

## HEALTH ALERT NETWORK HEALTH DISTRICT 4

### IMPORTANT INFORMATION FOR DISTRICT 4 MEDICAL PROVIDERS

#### **Please circulate to appropriate clinical, infection control and pharmacy staff.**

#### **Intravenous *Peramivir* Available from C.D.C. for Treatment of Certain Patients Hospitalized with Influenza**

November 4, 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.

*Peramivir* IV is available only directly from the Centers for Disease Control and Prevention to licensed clinicians with prescribing privileges. Clinicians do not need to obtain approval from the local Public Health District or the Idaho Department of Health and Welfare to request *Peramivir*.

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](http://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](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.

Two other neuraminidase inhibitor drugs i.e., Oseltamivir (Tamiflu®) and Zanamivir (Relenza®) 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/>.

You may contact the CDC at 1-800-CDC-INFO for any questions about obtaining *Peramivir* IV or e-mail [EUA.OCET@fda.hhs.gov](mailto:EUA.OCET@fda.hhs.gov) if you have questions related to this Emergency Use Authorization.

**NEW! October 29, 2009 “Peramivir IV Questions and Answers for Health Care Providers”**

[http://www.cdc.gov/h1n1flu/EUA/pdf/peramivir\\_qa.pdf](http://www.cdc.gov/h1n1flu/EUA/pdf/peramivir_qa.pdf)

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