



## H1N1 Flu

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# Interim Guidance on Antiviral Recommendations for Patients with Novel Influenza A (H1N1) Virus Infection and Their Close Contacts

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**Objective:** To provide updated interim guidance on the use of antiviral agents for treatment and chemoprophylaxis of novel influenza (H1N1) virus infection, and assist clinicians in prioritizing use of antivirals for treatment or chemoprophylaxis of patients at higher risk for influenza-related complications. Additional revisions to these recommendations for antiviral treatment should be expected as the epidemiology and clinical presentation of novel influenza A (H1N1) virus infection is better understood. This guidance can be adapted according to local epidemiologic data and antiviral supply considerations.

**High-risk groups:** A person who is at high-risk for complications of novel influenza (H1N1) virus infection is defined as the same for seasonal influenza at this time. As more epidemiologic and clinical data become available, these risk groups might be revised.

- Children younger than 5 years old. The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
- Adults 65 years of age and older.
- Persons with the following conditions:
  - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
  - Immunosuppression, including that caused by medications or by HIV;
  - Pregnant women;
  - Persons younger than 19 years of age who are receiving long-term aspirin therapy;
  - Residents of nursing homes and other chronic-care facilities.

**Transmission:** Transmission of novel influenza A (H1N1) is being studied as part of the ongoing outbreak investigation, but limited data available indicate that this virus is likely transmitted in ways similar to other influenza viruses. Seasonal human influenza viruses are thought to be transmitted between persons primarily through large-particle respiratory droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person). Transmission via these large-particle droplets requires close contact between source and recipient persons because droplets do not remain suspended in the air and generally travel only a short distance (< 6 feet). Contact with contaminated surfaces is another possible source of transmission and transmission via small-droplet nuclei (also called “airborne” transmission) might also occur, but the contribution of these modes of transmission to influenza epidemiology is uncertain. Because data on the transmission of novel H1N1 viruses are limited, the potential for ocular, conjunctival, or gastrointestinal infection is unknown. Since this is a novel influenza A (H1N1) virus in humans, transmission from infected persons to close contacts might be common. All respiratory secretions and bodily fluids (diarrheal stool) of novel influenza A (H1N1) cases should be considered potentially infectious.

**Close contact, for the purposes of this document,** is defined as having cared for or lived with a person who is a confirmed, probable or suspected case of novel influenza A (H1N1), or having been in a setting where there was a high likelihood of contact with respiratory droplets and/or body fluids of such a person. Examples of close contact include kissing or embracing, sharing eating or drinking utensils, physical examination, or any other contact between persons likely to result in exposure to respiratory droplets. Close contact typically does not include activities such as walking by an infected person or sitting across from a symptomatic patient in a waiting room or office.

### **Special Considerations for Children**

*Aspirin or aspirin-containing products (e.g. bismuth subsalicylate – Pepto Bismol) should not be administered to any confirmed or suspected ill case of novel influenza H1N1 virus infection aged 18 years old and younger due to the risk of Reye syndrome. For relief of fever, other anti-pyretic medications such as acetaminophen or non-steroidal anti-inflammatory drugs are recommended.*

*Children younger than 4 years of age should not be given over-the-counter cold medications without first speaking with a healthcare provider.*

## Antiviral Resistance

This novel (H1N1) influenza virus is sensitive (susceptible) to the neuraminidase inhibitor antiviral medications, zanamivir and oseltamivir. It is resistant to the adamantane antiviral medications, amantadine and rimantadine.

## Antiviral Treatment for Novel (H1N1) Influenza

For antiviral treatment of novel influenza (H1N1) virus infection, either oseltamivir or zanamivir are recommended [Table 1](#). Recommendations for use of antivirals may change as data on antiviral effectiveness, clinical spectrum of illness, adverse events from antiviral use, and antiviral susceptibility data become available.

Clinical judgment is an important factor in treatment decisions. Persons with suspected novel H1N1 influenza who present with an uncomplicated febrile

illness typically do not require treatment unless they are at higher risk for influenza complications, and in areas with limited antiviral medication availability, local public health authorities might provide additional guidance about prioritizing treatment within groups at higher risk for infection.

Treatment is recommended for:

1. All hospitalized patients with confirmed, probable or suspected novel influenza (H1N1).
2. Patients who are at higher risk for seasonal influenza complications (see above).

