

**DEPARTMENT OF SOCIAL AND HEALTH SERVICES
HEALTH AND RECOVERY SERVICES ADMINISTRATION
Olympia, Washington**

To: All Prescribers
Managed Care Organizations
Nursing Facility Administrators
Pharmacists
Regional Support Networks

Memo: 09-21
Issued: June 1, 2009

From: Douglas Porter, Assistant Secretary
Health and Recovery Services
Administration

For further information, go to:
<http://hrsa.dshs.wa.gov/pharmacy>

Subject: Prescription Drug Program: Minimum Dose Limits for Seroquel®/Seroquel XR® and Changes to the Washington PDL, EA List, and List of Limitations on Certain Drugs

Effective for dates of service on and after July 1, 2009, the Department of Social & Health Services (DSHS) will:

- Implement minimum dosage limits for Seroquel®/Seroquel XR® (quetiapine fumarate);
- Require the dispensing of 90-day supplies for clients who are stable on specific drugs;
- Implement a new drug class in the Washington Preferred Drug List (PDL);
- Make changes to the Washington PDL; and
- Made additions to the Expedited Authorization (EA) List.

Minimum Dosage Limits for Seroquel®/Seroquel XR® (quetiapine fumarate)

Effective July 1, 2009, DSHS will require prior authorization (PA) for prescriptions of Seroquel®/Seroquel XR® dosed daily at 50mg/day or less. For all Federal Drug Administration (FDA) approved indications, doses of 50mg/day are only recommended for one day during the titration phase, with doses of 300 to 400mg/day being reached by day four.

The FDA-approved indications and dosage ranges for Seroquel®/Seroquel XR® are:

FDA-Approved Indication	Dosage Range
Bipolar disorder depressive episodes	300mg/day
Bipolar I disorder manic episodes	400 -800mg/day
Bipolar I disorder adjunct maintenance therapy	400 -800mg/day
Schizophrenia	150 -750mg/day

Why Is DSHS Implementing This Limit?

Doses \leq 50mg/day are subtherapeutic for the FDA-approved indications, and there is little evidence to support the efficacy and safety of Seroquel®/Seroquel XR® for off-label uses at this dosage.

Using Seroquel®/Seroquel XR® for off-label uses without evidence of efficacy places the patient at an unwarranted risk of several serious adverse effects. The FDA labeling for Seroquel®/Seroquel XR® includes a black box warning regarding the increased risk of mortality in elderly patients with dementia and the increased risk of suicide. Atypical antipsychotics, including Seroquel®/Seroquel XR®, are associated with an increased risk of:

- Hyperglycemia and diabetes mellitus;
- Hyperlipidemia;
- Weight gain;
- Neuroleptic malignant syndrome;
- Tardive dyskinesia; and
- Orthostatic hypotension.

Note: DAW-1 by an endorsing prescriber does not override dosing limits for Seroquel®/Seroquel XR®.

Ninety Day Supply Requirement for Clients Stable on Specific Drugs

Effective for dates of service on and after July 1, 2009, DSHS will require the dispensing of a 90-day supply when clients are stable on specific drugs. The list of drugs for which DSHS requires a 90-day supply can be found at <http://hrsa.dshs.wa.gov/pharmacy>.

DSHS will consider clients stable on these specific medications after three consecutive fills of the same drug and strength. On the fourth and subsequent fill of any medication on the Ninety Day Supply list, DSHS's Point-of-Sale (POS) system will reject claims for less than a 90-day supply, with a message indicating a 90-day supply is required.

If the prescriber's order (including the number of available refills) requires that less than a 90-day supply be dispensed, the pharmacy may submit an Expedited Authorization (EA) code to receive payment for the shorter days' supply as indicated by the prescription. Please see 'Changes to the Expedited Authorization List' in this memo for the EA code and criteria.

New Drug Class Added to the Washington Preferred Drug List (PDL)

HRSA is adding the following drug class to the Washington PDL.

Drug Class	Preferred Drugs	Non-preferred Drugs
Combination Asthma Products	Generic: Brand: Advair Diskus® /HFA® <i>(fluticasone/salmeterol)</i> Symbicort® <i>(budesonide/formoterol)</i>	Generic: Brand:

What Are the Changes to the Washington Preferred Drug List (PDL)?

