

JULY 11, 2011 PDL CHANGES

LIMITATION ON OVER-THE-COUNTER (OTC) MEDICATIONS CLINICAL CRITERIA FOR USE OF LOW DOSE QUETIAPINE (SEROQUEL®) IN ADULTS

July 8, 2011

Dear Pharmacy Provider:

Limitation on Over-The-Counter (OTC) Medications

Effective July 11, 2011, coverage of Over the Counter (OTC) medications will be primarily limited to generics in categories determined to be medically necessary. All other OTC products will be excluded from coverage without the option for a prior authorization request through the Clinical Call Center. The new coverage guidelines apply to all state pharmacy benefit plans and include VPharm, our Part D “wrap” program. OTC coverage in our “limited OTC” plans will not change. As a reminder, DVHA only pays for OTCs when there is a specific medical necessity and a prescription for the OTC product. Some OTC medications are already managed on our Preferred Drug list (PDL) and other restrictions may apply. Though we have restricted OTC medications to primarily generics, beneficiaries will continue to have at least one choice in all medically necessary drug categories. We have included a quick reference chart for OTC coverage as the last page of this fax (also available on our website at <http://dvha.vermont.gov/for-providers>). The PDL can be found at <http://dvha.vermont.gov/forproviders/preferred-drug-list-clinical-criteria>.

Important Changes to Seroquel® (quetiapine) Adult Prescribing

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 less costly alternatives. Seroquel® is the second most costly medication for DVHA (after Suboxone®) and ranks as 5th in branded prescription volume as well.

After careful consideration, the DVHA will begin requiring prior authorization for all Seroquel® IR prescriptions where the daily dose is 50 mg/day or less beginning July 11th, 2011. Seroquel® 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® 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® use in MDD and GAD will be approved if prior authorization criteria (step therapy) are met.

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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.

Prescribers were sent a mailing that included the names of patients who require prior authorization for low dose quetiapine and were asked to fax in PA forms for those patients who need to continue on this therapy.

We greatly appreciate your understanding and cooperation with these efforts. If you have questions related to these changes in benefit coverage, please feel free to 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 pharmacy programs.

Sincerely,

Nancy Hogue, Pharm.D.
Director of Pharmacy Services