If a patient is not in a high-risk group or is not hospitalized, healthcare providers should use clinical judgment to guide treatment decisions, and when evaluating children should be aware that the risk for severe complications from seasonal influenza among children younger than 5 years old is highest among children younger than 2 years old. Many patients who have had novel influenza (H1N1) virus infection, but who are not in a high-risk group have had a self-limited respiratory illness similar to typical seasonal influenza. For most of these patients, the benefits of using antivirals may be modest. Therefore, testing, treatment and chemoprophylaxis efforts should be directed primarily at persons who are hospitalized or at higher risk for influenza complications.

Once the decision to administer antiviral treatment is made, treatment with zanamivir or oseltamivir should be initiated as soon as possible after the onset of symptoms. Evidence for benefits from antiviral treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of oseltamivir treatment of hospitalized patients with seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset. Recommended duration of treatment is five days. Antiviral doses recommended for treatment of novel H1N1 influenza virus infection in adults or children 1 year of age or older are the same as those recommended for seasonal influenza (Table 1). Oseltamivir use for children <1 year old was recently approved by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA), and dosing for these children is age-based (Table 2) (See [Emergency Use Authorization of Tamiflu \(oseltamivir\)](#)).

Note: Areas that continue to have seasonal influenza activity, especially those with circulation of oseltamivir-resistant seasonal human influenza A (H1N1) viruses, might prefer to use either zanamivir or a combination of oseltamivir and rimantadine or amantadine to provide adequate empiric treatment or chemoprophylaxis for patients who might have seasonal human influenza A (H1N1) virus infection.

## Antiviral Chemoprophylaxis for Novel (H1N1) Influenza

For antiviral chemoprophylaxis of novel (H1N1) influenza virus infection, either oseltamivir or zanamivir are recommended (Table 1). Duration of antiviral chemoprophylaxis *post-exposure* is 10 days after the last known exposure to novel (H1N1) influenza. The indication for post-exposure chemoprophylaxis is based upon close contact with a person who is a confirmed, probable or suspected case of novel influenza A (H1N1) virus infection during the infectious period of the case. The infectious period for persons infected with the novel influenza A (H1N1) virus is assumed to be similar to that observed in studies of seasonal influenza. With seasonal influenza, studies have shown that people may be able to transmit infection beginning one day before they develop symptoms to up to 7 days after they get sick. Children, especially younger children, might potentially be infectious for longer periods. However, for this guidance, the *infectious period* is defined as one day before until 7 days after the case's onset of illness. If the contact occurred with a case whose illness started more than 7 days before contact with the person under consideration for antivirals, then chemoprophylaxis is not necessary. For *pre-exposure* chemoprophylaxis, antiviral medications should be given during the potential exposure period and continued for 10 days after the last known exposure to a person with novel (H1N1) influenza virus infection during the cases infectious period. Oseltamivir can also be used for chemoprophylaxis under the EUA for children less than 1 year of age (see Children Under 1 Year of Age).

Post exposure antiviral chemoprophylaxis with either oseltamivir or zanamivir can be considered for the following:

1. Close contacts of cases (confirmed, probable, or suspected) who are at high-risk for complications of influenza
2. Health care personnel, public health workers, or first responders who have had a recognized, unprotected close contact exposure to a person with novel (H1N1) influenza virus infection (confirmed, probable, or suspected) during that person's infectious period. Information on appropriate personal protective equipment is available at: [Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A \(H1N1\) Virus Infection in a Healthcare Setting](#) and might be updated frequently as additional information on transmission becomes available.

Pre-exposure antiviral chemoprophylaxis should only be used in limited circumstances, and in consultation with local medical or public health authorities. Certain persons at ongoing occupational risk for exposure who are also at higher risk for complications of influenza (e.g., health care personnel, public health workers, or first responders who are working in communities with influenza A H1N1 outbreaks) should carefully follow guidelines for appropriate personal protective equipment or consider temporary reassignment.

## Antiviral Use for Control of Novel H1N1 Influenza Outbreaks

Use of antiviral drugs for treatment and chemoprophylaxis of influenza has been a cornerstone for the control of seasonal influenza outbreaks in nursing homes and other long term care facilities. (see MMWR: [Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\), 2008](#)). At this time, no outbreaks of novel influenza A (H1N1) have been reported in such settings. However, if such outbreaks were to occur, it is recommended that ill patients be treated with oseltamivir or zanamivir and that chemoprophylaxis with either oseltamivir or zanamivir be started as early as possible to reduce the spread of the virus as is recommended for seasonal influenza outbreaks in such settings. Chemoprophylaxis should be administered to all non-ill residents and should continue for a minimum of 2 weeks. If surveillance indicates that new cases continue to occur, chemoprophylaxis should be continued until approximately 7 days after illness onset in the last patient. In addition to antiviral medications, other outbreak-control measures include appropriate infection control, establishing cohorts of patients with confirmed or suspected influenza, restricting staff movement between wards or buildings, and restricting contact between ill staff or visitors and patients, and active surveillance for new cases. Medical directors of long-

term care facilities should review their plans for outbreak control of influenza. Additional guidance for infection control measures in long-term care facilities can be found at: [Using Antiviral Medications to Control Influenza Outbreaks in Institutions](#).

