NATIONAL PBM COMMUNICATION · May 5, 2009

Regadenoson (Lexiscan®) and Updated Labeling Changes

- On March 17, 2009, the Food and Drug Administration (FDA) approved a labeling revision for Regadenoson (Lexiscan®) to include adverse events reported post-marketing.
- Regadenoson (Lexiscan®) is an intravenous (IV) radionuclide stress agent that received FDA approval in April 2008 for use in myocardial perfusion imaging (MPI).
- Regadenoson (Lexiscan®) works as an A(2A) adenosine receptor agonist that produces coronary vasodilation and increases coronary blood flow.
- Changes to the WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections of the package insert include[2]:

    - ***Cardiovascular***
      Heart block (including third degree block), asystole, symptomatic hypotension, transient ischemic attack [see Warnings and Precautions (5)], and syncope requiring intervention with fluids and/or aminophylline have occurred.

    - ***Gastrointestinal***
      Abdominal pain, occasionally severe, has been reported a few minutes after Lexiscan administration, in association with nausea, vomiting, or myalgias; administration of aminophylline, an adenosine antagonist, appeared to lessen the pain. Diarrhea and fecal incontinence have also been reported following Lexiscan administration.

    - ***Musculoskeletal***
      Musculoskeletal pain has occurred, typically 10-20 minutes after Lexiscan administration; the pain was occasionally severe, localized in the arms and lower back and extended to the buttocks and lower legs bilaterally. Administration of aminophylline appeared to lessen the pain.

    - ***Respiratory***
      Dyspnea and wheezing have been reported following Lexiscan administration. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to Lexiscan exposure.

REFERENCES

1. FDA. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist. (Accessed 04/29/09).
2. FDA. http://www.fda.gov/cder/foi/label/2009/022161s003lbl.pdf. (Accessed 04/29/09).

ACTIONS:

- ***Facility COS:*** *Forward this document to all appropriate providers who prescribe/use/handle this agent (e.g.,* **cardiologists and nuclear medicine clinicians as well as** ***nurses and technicians who work in imaging settings,*** *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. Report completion of actions to the Facility Director.*
- ***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).*