NATIONAL PBM RESPONSE to FDA Information for Healthcare Professionals Regarding Exenatide (Byetta) August 19, 2008

On August 18, 2008, the FDA issued an "Information for Healthcare Professionals" sheet to alert clinicians of 6 cases of hemorrhagic or necrotizing pancreatitis in patients taking exenatide. Two patients died and 4 are recovering at the time of reporting. In October 2007, the FDA sent an alert regarding 30 postmarketing reports of pancreatitis in patients taking exenatide.

Patients should be instructed to report any unexplained persistent severe abdominal pain which may or may not be accompanied by vomiting to their provider immediately. If pancreatitis is suspected, exenatide should be discontinued. Exenatide should not be restarted if pancreatitis is confirmed. In patients with a history of pancreatitis, antidiabetic therapies other than exenatide should be considered.

Utilization of exenatide in the VA is relatively low. During the third quarter of fiscal year 2008, there were very few patients identified as having received a prescription for exenatide.

A search of the VA Adverse Drug Event Reporting System (VA ADERS) found no reported cases of pancreatitis in VA patients using exenatide.

Please refer to the FDA Information for Healthcare Professionals for detailed information available at the following link:

http://www.fda.gov/cder/drug/InfoSheets/HCP/exenatide2008HCP.htm