

**Effective Monday July 11<sup>th</sup>, 2011**  
**Important Changes to Seroquel<sup>®</sup> (quetiapine) Adult Prescribing**

May 31<sup>st</sup>, 2011

Dear Dr. **XXXXXX**:

The Department of Vermont Health Access (DVHA), the Department of Mental Health, the Drug Utilization Review (DUR) Board of the DVHA and an advisory group of Vermont psychiatrists have been discussing and evaluating Seroquel<sup>®</sup> (quetiapine) utilization trends in adults for several months. An analysis of medical and pharmacy data demonstrated that fewer than 20% of patients on Seroquel 50 mg or less had a diagnosis for which the drug is indicated, and 84% of patients started on doses of 50 mg or less who continue on therapy, are still on the same dose 4 months later. Many of the low-dose quetiapine prescriptions are associated with other indications such as insomnia and anxiety for which there are safer and more cost-effective alternatives. Additionally, reports indicate that quetiapine has become a drug of abuse that can be diverted and misused by the public.

Seroquel is FDA-approved for schizophrenia, bipolar disorder, and the extended-release formulation (XR) is approved for the adjunctive treatment of major depressive disorder. The atypical antipsychotic class as a whole demonstrates a higher serious side effect profile when used for the adjunctive treatment of major depressive disorder (MDD) and for generalized anxiety disorder (GAD) than FDA approved agents in other therapeutic categories. Additionally, the use of low dose quetiapine for sleep exposes the patient to the potential risk of diabetes, hyperlipidemia, weight gain, extrapyramidal side effects, and tardive dyskinesia. The effects of quetiapine on weight gain and metabolism are not dose related and can occur even at low doses. Given the side effect profile, quetiapine use should be given careful consideration even when prescribed at low doses for unlabelled uses, often as first line therapy, despite the availability of better studied, safe, efficacious and often less costly alternatives. Seroquel<sup>®</sup> is the second most costly medication for DVHA (after Suboxone<sup>®</sup>) and ranks as 5<sup>th</sup> in branded prescription volume as well.

After careful consideration, the DVHA will begin requiring prior authorization for all Seroquel<sup>®</sup> IR prescriptions where the daily dose is 50 mg/day or less beginning July 11<sup>th</sup>, 2011. Seroquel<sup>®</sup> XR will continue to require PA for all doses. The focus of the criteria is on its use for indications other than schizophrenia and bipolar disorder, where low doses may be prescribed. Seroquel<sup>®</sup> will not be approved for use solely as an hypnotic.

**Patients with schizophrenia or bipolar disorder require only the diagnosis or indication for approval of the prior authorization request.** Requests for Seroquel<sup>®</sup> use in MDD will be approved if prior authorization criteria are met.

Quetiapine is usually initiated at a low dose and then titrated upwards for approved indications. There was consideration to allow time for titration before requiring prior authorization, however, this could cause significant member and prescriber disruption in patients who had started therapy for the indication of insomnia but then denied later on when requiring prior authorization.

Medications for the treatment of insomnia, available in generic form, include zolpidem, trazodone, mirtazapine, hydroxyzine and doxepin as well as the traditional benzodiazepine hypnotics. The choice of an hypnotic agent depends on individual needs of the patient. Factors that contribute to insomnia such as poor sleep hygiene, restless leg syndrome, sleep apnea, depression, and anxiety require comprehensive management before prescribing an hypnotic.

DVHA recognizes that quetiapine may be prescribed as adjunctive therapy in MDD and in anxiety disorders. Requests for Seroquel® for these indications will require prerequisite step therapy as outlined on the prior authorization form enclosed.

We have attached a prior authorization form for each patient who received a Seroquel® prescription in the last 4 months and whose most recent claim is for  $\leq 50$  mg/day (total of all daily dosage strengths) and do not have an ICD-9 diagnosis of either schizophrenia or bipolar in our claims history. If your patient meets the criteria outlined on the PA form and Seroquel® therapy requires continuation, please complete the form, include other medications trialed where appropriate, and fax to our Clinical Call Center as soon as possible to prevent a disruption in therapy. Otherwise, please discontinue therapy or transition your patient to an appropriate alternative therapy.

If you have any questions related to this change in benefit coverage, please contact our on-site MedMetrics' Clinical Account Manager, Diane Neal, R.Ph, at 1-802-879-5605.

Thank you for your continued support of the State of Vermont's clinical pharmacy programs. We appreciate your partnership and support in providing high quality care to Vermont beneficiaries.

Sincerely,

Handwritten signature of Michael C. Farber, M.D.

Michael Farber, M.D.  
Medical Director