

## Issues Document: 2010-2011 Influenza Season

### Summary

Seasonal influenza (flu) generally begins in October and extends into May. This year, the seasonal influenza vaccination contains the 2009 H1N1 flu (previously referred to as “swine flu”) virus as one of the flu strain to help deliver a cross-coverage vaccination. These vaccines are already available on the market. This document is intended to provide a general update for the 2010-2011 flu season and to highlight how Express Scripts’ program offering can help you.

### Take-Away Points

- The influenza (flu) season generally begins in October and extends into May.
- The single best way to prevent the flu is to get a flu vaccine each year.
- The 2010-2011 seasonal influenza vaccine contains the influenza A (H1N1) vaccine virus derived from the 2009 pandemic influenza A (H1N1) virus. A second vaccination against the H1N1 virus is not anticipated this year.
- Yearly flu vaccination should begin in September, or as soon as vaccine is available, and continue throughout the flu season which can last as late as May.
- Antiviral medications may be appropriate for some patients to prevent or treat influenza.
- Express Scripts has a variety of program solutions to help our clients and their members including concurrent drug utilization review (DUR) messaging, vaccine coverage, and drug quantity level limits to prevent stockpiling, misuse, or overuse of Tamiflu and Relenza.
- For the 2010-2011 flu season, Express Scripts’ standard recommendation is coverage of the vaccine and professional services fee to administer the vaccine at the point-of-dispensing. Express Scripts also recommends adoption of the Standard per Rx Drug Quantity Management (DQM) program.
- Influenza is a dynamic virus, with new information coming out every week. The most up-to-date information can be found on CDC’s website. As always, Express Scripts will monitor this situation closely and provide updates as appropriate.

## BACKGROUND

### Seasonal Influenza

The flu season generally begins in October and extends into May. According to the Centers for Disease Control and Prevention (CDC), about 5-20% of the population gets the flu each year, resulting in more than 200,000 hospitalizations. About 36,000 people die from the flu each year.

### H1N1 Flu

The 2009 H1N1 flu was first detected in people in the United States in April 2009. The virus spreads from person-to-person similar to how seasonal influenza viruses spread. The 2009 H1N1 flu was problematic since it was a new, unique flu strain that humans have not been exposed to before. While not certain, it is likely that the 2009 H1N1 viruses will continue to spread along with seasonal viruses in the U.S. during the 2010-2011 flu season. The H1N1 virus vaccine is included in the 2010-2011 seasonal flu vaccine.



## Steps to Prevent Transmission of the Flu

- **Cover your mouth and nose.** Cover your nose and mouth with a tissue when you cough or sneeze. It may prevent those around you from getting sick. Throw the tissue in the trash after you use it.
- **Clean your hands.** Wash your hands often with soap and water, especially after you cough or sneeze. Alcohol-based hand cleaners are also effective.
- **Avoid touching your eyes, nose or mouth.** Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth.
- **Avoid close contact.** Avoid close contact with people who are sick. When you are sick, keep your distance from others to protect them from getting sick too.
- **Stay home when you are sick.** If you are sick with flu-like illness, CDC recommends that you stay home for at least 24 hours after your fever is gone except to get medical care or for other necessities. (Your fever should be gone without the use of a fever-reducing medicine.) Keep away from others as much as possible to keep from making others sick.

## WHO SHOULD BE VACCINATED?

### Seasonal Influenza

The best way to prevent seasonal flu is to get the seasonal influenza vaccine. The CDC recommends that people get vaccinated against seasonal influenza as soon as vaccines become available. While in the past there have been shortages of seasonal influenza vaccine, supplies are expected to be adequate for the 2010-2011 flu season. While everyone aged six months and older is advised to get vaccinated against seasonal influenza the CDC and the Advisory Committee on Immunization Practices recommends the following priority groups for vaccination:

1. Pregnant women
2. Children younger than 5, but especially children younger than 2 years old
3. People 50 years of age and older
4. People of any age with certain chronic medical conditions
5. People who live in nursing homes and other long-term care facilities
6. People who live with or care for those at high risk for complications from flu, including:
  - a. Health care workers
  - b. Household contacts of persons at high risk for complications from the flu
  - c. Household contacts and out of home caregivers of children less than 6 months of age (these children are too young to be vaccinated)



## TREATMENT & PREVENTION

### VACCINES

#### **Seasonal Influenza**

The annual flu vaccine contains three influenza virus types: one A (H1N1) type virus, one A (H3N2) virus and one B virus. The virus make-up changes each year based on international surveillance and scientists' estimations about which types and strains of viruses will circulate in a given year. This season, the influenza A (H1N1) vaccine is derived from the 2009 pandemic influenza A (H1N1) virus.

#### **2010-2011 trivalent vaccine virus strains:**

- A/California/7/09 (H1N1)-like virus
- A/Perth /16/2009 (H3N2)-like virus
- B/Brisbane/60/2008-like virus

#### ***Injectable versus Intranasal Vaccine***

There are two types of influenza vaccine. The first type is an inactive influenza vaccine that is given as an intramuscular injection. The second contains a live, but attenuated (weakened) nasally administered vaccine (FluMist<sup>®</sup> - MedImmune).

