



NATIONAL PBM BULLETIN

Focus on Patient Safety

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Since the introduction of the cyclooxygenase 2 (COX-2) inhibitors in January 1999, the PBM/MAP recommended that they be reserved for patients at high-risk for serious gastrointestinal (GI) complications. In 2001, the PBM-MAP added information from the VIGOR trial to the COX-2 criteria and cautioned providers when using COX-2 inhibitors in patients with a history of cardiovascular disease.

On September 30th, 2004, the manufacturer of rofecoxib (Vioxx®) voluntarily withdrew their product from worldwide markets based upon data from a three-year, randomized, prospective, placebo-controlled clinical trial called APPROVe (Adenomatous Polyp Prevention on VIOXX). In APPROVe, patients randomized to rofecoxib were reported to have experienced an increased relative risk for cardiovascular events compared to those on placebo. In response, the PBM identified those patients receiving rofecoxib and the PBM-MAP created preliminary guidance for switching those patients to alternative medications. In addition, a patient information template was developed to assist VISNs in making this information available to patients as quickly as possible. The recommendations and patient information document were approved by the MAP and VISN Formulary Leaders on September 30th, 2004, and expeditiously disseminated.

As a result of the rofecoxib withdrawal, the PBM is conducting an internal review to determine the rate of cardiovascular events in veteran patients on COX-2 agents and continuing an aggressive review of the published literature. On October 15, 2004, the manufacturer of valdecoxib (Bextra®) announced that an increased risk for MI and stroke was observed in patients receiving an injectable form of valdecoxib (parecoxib) after cardiac bypass surgery. Since there are no outcome data to support a GI safety advantage of valdecoxib but data do support a higher risk for MI and stroke in certain individuals, valdecoxib should be avoided until more conclusive data are obtained. Although current evidence does not support a similar cardiovascular risk for celecoxib, the question of a possible class effect arises. As a result, the COX-2 inhibitors should be avoided, if possible, in patients with a history of cardiovascular or cerebrovascular disease.

The combined effort between the PBM, MAP and VISN Formulary Leaders represents a continued commitment to the health and safety of our veterans within the scope of a rapidly changing drug information landscape.

As you can see from the graph below, VISN and facility implementation of the 2001 PBM-MAP guidance has greatly reduced the scope of the rofecoxib recall situation in VA.

UTILIZATION MANAGEMENT