In addition to use in nursing homes, antiviral chemoprophylaxis also can be considered for controlling influenza outbreaks in other closed or semiclosed settings (e.g., correctional facilities, or other settings in which persons live in close proximity). For more information about influenza outbreaks in facilities see: [Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\), 2008](#) or [Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America](#).

Table 1. Antiviral medication dosing recommendations for treatment or chemoprophylaxis of novel influenza A (H1N1) infection.

(Table extracted from [IDSA guidelines for seasonal influenza](#))

Agent, group		Treatment	Chemoprophylaxis
<b>Oseltamivir</b>			
<b>Adults</b>		75-mg capsule twice per day for 5 days	75-mg capsule once per day
<b>Children ≥ 12 months</b>	15 kg or less	60 mg per day divided into 2 doses	30 mg once per day
	15-23 kg	90 mg per day divided into 2 doses	45 mg once per day
	24-40 kg	120 mg per day divided into 2 doses	60 mg once per day
	>40 kg	150 mg per day divided into 2 doses	75 mg once per day
<b>Zanamivir</b>			
<b>Adults</b>		Two 5-mg inhalations (10 mg total) twice per day	Two 5-mg inhalations (10 mg total) once per day
<b>Children</b>		Two 5-mg inhalations (10 mg total) twice per day (age, 7 years or older)	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older)

## Children Under 1 Year of Age

Children under one year of age are at high risk for complications from seasonal human influenza virus infection. The characteristics of human infection novel (H1N1) influenza virus are still being studied, and it is not known whether infants are at higher risk for complications associated with novel (H1N1) influenza virus infection compared to older children and adults. Oseltamivir is not licensed for use in children less than 1 year of age. However, limited safety data on oseltamivir treatment for seasonal influenza in children less than one year of age suggest that severe adverse events are rare.

Because infants experience high rates of morbidity and mortality from influenza, infants with novel (H1N1) influenza virus infections may benefit from treatment using oseltamivir. (Tables 2 and 3, [Emergency Use Authorization of Tamiflu \(oseltamivir\)](#)).

Table 2. Dosing recommendations for antiviral treatment of children younger than 1 year using oseltamivir.

Age	Recommended treatment dose for 5 days
<3 months	12 mg twice daily
3-5 months	20 mg twice daily
6-11 months	25 mg twice daily

Table 3. Dosing recommendations for antiviral chemoprophylaxis of children younger than 1 year using oseltamivir.

Age	Recommended prophylaxis dose for 10 days
<3 months	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg once daily
6-11 months	25 mg once daily

Healthcare providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed novel (H1N1) influenza virus infection or who has been exposed to a confirmed novel (H1N1) influenza case, and carefully monitor infants for adverse events when oseltamivir is used. Additional information on oseltamivir for this age group can be found at: [Swine Flu: Emergency Use Authorization \(EUA\) of Medical Products and Devices](#).

## Pregnant Women

Pregnant women are known to be at higher risk for complications from infection with seasonal influenza viruses, and severe disease among pregnant women was reported during past pandemics. Cases of confirmed novel (H1N1) influenza virus infection in pregnant women resulting in severe disease have been reported, and a pregnant woman died in 1988 after being infected with another type of swine influenza virus. Oseltamivir and zanamivir are "Pregnancy Category " medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. Although a few adverse effects have been reported in pregnant women who took these medications, no relation between the use of these medications and those adverse events has been established. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women. The drug of choice for chemoprophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.

## Adverse Events and Contraindications

For further information about influenza antiviral medications, including contraindications and adverse effects, please see the following:

- [Antiviral Agents for Seasonal Influenza: Side Effects and Adverse Reactions](#)
- [MMWR: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\), 2008 MMWR August 8, 2008 / 57\(RR07\):1-60](#)
- Harper SA, Bradley JS, Englund JA, et al. [Infectious Diseases Society of America Guidelines. Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America.](#)

Adverse events from influenza antiviral medications should be reported through the [U.S. FDA Medwatch website](#).

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