CMS Guidance on Medicare Reimbursement for Fungal Meningitis Treatment

Announcement from the CDC

The Centers for Disease Control and Prevention (CDC) with state and local health departments and the Food and Drug Administration (FDA) are investigating a multi-state meningitis outbreak of fungal infections among patients who have received a steroid injection of a potentially contaminated product into the spinal area. This form of meningitis is not contagious. The investigation also includes fungal infections associated with injections in a peripheral joint space, such as a knee, shoulder or ankle. The CDC is offering advice online to healthcare professionals **here.**

Announcement from CMS

The CDC recommends diagnostic and therapeutic activities for symptomatic patients who have received a steroid injection of a potentially contaminated product into the spinal area. Symptoms of meningitis include fever, headache, stiff neck, nausea and vomiting, photophobia (sensitivity to light) and altered mental status. Therefore, CMS believes that, **aside from oral drugs (Medicare reimbursement from Part D)**, **items and services to diagnose and treat patients who have received contaminated medications qualify for the Medicare Part A or Part B benefit.**

The Centers for Medicare & Medicaid Services (CMS) is providing direction to Medicare contractors based on the Centers for Disease Control and Prevention’s (CDC) interim

treatment guidance for Central Nervous System (CNS). This guidance is also related to parameningeal infections and septic arthritis associated with contaminated steroid products produced by the New England Compounding Center (NECC).

Due to the severity of this situation, CMS advises providers that Medicare contractors are expected to **expedite all coverage determination requests** for these items and services to include antifungal medication.

The CDC has identified the following states as having received potentially-contaminated steroid products:

- California
- Michigan
- Pennsylvania
- Connecticut
- Minnesota
- Rhode Island
- Florida
- Nevada
- South Carolina
- Georgia
- New Hampshire
- Tennessee
- Idaho
- New Jersey
- Texas
- Illinois
- New York
- Virginia
- Indiana
- North Carolina
- West Virginia
- Maryland
- Ohio

While clinics in these states received contaminated products,

patients in additional states may be affected.

CDC FAQ

Q: How many cases have been reported?
A: See the CDC's Meningitis Map **here.**

Q: What is causing these infections?
The infections are caused by a fungus. At this point, the original source of the outbreak has not been determined; however, all infected patients identified thus far have received preservative-free (PF) methylprednisolone acetate (80mg/ml) from among the three lots voluntarily recalled by the New England Compounding Center (NECC) in Framingham, Massachusetts, on September 26, 2012. These three lots are:

- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

These medications were used for other types of injections, including injections into the joint (e.g., knee). To date, CDC has only identified infections in patients who received epidural steroid injections with these medications. However, patients who received other types of injections with these products may also be at risk.

Q: Are other medications from the New England Compounding Center (NECC) located in Framingham, Massachusetts associated with infections?
To date, CDC has not received reports of infections linked to other products from the New England Compounding Center. However, out of an abundance of caution, CDC recommends that patients cease use of any product produced by the New England

Compounding Center until further information is available. A list of products produced by the New England Compounding Center can be found through the FDA website **here.**

If patients have taken or used medications from New England Compounding Center, and they are worried that they are ill because of use of one of these products, they should seek medical attention. Again, CDC has not received any reports of infection linked to other products from New England Compounding Center.

Advice to Healthcare Professionals

FDA advises healthcare professionals to follow-up with patients who have been administered an injectable product **shipped by NECC on or after May 21, 2012**, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution. FDA does not urge patient follow-up at this time for NECC products of lower risk such as topicals (for example, lotions, creams, eyedrops not used in conjunction with surgery) and suppositories, or for patients who may have received an NECC product in these categories before May 21, 2012. Patients who received an NECC product prior to May 21, 2012 and who have not experienced symptoms of infection to date are at less risk of infection because of the amount of time that has elapsed since that date. FDA is not recommending that healthcare providers follow-up with these patients unless they have reported symptoms of infection.

Health care professionals should retain and secure all remaining products purchased from NECC. All NECC products are subject to voluntary recall. Clinics or customers with product on hand should contact NECC at 1-800-994-6322 or via fax at 508-820-1616 to obtain instructions on how to return products to NECC.

Clinicians and patients are also requested to report any

suspected adverse events following use of these products to FDA’s MedWatch program at **1-800-332-1088** or www.fda.gov/medwatch.

Healthcare professionals and patients may dial FDA’s Drug Information Line at 855-543-DRUG (3784) and press * to get the most recent information regarding the meningitis recall and speak directly to a pharmacist.

If you have identified NECC customers who received product that do not appear on these lists, please contact FDA’s Drug Information Line to report this problem.

FDA continues its investigation and may issue additional public communications as appropriate.