

## 2009 Fact Sheet:

# New limits on Seroquel/Seroquel XR

SEROQUEL: NEW LIMIT BLOCKING LOW-DOSE SEROQUEL/SEROQUEL XR  
Beginning July 1, 2009, DSHS will require prior authorization for prescriptions of Seroquel/Seroquel XR dosed daily at 50mg or less.

DSHS will automatically approve the use of higher doses of Seroquel/Seroquel XR associated with FDA-approved indications. Doses 50mg/day or lower used as a starting dose in the titration upward phase will be automatically approved. The FDA-approved indications and dosage ranges for Seroquel/Seroquel XR are:

- Schizophrenia 150-800mg/day
- Bipolar disorder depressive episodes 300mg/day
- Bipolar I disorder manic episodes 400-800mg/day
- Bipolar I disorder adjunct maintenance therapy 400-800mg/day

### WHY ARE WE ADOPTING THESE INTERVENTIONS?

- A study of Medicaid's utilization of Seroquel/Seroquel XR showed many patients were being prescribed low doses for off-label indications such as insomnia.
- Seroquel/Seroquel XR have a "black box" warning that states:
  - Antipsychotic drugs are associated with an increased risk of death in the elderly. Seroquel/Seroquel XR are not approved for elderly patients with dementia-related psychoses.
  - There is an increased risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder and other psychiatric disorders.

### WHAT IS THE SCIENCE BEHIND THIS DECISION?

Doses  $\geq$  50mg/day are sub-therapeutic 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. Atypical antipsychotics, including Seroquel/XR, have FDA warnings that include an increased risk of hyperglycemia and diabetes mellitus, hyperlipidemia, weight gain, neuroleptic malignant syndrome, tardive dyskinesia, leukopenia, neutropenia, agranulocytosis, and cataracts.

Using Seroquel/Seroquel XR for off-label uses without evidence of efficacy places the patient at an unwarranted risk of serious and potentially life-threatening adverse effects.