NATIONAL PBM COMMUNICATION · September 29, 2009

Sitagliptin and Acute Pancreatitis (marketed as Januvia and Janumet)

- Between October 2006 and February 2009, FDA's Adverse Event Reporting System (AERS) received 88 reports of acute pancreatitis in patients using sitagliptin or sitagliptin/metformin.[1]
    - 58/88 (66%) of the patients were hospitalized, 4 of whom were admitted to the intensive care unit (ICU).
    - 2 patients developed hemorrhagic or necrotizing pancreatitis resulting in prolonged hospitalization in ICU.
    - Abdominal pain, nausea and vomiting were the most commonly reported adverse events among the 88 cases.
    - 19/88 (21%) cases reported symptoms of pancreatitis appearing within 30 days of initiating sitagliptin.
    - 47/88 (53%) cases resolved upon discontinuation of sitagliptin.
    - 45/88 (51%) cases involved patients with risk factors for pancreatitis (i.e., diabetes, obesity, high cholesterol and/or high triglycerides).
- FDA is revising the prescribing information for Januvia (sitagliptin) and Janumet (sitagliptin/metformin) to include information on: [1]
    - Reported cases of acute pancreatitis, including hemorrhagic or necrotizing pancreatitis.
    - Recommendations for healthcare care professionals to:
        - *Monitor patients carefully for the development of pancreatitis after initiation or dose increases of sitagliptin or sitagliptin/metformin.*
        - *Discontinue sitagliptin or sitagliptin/metformin if pancreatitis is suspected while using these products.*
        - *Use sitagliptin or sitagliptin/metformin with caution and with appropriate monitoring in patients with a history of pancreatitis.*
- Additional recommendations from the FDA include: [1]
    - *Be aware of the possibility for and monitor for the emergence of the signs and symptoms of pancreatitis such as nausea, vomiting, anorexia, and persistent severe abdominal pain, sometimes radiating to the back.*
    - *Understand that if pancreatitis is suspected in a patient, supportive medical care should be instituted. The patient should be monitored closely with appropriate laboratory studies such as serum and urine amylase, amylase/creatinine clearance ratio, electrolytes, serum calcium, glucose, and lipase.*
    - *Inform patients of the signs and symptoms of acute pancreatitis so they are aware of and able to notify their healthcare professional if they experience any unusual signs or symptoms.*
- Within the VA, there have been no reports of acute pancreatitis associated with sitagliptin use from March 2006 until present.

REFERENCES:

1. FDA Information for Healthcare Professionals. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm183764.htm (Accessed September 25, 2009).

ACTIONS:

- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers and endocrinologists,*** *including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*