Healthy persons 2 to 49 years of age can be vaccinated with either the injectable or intranasal flu vaccine. Children 6 months to 8 years who have not been previously vaccinated, or who only received one vaccination their first year of vaccination, should receive two vaccinations separated by four or more weeks. FluMist should not be given to certain populations including: children 6 to 23 months of age, adults older than 49 years of age, children less than 5 years of age with possible reactive airway disease, pregnant women and patients with higher risk of flu-related complications due to an underlying medical condition.

### ANTIVIRALS

#### **Seasonal Influenza**

Antiviral medications are used as a second line of defense (after vaccination) for the prevention and treatment of influenza. It is important to remember that flu antiviral drugs are not a substitute for getting vaccinated.

#### **Treatment\***

After June 23, 2010, Tamiflu<sup>®</sup> (oseltamivir) and Relenza<sup>®</sup> (zanamivir) should be distributed and dispensed in compliance with FDA regulations and State laws, and in accordance with FDA-approved product labeling.

**Tamiflu** is approved by the FDA for the following indications:

- Treatment of uncomplicated acute illness due to influenza A and B virus infection in patients 1 year and older who have been symptomatic for no more than two days.
- Prophylaxis (prevention) of influenza A and B virus in patients 1 year and older.



**Relenza** is approved by the FDA for the following indications:

- Treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than two days.
- Prophylaxis (prevention) of influenza A and B virus in adults and pediatric patients 5 years of age and older.

\* Recommendations on the use of antiviral drugs for the 2010-2011 flu season are currently in development. This section will be updated when 2010-2011 treatment guidelines have been updated.

## EXPRESS SCRIPTS' PROGRAM OFFERING

### Vaccine Professional Services Fee

Express Scripts is able to support the payment of vaccine professional services fees – the fees associated with the physical injection of a vaccine by a health care practitioner – during adjudication of the vaccine in the pharmacy.

Consistent with the CDC, Express Scripts encourages clients to provide reimbursement for the vaccine professional services fee associated with the seasonal influenza vaccine at the point-of-dispensing. Express Scripts expects that the fee will be \$15 per influenza vaccination.

### Drug Quantity Management (DQM)

Express Scripts has DQM programs for both Tamiflu and Relenza. The programs are primarily intended to prevent stockpiling, misuse, or overuse of these two medications. Express Scripts has two distinct DQM programs: *Standard per Rx* and *Select per Days*.

- The *Standard per Rx program* allows patients to receive enough Tamiflu/Relenza to either cover the standard course of treatment or up to 10 days of chemoprophylaxis.
- The *Select per Days program* allows patients to receive up to two courses of treatment over the plan year. For both programs, exceptions are available if clinically appropriate.

**Recommendation:** For the 2010-2011 flu season, Express Scripts recommends that clients have the Standard per Rx DQM program in place. This program ensures optimal quantities of medications are dispensed per copayment for the defined list of drugs. We also recommend that clients include taking automatic updates when enrolling in this program.



## Concurrent Drug Utilization Review (DUR)

Through Express Scripts' concurrent DUR program, pharmacists receive a message at the point-of-dispensing. For the 2010-2011 flu season, this message will be updated when CDC treatment guidelines are updated regarding the use of amantadine and rimantadine.

## Healthcare Reform

The U.S. Preventive Services Task Force (USPSTF) has compiled a list of recommended treatments for specific preventive purposes. Based on the USPSTF guidance, Express Scripts' standard recommendation is to cover the influenza vaccine and the professional administration fee at a \$0 copay.

**Express Scripts Recommendation:** For the 2010-2011 flu season, Express Scripts standard recommendation is coverage of the influenza vaccine and professional services fee at the point-of-dispensing and adoption of the Drug Quantity Management Program (*Standard per Rx*) with automatic updates.

## Next Step (For Clients)

If you would like to implement or learn more about Express Scripts' program recommendations for seasonal influenza, please contact your Express Scripts' account team.

## Stay Informed

To access the most up-to-date information on seasonal influenza, please see the CDC's website at <http://www.cdc.gov/flu/>.

## References

1. Seasonal Flu information found on the Centers for Disease Control and Prevention (CDC) website. Last accessed August 30th, 2010: <http://www.cdc.gov/flu/>.
2. 2009 H1N1 Flu information found on the Centers for Disease Control and Prevention (CDC) website. Last accessed August 30th, 2010: <http://www.cdc.gov/h1n1flu/>.
3. Vaccines, Blood & Biologics: Influenza virus vaccine for the 2010-2011 season. FDA Website. Last accessed August 30th, 2010: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm202750.htm>
4. Questions and Answers Regarding Termination of the Emergency Use Authorizations (EUAs) for Tamiflu (oseltamivir) and Relenza (zanamivir). CDC Website. Last accessed August 30th, 2010: [http://www.cdc.gov/H1N1flu/EUA/pdf/Relenza\\_Tamiflu\\_Attachment\\_1\\_22Jun2010.pdf](http://www.cdc.gov/H1N1flu/EUA/pdf/Relenza_Tamiflu_Attachment_1_22Jun2010.pdf)
5. Information regarding Termination and Disposition of CDC-requested and FDA-issued EUA Products. CDC Website. Last accessed August 30th, 2010: <http://www.cdc.gov/h1n1flu/eua/>

