

2009-2010 Influenza Season Update #12

Assuring Access to Anti-Influenza Medications

To: Health Care Providers
From: Wendy Davis, MD, Commissioner of Health

– Please Distribute Widely –

The Vermont Department of Health is working to assure ready access to antiviral medications for treating people with influenza. The Centers for Disease Control & Prevention (CDC) guidelines for treatment are available at: <http://www.cdc.gov/H1N1flu/antivirals/> Approved anti-influenza medications include oseltamivir (Tamiflu) and zanamivir (Relenza). Peramivir, an anti-influenza drug administered intravenously, is also approved through an Emergency Use Authorization from the U.S. Food & Drug Administration – See 2009-2010 Influenza Season Update #9, dated Nov. 6 www.healthvermont.gov and select health advisories from the left navigational column or go directly to: http://healthvermont.gov/advisory/2009/110609influenza_season_update9.aspx.

Monitoring Antiviral Supplies

To assure that health care providers have access to antivirals to treat influenza, the Health Department is monitoring the commercial antiviral stock at a regional pharmaceutical distributor, Burlington Drug Company. We are also asking retail and hospital pharmacies to report antiviral use patterns in their settings, as well as their ability to obtain medications from their suppliers. We are in regular communication with CDC about national supplies, and also hear about from health care providers about local supply issues. At this time, there appear to be no critical shortages of antivirals either nationally or locally. We ask that providers rely on commercial suppliers before turning to the state antiviral cache.

State Antiviral Cache

The Health Department also maintains and authorizes use of antivirals from a state antiviral cache. The state cache was created in preparation for a severe influenza pandemic and the possibility that commercial antiviral supplies would not be available or sufficient to meet demand. This cache was created by combining medications from the Strategic National Stockpile (SNS) with additional antivirals purchased with state and hospital funds. (These funds were used to purchase medications at discount through federal purchasing agreements with Roche and GlaxoSmithKline.) In total, the state cache holds 146,055 treatment courses – enough to provide a single treatment course to nearly 25 percent of the state's population.

Compounding Tamiflu Oral Suspension

Roche is the sole manufacturer of Tamiflu products available in the U.S. Forms of Tamiflu include 30, 45 and 75 mg capsules, and oral suspension that provides 12 mg/mL. Shortages of Tamiflu oral suspension began in October, and pharmaceutical distributors report that re-supply of suspension is not expected until at least mid-December. In response, pharmacists began compounding oral suspension from capsule forms. While the manufactured suspension is preferred, compounding is an acceptable alternative during a shortage. See compounding information and instructions at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm>

Antiviral Access FAQs:

How does the Vermont Department of Health know there no critical shortages right now?

In late October, the Health Department noted the decline and depletion of on-hand stock of Tamiflu capsules at the regional distributor. In response to the situation, Roche re-supplied this distributor with more than 1,000 treatment courses. During the ongoing suspension shortage, the Health Department has promoted compounding in order to assure access to medication for patients who cannot swallow capsules. Hospital and retail pharmacists continue to compound oral suspension to meet these needs.

The box of antiviral suspension from the state cache says the product expired in 2006.

How can it still be used?

An Emergency Use Authorization (EUA) was issued by the U.S. Food & Drug Administration after testing the product to assure its potency was maintained as part of its Shelf Life Extension Program (SLEP). See new expiration dates at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>

When can a pharmacy use state cache antivirals? Do they need to ask prior to dispensing?

Pharmacies that hold antivirals from the state cache may use them, without getting prior permission, when routine supplies cannot meet demand. State cache antivirals are only authorized for treatment. Examples of circumstances for use of state cache antivirals include:

- On-hand stocks are depleted and cannot be re-supplied.
- Patient would not be able to access antiviral treatment unless offered at no cost.

What are the requirements for use of state cache antivirals?

Dispensing pharmacies must comply with the following requirements:

- They cannot charge for the medication dispensed. The Health Department recommends that any provider who agrees to dispense government-provided antivirals will not charge an administration fee that exceeds the established regional Medicaid rate. Current Procedural Terminology (CPT) codes and fee-for-service Qs and As can be found within the “downloads” section at: <http://www.cms.hhs.gov/H1N1/>
- Dispensing fee information for each state for Medicaid can be found at: <http://www.cms.hhs.gov/Reimbursement/Downloads/reimbursementchart2q2009.pdf>
- Dispensing pharmacies are must report aggregate numbers of treatment courses dispensed by the following categories to the Health Department each week:
 - > children younger than 5 years
 - > adults older than 64 years
 - > pregnant women
 - > people with medical conditions that predispose them for flu complications
 - > other
- Drugs dispensed within an EUA must be accompanied by information for patients that explain the EUA and SLEP programs, so patients can understand that the medication strength has been evaluated and is deemed sufficient for treatment through the new SLEP expiration date.

For more information about the state cache requirements, contact Lori Shatney, Vermont Department of Health SNS Coordinator, lshatne@vdh.state.vt.us or 802-865-7735.