NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
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MARK BENTON • Chief Deputy Secretary for Health
KELLY KIMPLE • Acting Director, Division of Public Health

Dear Providers,

Since April 2024, human infections of novel influenza A(H5N1) have occurred in the United States, following exposure to infected dairy cows and poultry. While the Centers for Disease Control and Prevention (CDC) consider the risk to the general public to be low, some groups of people with job-related or recreational exposures to birds, dairy cattle, or other H5 virus-infected animals, are at greater risk of infection. According to CDC guidance, antiviral treatment with oseltamivir is recommended as soon as possible for outpatients and hospitalized patients with suspected or confirmed novel influenza A virus infection. Suspected novel influenza infection is a reportable condition in North Carolina and suspected cases should be reported immediately to the Communicable Disease Branch Epidemiologist on Call at 919-733-4319.

On July 19, 2024, CDC issued Emergency Use Instructions (EUI) for the oral antiviral oseltamivir (brand name Tamiflu®) for treatment or post-exposure prophylaxis (PEP) of pandemic influenza A viruses and novel influenza A viruses with pandemic potential. EUIs provide information about emergency use of Food and Drug Administration (FDA)-approved medical products that differ from or go beyond the information provided in the FDA-approved labeling (package insert).

Oseltamivir is approved by the FDA for the treatment of acute, uncomplicated illness due to influenza A and B virus infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours and for prophylaxis of influenza A and B in patients 1 year and older. The CDC-issued oseltamivir EUI provides information on the following recommended uses of oseltamivir that differ or go beyond the FDA approved Package Insert:

- Initiation of treatment after 48 hours from symptom onset.
- Treatment of severely ill hospitalized patients, including longer courses of treatment (e.g., 10 days) based on clinical judgment.
- Higher total daily dose and flexible duration for PEP. The EUI-recommended dosing regimen in most cases is twice daily for 5 or 10 days in asymptomatic close contacts of a confirmed or probable novel influenza A case or asymptomatic persons exposed to animals infected with highly pathogenic avian influenza A(H5N1) virus or other novel influenza A viruses.
- Treatment of term neonates under 2 weeks of age.
- PEP in neonates and infants less than 1 year of age.
- Treatment and PEP dosing regimens for preterm neonates and infants.

The full CDC-issued oseltamivir EUI fact sheets for healthcare providers and recipients and caregivers are provided below:

- Oseltamivr Emergency Use Instructions (EUI) Fact Sheet for Healthcare Providers
- Oseltamivir Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers

All patients receiving oseltamivir for the treatment or prevention of novel influenza A should receive a copy of the *Oseltamivir EUI Fact Sheet for Recipients and Caregivers* from their physician or pharmacy.

For additional information regarding oseltamivir and other FDA-approved influenza antivirals, refer to CDC's Interim Guidance on the Use of Antiviral Medications for Treatment of Human Infections with Novel Influenza A Viruses Associated with Severe Human Disease and Interim Guidance on Follow-up of Close Contacts of Persons Infected with Novel Influenza A Viruses and Use of Antiviral Medications for Chemoprophylaxis.

Additional information on novel influenza A H5N1 is available on North Carolina's influenza webpage.