



This is an official **DHEC Health Advisory**

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10192-DHA-10-28-09 H1N1

Intravenous Peramivir and other Antiviral Treatment Options for Influenza in Hospitalized Patients for the 2009-2010 Season

Background

On Friday 23 Oct 09, the FDA issued an Emergency Use Authorization (EUA) for a new neuraminidase inhibitor, peramivir IV. Peramivir is an investigational intravenous antiviral drug authorized to treat certain adult and pediatric patients who have been hospitalized due to severe flu illness. Although now authorized by the FDA for use under very specific circumstances, peramivir has not yet attained FDA approval.

This drug is being made available directly to physicians. They will request this product from CDC and it will be deployed from the Strategic National Stockpile for delivery directly to the hospital facility.

EUA for Intravenous (IV) peramivir

Empiric antiviral treatment with oral oseltamivir or orally inhaled zanamivir should be administered as soon as possible for all persons with suspected or confirmed influenza requiring hospitalization. Initiation of antiviral treatment should not be delayed pending laboratory confirmation of influenza.

Intravenous (IV) peramivir has been authorized for use by the US Food and Drug Administration (FDA), subject to the Emergency Use Authorization (EUA) terms and conditions.

IV peramivir may be appropriate for certain hospitalized and critically ill patients with suspected or confirmed 2009 H1N1 influenza, such as patients not responding to either an oral or inhaled antiviral therapy and patients without a dependable oral or inhaled route of drug delivery (e.g. patients unable or unlikely to absorb oseltamivir due to ileus or high nasogastric tube output).

Clinicians should carefully review the healthcare provider fact sheet on peramivir. This fact sheet also includes the terms and conditions of the EUA and safety and efficacy data on peramivir.

Guidance for Requesting Peramivir

If after reviewing these and other materials on CDC website, you have clinical questions relating to use of Peramivir, please contact CDC INFO at 1-800-232-4636, 24 hours a day, 7 days a week (For TTY, call 1-888-232-6348).

If after reviewing these materials, you would like to proceed with requesting Peramivir IV, go to the following website <http://emergency.cdc.gov/h1n1antivirals/> and click on the link entitled "To Initiate a Peramivir Request" button.

If you have questions relating to emergency use authorizations, contact: EUA.OCET@fda.hhs.gov

Other Antiviral Treatment Options for Patients Hospitalized due to Complicated Influenza

Currently there is no FDA-approved intravenous formulation of antiviral product for the treatment of hospitalized patients with influenza. Oral Tamiflu® (oseltamivir) and inhalation Relenza® (zanamivir) are FDA-approved for the treatment of uncomplicated acute illness due to influenza. Use of these medications is authorized for emergency use for the treatment of hospitalized patients with 2009 H1N1 influenza under FDA-issued EUAs.

The FDA-issued EUA for Tamiflu® authorizes use of Tamiflu® for the treatment of patients hospitalized due to complicated influenza and in patients symptomatic for more than 2 days, including pediatric patients less than 1 year old. The authorized use of Tamiflu® is subject to the terms and conditions of the EUA. For more information on the Tamiflu® EUA, please see: www.cdc.gov/h1n1flu/eua/tamiflu.htm The FDA-issued EUA for Relenza® authorized use of Relenza® for the treatment of patients hospitalized due to complicated influenza and in patients symptomatic for more than 2 days. The authorized use of Relenza® is subject to the terms and conditions of the EUA. For more information on the Relenza® EUA, please see: www.cdc.gov/h1n1flu/eua/relenza.htm

Sources for additional information

Resources regarding the Emergency Use Authorization of Peramivir IV

- <http://www.cdc.gov/h1n1flu/eua/peramivir.htm>

Antiviral Treatment Options, including Intravenous Peramivir, for Treatment of Influenza in Hospitalized Patients for the 2009-2010 Season

- http://www.cdc.gov/H1N1flu/EUA/peramivir_recommendations.htm

Fact Sheet for Healthcare providers on Emergency Use Authorization of Peramivir IV

- http://www.cdc.gov/h1n1flu/eua/Final%20HCP%20Fact%20sheet%20Peramivir%20IV_CDC.pdf

DHEC contact information for reportable diseases and reporting requirements

Reporting of outbreaks/clusters of cases of influenza (both seasonal and novel H1N1), aggregate positive influenza rapid tests, positive virus cultures for influenza and influenza deaths are consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2009 List of Reportable Conditions available at: <http://www.scdhec.gov/administration/library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2009

Mail or call reports to the Epidemiology Office in each Public Health Region.

Region 1

Anderson, Oconee

220 McGee Road
Anderson, SC 29625
Phone: (864) 260-4358
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Region 2

Greenville, Pickens

PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: 1-800-993-1186

Cherokee, Spartanburg, Union

PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227, x- 210
Fax: (864) 596-3443
Nights / Weekends: 1-800-993-1186

Region 3

Chester, Lancaster, York

PO Box 817
1833 Pageland Highway
Lancaster, SC 29720
Phone: (803) 286-9948
Fax: (803) 286-5418
Nights / Weekends: 1-866-867-3886

Region 3 (continued)

Fairfield, Lexington, Newberry, Richland

2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: 1-888-554-9915

Region 4

Clarendon, Kershaw, Lee, Sumter

PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 775-9941
Nights/Weekends: 1-877-831-4647

Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion

145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 660-8145

Region 5

Bamberg, Calhoun, Orangeburg

PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 533-7134
Nights / Weekends: (803) 954-8513

Aiken, Allendale, Barnwell

1680 Richland Avenue, W. Suite 40
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
Nights / Weekends: (803) 827-8668 or
1-800-614-1519

Region 6

Georgetown, Horry, Williamsburg

1931 Industrial Park Road
Conway, SC 29526-5482
Phone: (843) 915-8804
Fax: (843) 365-0085
Nights / Weekends: (843) 381-6710

Region 7

Berkeley, Charleston, Dorchester

4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 953-0060
Fax: (843) 953-0051
Nights / Weekends: (843) 219-8470

Region 8

Beaufort, Colleton, Hampton, Jasper

219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 525-5910
Fax: (843) 549-6845
Nights / Weekends: 1-800-614-4698

DHEC Bureau of Disease Control

Division of Acute Disease Epidemiology

1751 Calhoun Street
Box 101106
Columbia, SC 29211
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902



www.scdhec.gov

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.