Changes on the Washington PDL are highlighted in yellow.

Drug Class	Preferred Drugs	Nonpreferred Drugs
Inhaled Beta-Agonists	Generic short-acting nebulized: albuterol inhalation solution Brand short-acting inhaled: ProAir™ HFA (<i>albuterol</i>) inhaler Proventil® HFA (<i>albuterol</i>) inhaler Ventolin® HFA (<i>albuterol</i>) inhaler Brand long-acting : Foradil® Aerolizer® (<i>formoterol</i>) Serevent® Diskus® (<i>salmeterol</i>)	Brand short-acting nebulized: Accuneb® (<i>albuterol</i>) inhalation solution Proventil® (<i>albuterol</i>) inhalation solution Xopenex® (<i>levalbuterol</i>) inhalation solution Brand short-acting inhaled: Maxair Autohaler™ (<i>pirbuterol</i>) inhaler Xopenex® HFA (<i>levalbuterol</i>) inhaler Brand long-acting (nebulized): Brovana™ (<i>arformoterol</i>) Perforomist™ (<i>formoterol</i>)** **Not subject to TIP or DAW-1 override.

Drug Class	Preferred Drugs	Nonpreferred Drugs
Inhaled Corticosteroids	<p>Generic:</p> <p>Brand: Aerobid/Aerobid-M® (<i>flunisolide MDI</i>) Azmacort® (<i>triamcinolone acetonide MDI</i>) Flovent® HFA/Diskus® (<i>fluticasone propionate HFA/DPI</i>) Qvar® (<i>beclomethasone dipropionate MDI</i>) Pulmicort Respules® (<i>budesonide inhalation suspension</i>) Pulmicort Turbuhaler®/Flexhaler® (<i>budesonide DPI</i>)</p>	<p>Generic:</p> <p>Brand: Alvesco® (<i>ciclesonide HFA</i>)** Asmanex Twisthaler® (<i>mometasone furoate DPI</i>)</p> <p>**Not subject to TIP or DAW-1 override.</p>
Overactive Bladder/Urinary Incontinence	<p>Generic short acting: oxybutynin chloride tablets/syrup</p> <p>Generic long acting: oxybutynin ER</p> <p>Brand long acting: Oxytrol® (<i>oxybutynin chloride</i>) Vesicare® (<i>solifenacin succinate</i>)</p>	<p>Generic short acting: flavoxate HCl</p> <p>Brand short acting: Detrol® (<i>tolterodine tartrate</i>) Ditropan® (<i>oxybutynin chloride</i>) Sanctura® (<i>trospium chloride</i>) Urispas® (<i>flavoxate HCl</i>)</p> <p>Brand long acting: Detrol LA® (<i>tolterodine tartrate</i>) Ditropan XL® (<i>oxybutynin chloride</i>) Enablex® (<i>darifenacin hydrobromide</i>) Gelnique® (<i>oxybutynin chloride</i>) topical gel** Sanctura XR® (<i>trospium chloride</i>) Toviaz® (<i>fesoterodine fumarate</i>)**</p> <p>**Not subject to TIP or DAW-1 override.</p>

