NATIONAL PBM BULLETIN

FEBRUARY 7, 2008

DEPARTMENT OF VETERANS AFFAIRS - VETERANS HEALTH ADMINISTRATION
PHARMACY BENEFITS MANAGEMENT SERVICE (PBM), MEDICAL ADVISORY PANEL (MAP), AND
CENTER FOR MEDICATION SAFETY PSCI (VA MEDSAFE)

CHEMOTHERAPY FINAL DOSE CONCENTRATIONS FOR TEMSIROLIMUS (TORISEL™) ADDENDUM

I. ISSUE

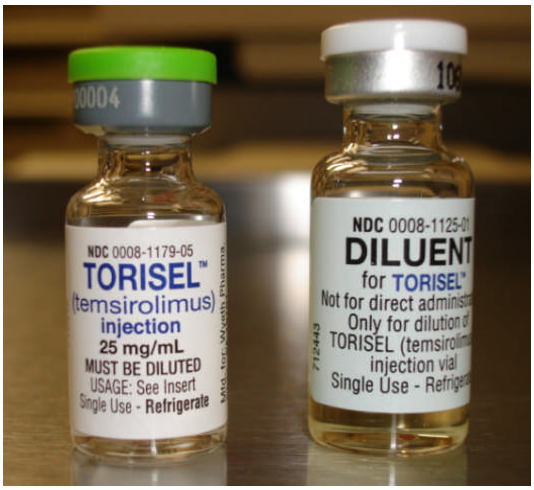
A concentration error has been reported during the preparation of Torisel™ (temsirolimus) injection at one VAMC. A PBM National Bulletin was sent out on January 22, 2008, with details of the event and recommendations to prevent potential future errors of the same nature. This addendum communicates additional information provided by Wyeth, the manufacturer of Torisel™ (temsirolimus) injection, in order to further clarify the final volume and concentration after preparation.

II. BACKGROUND

Per Wyeth:

1) "The product comes as a kit containing two vials: the first vial is the active drug and is labeled as 25 milligrams (mg)/ milliliter (ml); **this is supplied as 30 mg in a total volume of 1.2 ml**. The second vial contains 1.8 ml of diluent."

2) "To prepare drug for administration, the diluent is added to the vial of active Torisel® to yield a **total** volume of **3.0 ml or a final concentration of 10 mg/ml."**



III. VA MEDSAFE RECOMMENDATIONS remain the same and appear below:

1. When preparing temsirolimus (Torisel™) injection, staff must be aware of temsirolimus concentrations before and after dilution.
2. Pharmacy must keep the package insert with the full instructions for dilution of temsirolimus (Torisel™) injection with the vials of both active drug and diluent, since no instructions appear on the vials themselves.
3. Pharmacy must create a warning system to notify staff of the change in concentration when preparing the final dilution of temsirolimus (Torisel™) injection (i.e., computer alerts during the ordering/verifying process and/or warning stickers on packaging).