



NATIONAL PBM BULLETIN

March 29, 2005

From: Pharmacy Benefits Management Strategic Healthcare Group (PBM SHG)
To: VA Clinicians
Subj: **Clinical Guidance on Replacement Product Recommendations for Avandamet and Paxil CR in the VA**

The PBM was asked to develop clinical guidance for replacement products for Avandamet (rosiglitazone and metformin) and Paxil CR (paroxetine controlled-release). The following have been reviewed and approved by Mark Shelhorse, MD, Acting Chief Consultant for Mental Health and Leonard Pogach, MD, National Program Director, Diabetes, and has been shared with the VISN Formulary Leaders and Medical Advisory Panel. Please share this information with those you deem it appropriate.

The FDA's decision to halt the distribution of all strengths of Avandamet (rosiglitazone and metformin) and Paxil CR (paroxetine controlled-release) may result in a shortage of these products. Fortunately, both medications are available in other formulations and the replacement recommendations are shown in the table. Avandamet is usually taken twice a day and so should its replacement. For example, a patient taking Avandamet 2 mg/500 mg twice a day should take in its place one rosiglitazone 2 mg tablet twice a day and one metformin 500 mg tablet twice a day. Paxil CR is usually taken once a day and so should its replacement product; however, patients taking Paxil CR 37.5 mg per day (or higher) may need to have their dose divided, e.g., 20 mg twice a day.

Patients are expected to tolerate these replacement products, although some patients switched from Paxil CR to immediate-release paroxetine may experience adverse effects similar to when initiating treatment or withdrawal symptoms.

Product Recalled	Replacement Product
Avandamet 1 mg/500 mg	Rosiglitazone 1 mg + Metformin 500 mg
Avandamet 2 mg/500 mg	Rosiglitazone 2 mg + Metformin 500 mg
Avandamet 2 mg/1000 mg	Rosiglitazone 2 mg + Metformin 1000 mg
Avandamet 4 mg/500 mg	Rosiglitazone 4 mg + Metformin 500 mg

Avandamet 4 mg/1000 mg	Rosiglitazone 4 mg + Metformin 1000 mg
Paxil CR 12.5 mg	Paroxetine 10 mg (immediate-release)
Paxil CR 25 mg	Paroxetine 20 mg
Paxil CR 37.5 mg	Paroxetine 40 mg (or 2 x 20 mg tablets)

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