

## 2009 Fact Sheet:

# New limits on lamotrigine (Lamictal)

### LAMOTRIGINE (LAMICTAL): EXPEDITED AUTHORIZATION REQUIRED

Beginning July 1, 2009, DSHS will automatically authorize lamotrigine (Lamictal) for FDA-approved indications using Expedited Authorization (EA) codes. Prior authorization will be required for all off-label use.

DSHS will approve the use of lamotrigine (Lamictal) for the FDA-approved indications listed below with the appropriate Expedited Authorization code:

- Treatment of epilepsy/seizures (EA code 083)
- Maintenance treatment of Bipolar I Disorder (EA code 084)

Prescribers who have patients currently receiving lamotrigine for off-label indications will be asked to prescribe an alternative medication. DSHS will provide authorization to facilitate a two-month taper off lamotrigine (Lamictal).

### WHY ARE WE ADOPTING THESE INTERVENTIONS?

- A study of Medicaid's utilization of lamotrigine (Lamictal) showed that many patients were being prescribed the drug for off-label indications. These indications have not been studied and approved by the FDA.
- Lamotrigine (Lamictal) has a "black box" warning that states serious rashes resulting in hospitalization and discontinuation of treatment, including Stephen-Johnson Syndrome, have been reported in association with the use of lamotrigine (Lamictal)
- FDA labeling restricts the use of lamotrigine (Lamictal) to the following indications:
  - Adjunctive therapy for partial seizures, the generalized seizures of Lennox-Gastaut Syndrome, and primary generalized tonic-clonic seizures in adult and pediatric patients ( $\geq 2$  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
  - Maintenance treatment of Bipolar I Disorder

### WHAT IS THE SCIENCE BEHIND THIS DECISION?

The October 2008 Updated Final Report by the Drug Effectiveness Review Project at the Oregon Health Sciences University states there is little evidence to support the use of lamotrigine (Lamictal) for off-label uses, and the use of lamotrigine has known adverse effects and risks. For example, an FDA analysis of placebo-controlled trials indicates that lamotrigine (Lamictal) is associated with statistically significant increases in risk of suicidal ideation or behaviors.