DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D.

Director, Medicare Drug Benefit and C & D Data Group

Jeffrey Kelman, M.D., Chief Medical Officer

SUBJECT: Meningitis Outbreak

DATE: October 16, 2012

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance in response to the Centers for Disease Control and Prevention's (CDC) interim treatment guidance for central nervous system (CNS) and/or parameningeal infections and septic arthritis associated with contaminated steroid products produced by the New England Compounding Center (NECC): http://www.cdc.gov/hai/outbreaks/clinicians/index.html.

While the CDC has identified specific states with clinics that have received contaminated product, patients in other states may be impacted and additional information on the outbreak can be found at:

http://www.cdc.gov/hai/outbreaks/clinicians/faq_meningitis_outbreak.html

We urge Part D sponsors to review the information available from the CDC, monitor it for updates, and take the steps necessary to ensure timely access to CDC recommended drug therapies for CNS and/or parameningeal infections and septic arthritis associated with contaminated steroid products produced by NECC.

At this time, CMS expects Part D sponsors to be prepared for new Part D prescription requests for voriconazole as part of the regimen specified in the CDC interim treatment guidance referenced above. Given the severity of this situation, we also expect Part D sponsors to expedite all coverage determination requests for this medication, and other appropriate antifungal medications, due to the potentially life-threatening consequences of a delay in therapy for those patients with CNS and/or parameningeal infections and septic arthritis.

If you have any questions regarding this memorandum, please contact Craig Miner at 410-786-7937 or craig.miner@cms.hhs.gov.