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# NATIONAL PBM BULLETIN

May 1, 2014

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## DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION (VHA) PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP), AND CENTER FOR MEDICATION SAFETY (VA MEDSAFE)

### ADVERSE NEUROLOGIC EVENTS AND EPIDURAL CORTICOSTEROID INJECTIONS FOR PAIN

#### I. ISSUE

FDA warns that epidural corticosteroid injections may lead to rare but serious neurologic adverse events including spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke, and death.

#### II. BACKGROUND

FDA requires the addition of a *Warning* to the drug labels of injectable corticosteroids to describe the rare but serious neurologic risks related to their epidural use. Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone. Epidural use of these agents serves as an accepted method for treating neck and back pain, and radiating pain in the arms and legs. However, corticosteroids do not hold an FDA approval for epidural administration, and the effectiveness and safety of corticosteroid injections into the epidural space remains unknown. FDA continues to investigate this issue and plans to convene an Advisory Committee meeting of external experts to discuss the benefits and risks of epidural corticosteroid injections as well as to determine any further actions, if needed.

#### III. DISCUSSION

FDA reviewed its Adverse Event Reporting System (FAERS) database and the medical literature for cases of neurologic adverse events associated with epidural corticosteroid injections and identified serious outcomes such as death, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke, seizures, nerve injury, and brain edema. Symptoms occurred within 48 hours of administration with confirmation of diagnoses (in some cases) via magnetic resonance imaging or computed tomography scan. Many did not recover from these adverse events.

#### IV. PROVIDER RECOMMENDATIONS

FDA recommends that providers:

- Consider and discuss with their patients:
  - the benefits versus risks of epidural corticosteroid injections;
  - other possible treatment options.
- Educate patients on symptoms that may suggest the development of an adverse neurologic event following administration of an epidural corticosteroid injection, such as: loss of vision or vision changes; tingling in their arms or legs; sudden weakness or numbness in their face, arm, or leg on one or both sides of the body; dizziness; severe headache; or seizures.
- Counsel patients to seek emergency medical attention immediately if they experience any of the above symptoms after receiving an epidural corticosteroid injection.

Providers should continue to report any adverse reactions with the use of epidural corticosteroid injections by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (phone: 1-800-FDA-1088, fax: 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

#### V. REFERENCES

FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain. <http://www.fda.gov/Drugs/DrugSafety/ucm394280.htm> . Accessed 04/23/14.

#### ACTIONS

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS and Chief Nurse Executives**: Forward this document to all appropriate providers and health care staff (e.g., **primary care providers and pain management specialists, 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).