Drug Class	Preferred Drugs	Nonpreferred Drugs
Proton Pump Inhibitors (Limited to 90 days duration.)	<p>Generic: omeprazole OTC omeprazole Rx pantoprazole</p> <p>Brand: Prilosec OTC® (<i>omeprazole magnesium</i>) tablets Prevacid® (<i>lansoprazole</i>) capsules Prevacid® SoluTab™ (<i>lansoprazole</i>)* Prevacid® (<i>lansoprazole</i>) suspension* Zegerid® (<i>omeprazole sodium bicarbonate</i>) *EA required</p>	<p>Generic:</p> <p>Brand: Aciphex® (<i>rabeprazole</i>) Kapidex® (<i>dexlansoprazole</i>)** Nexium® (<i>esomeprazole</i>) Prilosec® Rx (<i>omeprazole</i>) Protonix® (<i>pantoprazole</i>)</p> <p>**Not subject to TIP or DAW-1 override.</p>
Second Generation Antidepressants (Not subject to TIP)	<p>Generic: bupropion HCl /SR/XL* citalopram fluoxetine HCl mirtazapine/soltab paroxetine HCl sertraline venlafaxine HCl</p> <p>Brand: Effexor® XR (<i>venlafaxine HCl</i>)</p> <p>*EA required</p>	<p>Generic: fluvoxamine nefazodone paroxetine CR venlafaxine XR</p> <p>Brand: Aplenzin (<i>bupropion hydrobromide ER</i>)** Celexa® (<i>citalopram</i>) Cymbalta® (<i>duloxetine HCl</i>) Effexor® (<i>venlafaxine HCl</i>) Lexapro® (<i>escitalopram</i>) Luvox CR (<i>fluvoxamine</i>)** Paxil® /CR (<i>paroxetine HCl</i>) Pexeva® (<i>paroxetine mesylate</i>) Pristiq® (<i>desvenlafaxine</i>)** Prozac® /Prozac Weekly® (<i>fluoxetine HCl</i>) Remeron® /SolTab (<i>mirtazapine</i>) Wellbutrin® /SR/XL (<i>bupropion HCl</i>/SR/XL) Zoloft® (<i>sertraline</i>)</p> <p>**Not subject to DAW-1 override.</p>

Changes to the Expedited Authorization (EA) List

- **Effective July 1, 2009**, DSHS is adding Lamictal® (lamotrigine) to the EA list.

Lamotrigine has the following FDA-approved indications:

- ✓ Adjunctive therapy for partial seizures, the generalized seizures of Lennox-Gastaut syndrome, and primary generalized tonic-clonic seizures in adults and pediatric patients (≥ 2 years of age).
- ✓ Conversion to monotherapy in adults with partial seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single anti-epileptic drug.
- ✓ Maintenance treatment of Bipolar I Disorder.

DSHS requires prior authorization (PA) if the EA criteria listed below are not met. DSHS will grant patients who currently are receiving lamotrigine and do not meet the EA criteria a two-month authorization to allow time to taper off of lamotrigine.

Drug	Code	Criteria
Lamictal® (<i>lamotrigine</i>)	083	Treatment of epilepsy/seizures
	084	Treatment of Bipolar Disorder
lamotrigine	083	Treatment of epilepsy/seizures
	084	Treatment of Bipolar Disorder

Why Is DSHS Implementing These Criteria?

According to the Drug Effectiveness Review Project Final Report Update 2, dated October 2008, there is little evidence to support the use of lamotrigine for off-label uses, and the use of lamotrigine has known adverse effects and risks. For example, FDA analysis of placebo-controlled trials indicates that lamotrigine is associated with statistically significant increases in risk of suicidal thoughts or behaviors. The FDA black box warning for lamotrigine warns that serious rashes resulting in hospitalizations, including Stevens-Johnson Syndrome, have been reported in association with the use of lamotrigine.

Changes to Expedited Authorization (EA) List (cont.)

- DSHS is adding levetiracetam, the generic for Keppra®, to the EA List as a separate entry from Keppra®/XR. Savella® is being added to the EA List.

Drug	Code	Criteria
levetiracetam	036	Treatment of seizures.
Savella® (<i>milnacipran HCl</i>)	066	Treatment of fibromyalgia.

- **Effective July 1, 2009**, DSHS is adding an EA code to allow the dispensing of less than a 90-day supply for drugs on the Ninety Day Supply list. This EA code is to be used only when the physician's order requires that a less than 90-day supply be dispensed.

Drug	Code	Criteria
90-day supply required	090	The prescription is written for less than a 90-day supply.

Updated Washington PDL and EA List

DSHS has updated the Washington PDL and EA List with the changes discussed in this memo. You may view and download the updated lists at:

http://hrsa.dshs.wa.gov/download/Billing%20Instructions%20Web%20Pages/Prescription_Drug_Program.html.

How Can I Get DSHS/HRSA Provider Documents?

To obtain DSHS/HRSA provider numbered memoranda and billing instructions, go to the DSHS/HRSA website at <http://hrsa.dshs.wa.gov> (click the *Billing Instructions and Numbered Memorandum* link). These documents may be downloaded and printed.