INVESTIGATIONAL IV ANTIVIRAL (PERAMIVIR) USE IN HOSPITALIZED PATIENTS WITH INFLUENZA

TO: West Virginia Healthcare Providers and Hospitals

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LOCAL HEALTH DEPARTMENTS: PLEASE DISTRIBUTE TO HOSPITAL-BASED PHYSICIANS, INFECTION CONTROL PREVENTIONISTS, HOSPITAL-BASED PHARMACISTS, COMMUNITY HEALTH PROVIDERS MANAGING INPATIENTS, AND OTHER APPLICABLE PARTNERS

OTHER RECIPIENTS: PLEASE DISTRIBUTE TO APPLICABLE MEMBERS, STAFF, ETC.

The Food and Drug Administration (FDA) has released a “Dear Colleague” letter to provide information about the use of an investigational antiviral drug Peramivir intravenous (IV) under Emergency Use Authorization (EUA) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 Influenza infection who are admitted to a hospital.

Use of Peramivir is appropriate for the following reasons:

1. The patient is not responding to either oral or inhaled antiviral therapy, or
2. When drug delivery by routes other than an intravenous route – e.g., enteral (Tamiflu) or inhaled (Zanamivir) – is not expected to be dependable or feasible;
3. For adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

There are no FDA-approved intravenously administered antiviral drugs for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

To learn more or to request use of this medication, clinicians should go to CDC’s portal on peramivir use (found at http://www.cdc.gov/h1n1flu/eua/peramivir.htm ).

Clinicians
considering use of Peramivir IV under EUA must read the content of the FDA-issued “Emergency Use Authorization of Peramivir IV: Fact Sheet For Health Care Providers” found at the link above prior to initiating a request and must agree to comply with terms and conditions of authorized use of Peramivir per the FDA-issued EUA. Clinicians who, after reading the Fact Sheet for Health Care Providers, wish to obtain Peramivir IV for a patient can download the request form (or access an electronic request portal) at the website noted above (http://www.cdc.gov/h1n1flu/eua/peramivir.htm).

Additionally, clinical studies of Peramivir in hospitalized patients are currently underway. Clinicians who wish to consider whether their patients would be appropriate for inclusion in those studies should refer to http://www.ClinicalTrials.gov for more information.

Clinicians and public health officials are reminded that two other neuraminidase inhibitor drugs, i.e., oseltamivir (Tamiflu®) and Zanamivir (Relenza®) are available, and their use is appropriate in some patients with 2009 H1N1 influenza infections. All clinicians seeing patients with 2009 H1N1 infection should be familiar with current antiviral guidance (found at http://www.cdc.gov/H1N1flu/recommendations.htm). This guidance was last updated on October 16 (information disseminated as part of WV Health Advisory #26 found at www.wvflu.org/providers.html).

Additional information on 2009 Influenza H1N1 diagnosis and patient management using peramivir is available at http://emergency.cdc.gov/h1n1antivirals or by calling 1-800-CDC-INFo (1-800-232-4636), 24 hours a day, 7 days a week. Updates are placed on the website and made available to callers whenever new information becomes available. You are encouraged to access the website regularly.

Links to information on Peramivir can also be accessed from the revised West Virginia H1N1 Resource Center at www.wvflu.org, Providers section. For in-state assistance, the WV Bureau for Public Health, Division of Infectious Disease Epidemiology can be reached 24 hours a day at 1-800-423-1271.

This message was directly distributed by the West Virginia Bureau for Public Health to Hospital-based physicians, Infection Control Preventists, and hospital-associated Pharmacists. Receiving entities are responsible for further disseminating the information as appropriate to the target audience.

**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.