

**NURSE PROTOCOL FOR  
ANTIVIRAL TREATMENT AND CHEMOPROPHYLAXIS  
OF INFLUENZA A (H1N1) VIRUS INFECTION**

**DEFINITION** The novel H1N1 Influenza virus is a very unusual virus. This particular genetic combination of influenza segments has not been recognized before in the United States or elsewhere.

**ETIOLOGY** The hallmark of influenza viruses is their ability to undergo constant and dramatic change. Many different animals and humans get infected with influenza viruses, but the viruses generally stick with one species or another. However, sometimes influenza viruses jump from one species to another, and sometimes, viruses from different species can infect the same host and result in a new combination of virus genes. This last scenario is what happened and resulted in the novel H1N1 influenza virus.

**SUBJECTIVE** The patient reports the following influenza-like symptoms: fever of  $\geq 100$  degrees Fahrenheit, cough or sore throat. Additional symptoms may include running nose, nausea, vomiting, diarrhea, body aches, headaches, and fatigue. The patient reports being a member of one of the target groups listed in Table 1.

- OBJECTIVE**
1. The patient has or had a documented temperature of 100 degrees Fahrenheit or higher; **AND**
  2. May appear ill.
  3. May be coughing and/or sneezing.
  4. H1N1 is circulating in the community or the patient reports a recent exposure to an H1N1 cluster or case.

**ASSESSMENT** The patient meets criteria for antiviral treatment of H1N1 infection or antiviral chemoprophylaxis for H1N1 infection.

**TARGET GROUPS**

**Table 1: Antiviral Drug Priority Group Recommendations\***

	<b>Group</b>	<b>Strategy**</b>	<b>Rationale</b>
<b>1</b>	Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers.	<b>T</b>	Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.
<b>2</b>	High risk outpatients-immunocompromised persons (chronic steroid use, HIV positive, chemotherapy, metastatic cancer) and pregnant women.	<b>T</b>	Groups at greatest risk of hospitalization and death.

	<b>Group</b>	<b>Strategy**</b>	<b>Rationale</b>
<b>3</b>	High risk outpatients – young children < 5 years, persons >65 yrs old, and persons with chronic medical conditions (i.e., asthma, emphysema, cardiac, sickle cell anemia, neurodevelopmental disabilities, morbid obesity, kidney , liver and metabolic diseases).	<b>T</b>	Greatest risk of hospitalization and death.
<b>4</b>	Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers).	<b>T</b>	Groups are critical for an effective public health response to a pandemic.
<b>5</b>	Persons less than 19 years of age who are receiving long-term aspirin therapy.	<b>T</b>	At risk of developing Reyes syndrome.

\*\* Strategy: Treatment (T) requires a total of 10 capsules and is defined as 1 course. Treatment should be initiated as early as possible without waiting for laboratory confirmation because studies show that treatment initiated early (within 48 hours of illness onset) is more likely to provide benefit. However, some studies of treatment of 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. **For this reason, high-risk patients with suspected H1N1 should be treated even if they present after 48 hours per the CDC’s recommendation.**

A person not in one of the target groups listed in Table 1, but who is a suspected influenza patient presenting with warning symptoms (e.g., dyspnea) or signs (e.g., tachypnea, unexplained oxygen desaturation) for lower respiratory tract illness and therefore, should promptly receive empiric antiviral therapy.

Since H1N1 is widespread in Georgia, the primary goal of antiviral therapy will be to treat those at highest risk of severe illness and death, and to preserve the delivery of healthcare and other essential critical services through early treatment and limited prophylaxis to persons at high risk of developing complications.

**PLAN THERAPEUTIC**

Table 1. Antiviral medication dosing recommendations for treatment or chemoprophylaxis of novel influenza A (H1N1) infection. (Table extracted from <a href="#">IDSA guidelines for seasonal influenza.</a> )		
<b>Agent, group</b>	<b>Treatment</b>	<b>Chemoprophylaxis*</b>
<b>Oseltamivir</b>		
<b>Adults</b>	75-mg capsule twice per day for 5 days	75-mg capsule once per day for 10 days after the last exposure

