Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

October 25, 2009

Dear Colleague,

On Friday, October 23, 2009, the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the use of the investigational antiviral drug Peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, Peramivir IV is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons:

1. The patient is not responding to either oral or inhaled antiviral therapy, or

2. When drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- 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.

Clinicians considering use of 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 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 http://www.cdc.gov/H1N1flu/EUA/peramivir_recommendations.htm

Additionally, clinical studies of Peramivir IV 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 on these trials.

Clinicians and public health officials are reminded that two other neuraminidase inhibitor drugs i.e., oseltamivir (Tamiflu®) and Zanamivir (Relanza®) are available, and their use may be appropriate in some patients with 2009 H1N1 influenza infections. Conditions for use of these agents and additional guidance are available at http://www.cdc.gov/H1N1flu/recommendations.htm and http://www.cdc.gov/h1n1flu/eua/.

Additional information on 2009 Influenza H1N1 diagnosis and patient management 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. We encourage you to access the website regularly. In addition, state and local health department officials may call 770-488-7100 (CDC Emergency Operations Center) and request assistance at any hour if the need is urgent.

Thank you in advance for your efforts to make clinicians in your state aware that Peramivir IV is available, and that it may be requested for use in their seriously ill patients under the conditions of the EUA. Please let us know if you have questions or require additional information.

Sincerely,

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