



MISSISSIPPI STATE DEPARTMENT OF HEALTH

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MS Health Alert Network (HAN) UPDATE

MESSAGE ID: MSHAN-20091106-1630-UPD (Health Update to MSHAN-20091026-1630-ADV)

RECIPIENTS: Physicians, and Hospitals (Admin & ED & InfCtl) – Statewide

DATE: November 06, 2009

SUBJECT: *Updated Emergency Use Authorization of Peramivir IV*

Dear Colleagues,

Introduction: On October 23, 2009, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved drug peramivir, administered intravenously for the treatment of 2009 H1N1 influenza infections in certain adult and pediatric patients.

Background: Currently there is no intravenous formulation of antiviral product approved by the (FDA) for the treatment of hospitalized patients with influenza. Peramivir, a neuraminidase inhibitor, is an **unapproved (investigational)** antiviral drug available in an intravenous (IV) formulation. Peramivir IV is currently under development for treatment of acute influenza in patients who require hospitalization due to the severity of influenza virus infection. The efficacy and safety of peramivir have not yet been established. The FDA has issued an EUA to allow use of peramivir IV to treat certain adult and pediatric patients with suspected or laboratory confirmed 2009 H1N1 virus infection or infection due to nonsubtypable influenza A virus suspected to be H1N1 based on community epidemiology.

Recommendations: The peramivir product is authorized **only** for the following patients who are admitted to a hospital:

1. Adult patients for whom therapy with an IV agent is clinically appropriate based on one or more of the following:
 - a. Patient not responding to either oral or inhaled antiviral therapy, or
 - b. Drug delivery by a route other than IV is not expected to be dependable or is not feasible, or
 - c. The clinician judges IV therapy is appropriate due to other circumstances.
2. Pediatric patients for whom an IV agent is clinically appropriate because:
 - a. Patient not responding to either oral or inhaled antiviral therapy, or
 - b. Drug delivery by route other than IV is not expected to be dependable or is not feasible.

To request peramivir IV, physicians should complete the Peramivir IV Request Form, available at using **one** of the methods below. **The request must be completed by the physician and can not be delegated to support staff.**

- i. Complete the form online at <http://emergency.cdc.gov/h1n1antivirals>
- ii. Download and print the forms from http://www.cdc.gov/h1n1flu/eua/MASTER%20Manual%20PERAMIVIR%20Request%20FormV2_rev25Oct09CDC.pdf then complete them and fax them to the number on the form

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Clinicians considering peramivir IV under EUA must read and understand the content of the FDA-issued Emergency Use Authorization of Peramivir IV: Fact Sheet For Health Care Providers (www.cdc.gov/h1n1flu/eua) prior to initiating a request and must agree to comply with terms and conditions of authorized use of peramivir IV per the FDA-issued EUA in order to successfully complete and transmit the request for this product. Further information is available at <http://www.cdc.gov/h1n1flu/eua/peramivir.htm> or call CDC INFO at 1-800-232-4636, 24 hours a day, 7 days a week.

Sincerely,



Mary Currier, MD, MPH
State Epidemiologist
Mississippi State Department of Health

Categories of Health Alert messages:

- Health Alert** conveys the highest level of importance; warrants immediate action or attention.
- Health Advisory** provides important information for a specific incident or situation; may not require immediate action.
- Health Update** provides updated information regarding an incident or situation; unlikely to require immediate action.
- Health Message** provides information regarding an incident or situation; unlikely to require immediate action.

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