depending on which dosage form is dispensed. Ranitidine capsules are significantly more expensive than the tablets. Fluoxetine tablets are significantly more expensive than the capsules. Therefore, the Maryland Pharmacy Program will no longer cover the more expensive forms without preauthorization by the prescriber. Effective November 15, 2004, prescribers must call 800-492-5231 if they find it medically necessary to prescribe ranitidine capsules or fluoxetine tablets.

V. Two Drug Classes Removed from the Preferred Drug List

Two drug classes -- **Intermittent Claudication Agents** and **Estrogen Agents, Oral and Transdermal**—were removed from the Preferred Drug List (PDL). The previous Maryland Pharmacy Program Advisory (Advisory # 11: Preferred Drug List-The Second Year dated October 27, 2004) excludes these classes.

Full consideration for the recipient continues to be a top priority. Recipients having problems obtaining prescribed medications from the pharmacy may call the Maryland Pharmacy Access Hotline at 1-800-492-5231. Questions concerning this Advisory should be directed to the Division of Pharmacy Services, 410-767-1455.

**MARYLAND PHARMACY PROGRAM
PRIOR AUTHORIZATION REQUEST
ACTIQ®**

Recipient Name: _____ **DOB:**

Medicaid ID #:

Patient Location: ___ Outpatient ___ Nursing Home ___ Group Home

Actiq® Prior Authorization Criteria - Patient must meet all five criteria below:

Yes No 1. Diagnosis of cancer. State specific cancer diagnosis _____

Yes No 2. Over 16 years of age.

Yes No 3. Under the care of an oncologist or pain specialist who is experienced in the use OF Schedule II opioids to treat cancer pain II

Yes No 4. Currently receiving and tolerant to opioid therapy. (i.e. patient is taking at least 60 mg. of morphine per day, 50 mcg. transdermal fentanyl/hour or an equianalgesic dose of another opioid for a week or longer).

Yes No 5. Does not have any of the following contraindications: hypersensitivity to opiates; hypoxia/hypercarbia; severe asthma or chronic obstructive pulmonary disease; or paralyti cileus.

List all current opioid therapy and duration of use:

<u>Drug</u>	<u>Total daily dose</u>	<u>Duration of therapy</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

I certify that use of Actiq® for this patient is consistent with the FDA approved labeling.

Prescriber Signature: _____ **Date:** _____

Prescriber Name: _____ **DEA#:**

Address: _____

Phone #:

Is prescriber a Pain Management Specialist or Oncologist? Yes ___ No ___ If no indicate area of practice (such as Internal Medicine, Family Practice) _____.

FAX THIS FORM TO: 800-932-3921
For information on a Prior-Authorization request, please call First Health Services at 800-932-3918