



RETRODUR INTERVENTION NOTICE :
Zolpidem (Ambien®, Ambien CR®, Edluar™, Intermezzo®, Zolpimist™)

May 11, 2018

Dear Medicaid Provider,

The New York State (NYS) Medicaid Drug Utilization Review (DUR) Program retrospectively reviews the prescribing and dispensing of outpatient prescription medications to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. Under the purview of the DUR Program, the NYS Medicaid DUR Board reviewed zolpidem within the NYS Medicaid program. NYS Medicaid pharmacy claims data indicate that you may have written prescription(s) for zolpidem, and therefore, are receiving this letter.

The DUR Board evaluated zolpidem information presented by clinical research staff from the State University of New York at Buffalo, School of Pharmacy and Pharmaceutical Sciences. The primary objective was to determine whether there was inappropriate use of zolpidem products based on the Food and Drug Administration's (FDA) warnings that female patients have lower clearance rates than males. **The FDA recommends lower initial doses of zolpidem for females and strongly recommends that all patients not exceed recommended daily dosage limits.** The board considered information relating to FDA-approved and compendia-supported indications, and reviewed retrospective utilization among Medicaid members. Important points presented to and discussed by the board regarding zolpidem included:

- In fee-for-service and managed care:
 - For female members initiating a zolpidem product for the first time, 62.9% exceeded the recommended initial dosage limits.
 - For zolpidem IR: 56.7% of female members initiated treatment with the 10 mg. strength.
 - For zolpidem controlled-release (CR): 71.0% of female members initiated treatment with the 12.5 mg strength.

The board recommended educational interventions to prescribers highlighting safety concerns associated with use of higher doses of zolpidem. **The FDA recommends lower initial doses since females have lower clearance rates leading to higher concentrations and increased risk for next-day impairment and other adverse events.**

In providing this information to you, the DUR Program recognizes that safe and effective pharmacotherapy depends on the assessment of the patient's entire clinical profile. We ask that you consider the information provided regarding the prescribing of zolpidem for your patients.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
Manager, Drug Utilization Review Program