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

<b>Chemoprophylaxis*</b>			
<b>Oseltamivir</b>			
<b>Children ≥ 12 months</b>	15 kg or less	60 mg per day divided into 2 doses for 5 days	30 mg once per day for 10 days after the last exposure
	16-23 kg	90 mg per day divided into 2 doses for 5 days	45 mg once per day for 10 days after the last exposure
	24-40 kg	120 mg per day divided into 2 doses for 5 days	60 mg once per day for 10 days after the last exposure
	>40 kg	150 mg per day divided into 2 doses for 5 days	75 mg once per day for 10 days after the last exposure
<b>Zanamivir</b>			
<b>Adults</b>		Two 5-mg inhalations (10 mg total) twice per day for 5 days	Two 5-mg inhalations (10 mg total) once per day for 10 days after the last exposure
<b>Children</b>		Two 5-mg inhalations (10 mg total) twice per day (age, 7 years or older) for 5 days	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older for 10 days after the last exposure)

\*Chemoprophylaxis: Dosage regimen applies to post-exposure.

### **Children Under 1 Year of Age**

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.

<b>Age</b>	<b>Recommended treatment dose for 5 days</b>
<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

### Antiviral Chemoprophylaxis

The infectious period for influenza is defined as one day before until 24 hours after fever ends. Postexposure antivirals with either oseltamivir or zanamivir should be considered for:

- Persons at high risk (priority groups in Table 1) for complications of influenza and are a close contact of a person with confirmed, probable or suspected 2009 H1N1 or seasonal influenza during the infectious period.
- Health care personnel, public health workers, or first responders who have had a recognized, unprotected close contact exposure to a person with confirmed, probable, or suspected 2009 H1N1 or seasonal flu during the person's infectious period.
- Antiviral agents **should not** be used for post exposure chemoprophylaxis in healthy children and adults
- Chemoprophylaxis is **generally not recommended** if more than 48 hours have elapsed since the last contact with an infectious person
- Chemoprophylaxis is **not indicated** when the contact occurred before or after, but not during, the infectious period.

Close contact is defined by the CDC as having cared for or lived with a person who is confirmed, probable or suspected case of influenza or having been in a setting where there is a high likelihood of contact with respiratory droplets or bodily fluids of such person.

The sole caretaker of children less than five or other high-risk individuals may also be considered for antiviral post exposure prophylaxis.

### PRECAUTIONS AND CONTRAINDICATIONS

1. Because of the potential for interference between Oseltamivir OR Zanamivir with Flumist (LAIV), do not administer live attenuated influenza vaccine within 2 weeks before or 48 hours after administration of oseltamivir, unless medically indicated.
2. If taking either Oseltamivir or Zanamivir, advise client or caretaker to observe for signs of unusual behavior and contact a health care provider immediately if the patient shows any signs of unusual behavior.

### Oseltamivir

1. The drug probenecid may decrease clearance of oseltamivir.
2. Use caution in renal impairment (decrease dose of oseltamivir if CrCl <30 mL/min), chronic cardiac or respiratory disease, and breastfeeding.
3. Oseltamivir may cause nausea or vomiting.
4. The safety and pharmacokinetics in patients with severe hepatic function impairment have not been evaluated.
5. It is not known whether oseltamivir or oseltamivir carboxylate is excreted in human milk. Because the molecular weight of oseltamivir (about 312 for the free base) is low enough, excretion into breast milk should be expected.

### Zanamivir

1. Do not use zanamivir if patient has underlying airway disease (e.g., obstructive airway disease or asthma).
2. Monitor respiratory status. Zanamivir may cause bronchospasm.
3. No dosage adjustments are necessary in patients with renal function impairment, however, consider the potential for drug accumulation.
4. History of allergic reaction to any ingredient of Zanamivir, including lactose (which contains milk proteins).
5. It has been suggested that Zanamivir is excreted in breast milk.
6. Patients should be instructed in the use of the delivery system. Instructions should include a demonstration whenever possible. If prescribed for children, it should be used only under adult supervision and instruction, and the supervising adult should first be instructed by a health care provider.

### **PREGNANCY**

Pregnant women who meet current case definitions for confirmed, probable or suspected Swine Influenza A (H1N1) infection should receive empiric antiviral treatment. Any pregnant woman with an acute febrile respiratory infection, should be evaluated by a physician, since she is at greater risk of complications, such as pneumonia and pre-term labor. **Pregnant women who are close contacts of persons with suspected, probable or confirmed cases of Swine Influenza A (H1N1) infection should receive chemoprophylaxis.**

Oseltamivir (Tamiflu®) and zanamivir are "Pregnancy Category C" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. However, no adverse effects have been reported among women who received oseltamivir or zanamivir during pregnancy or among infants born to women who have received oseltamivir or zanamivir. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because zanamivir is an inhaled medication and has less systemic absorption, some experts prefer zanamivir over oseltamivir for

chemoprophylaxis in pregnant women when feasible. Oseltamivir is preferred for treatment of pregnant women because of its systemic activity.

## **HIGH RISK GROUPS**

The priority use for influenza antiviral drugs during this outbreak will be to treat people with severe influenza illness and those at risk of severe disease. A person who is at high-risk for complications of Influenza A (H1N1) virus infection is defined as the priority groups in Table 1.

## **CLIENT EDUCATION/COUNSELING**

Patients given chemoprophylaxis should be informed that the risk of influenza infection is lessened, but not entirely eliminated, and protection stops when the medication is stopped. If they develop influenza like symptoms they should call their healthcare provider.

Patients receiving treatment should be advised that they remain potentially infectious to others while on treatment. Despite treatment with antiviral agents, including treatment with the neuraminidase inhibitors, patients may continue to shed influenza virus for up to four or more days after beginning therapy. Therefore, patients should continue good hand washing and respiratory hygiene practices during the entire period on therapy to prevent the transmission of virus to close contacts.

Each patient receiving antiviral treatment or chemoprophylaxis should be provided the respective fact sheet and instruction sheet:

1. *Tamiflu Fact Sheet for Patients and Parents*
2. *Zanamivir Summary Fact Sheet for Patients and Parents*
3. *How to Use Relenza (zanamivir) Step-by-Step*

## **FOLLOW-UP**

1. The patient should be encouraged to contact 1-866-752-3442 if they have any follow-up questions or issues or they may call their county health department or their private physician.
2. No follow-up needed if symptoms are resolving in 3-4 days.
3. If there is deterioration with return of fever after apparent improvement after 3 days of illness (suspect pneumonia).

## **CONSULTATION/REFERRAL**

1. Any pregnant woman, with an acute febrile respiratory infection, should be evaluated by a physician, since she is at greater risk of complications, such as pneumonia and pre-term labor.
2. Difficulty breathing.
3. Chest pain.
4. Bluish or gray skin color.
5. Severe vomiting and can not hold down fluids.
6. Confusion or seizures.

7. Children who are difficult to wake up or console.
8. Symptoms that last longer than three or four days without improvement.
9. Fever and other symptoms go away then return worse.
10. Complications of influenza, which include:
  - a. Primary influenza pneumonia.
  - b. Secondary bacterial pneumonia.
  - c. Myositis (calf tenderness, refusal to walk in children).
  - d. Central nervous system problems (persistent lethargy, confusion, uncharacteristic behavior).
  - e. Reye syndrome (associated primarily with influenza B).
  - f. Dehydration.
  - g. Acute Respiratory Distress Syndrome.
  - h. Death.

## REFERENCES

1. *Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season*, September 8, 2009, <<http://www.cdc.gov/h1n1flu/recommendations.htm>>.
2. *Interim Guidance on Antiviral Recommendations for Patients with Novel Influenza A (H1N1) Virus Infection and Their Close Contacts*, August 8, 2009, <<http://www.cdc.gov/h1n1flu/recommendations.htm>>.
3. *2009 H1N1 Flu (Swine Flu)*, September 4, 2009, <<http://www.cdc.gov/h1n1flu/>>.
4. *Interim Guidance on Case Definitions to be Used for Investigations of Novel Influenza A (H1N1) Cases*, June 1, 2009, <[http://www.cdc.gov/h1n1flu/casedef\\_swineflu.htm](http://www.cdc.gov/h1n1flu/casedef_swineflu.htm)>.
5. *eFacts and Comparisons 4.0*, Wolters Kluwer Health, Inc., <http://online.factsandcomparisons.com/MonoDisp.aspx?monoid=fandc-hcp12826&quick=Tamiflu&search=Tamiflu&disease=>> (September 14, 2009).
6. *eFacts and Comparisons 4.0*, Wolters Kluwer Health, Inc., <http://online.factsandcomparisons.com/MonoDisp.aspx?monoid=fandc-hcp12900&book=DFC&searched=zanamivir&disease=&nostem=False&asbooks=>> (September 14, 2009).