

U.S. Government Foots H1N1 Vaccination Bill

BY MITCHEL L. ZOLER

The U.S. government has picked up most of the tab for its aggressive campaign to get vaccine against pandemic influenza A(H1N1) into a majority of its residents, spending more than \$6 billion in the process.

The federal government purchased all of the pandemic H1N1 vaccine being distributed to Americans, starting with the initial doses that began to reach high-risk people in early October.

The government also paid for ancillary supplies such as syringes, needles, and alcohol swabs, as well as campaigns to promote the vaccine, according to the Centers for Disease Control and Prevention (www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm).

Last June, Congress appropriated \$7.65 billion for H1N1 and other pandemic influenza preparedness and response activities, said Elleen Kane, a spokeswoman for the Department of Health and Human Services. From that, HHS has either spent or plans to spend \$6.15 billion; another \$240 million is being spent by other government agencies, bringing the total expense to \$6.39 billion. HHS officials are monitoring whether additional expenditures will be needed, Ms. Kane said.

Almost a quarter of the \$6.15 billion has gone to states and hospitals to support their planning and preparation for

vaccination campaigns. The rest of the money went toward buying the vaccine itself, syringes, needles, antiviral drugs, surveillance materials, and other H1N1 response activities.

Although the government has covered most vaccination expenses, the CDC gave a green light to providers to charge for the administration of pandemic flu vaccine. Both public and private providers administering the vaccine need

designation as a 2009 H1N1 vaccinator by the public health authority in the jurisdiction where they practice. Public health departments are allowed to use federal money to pay for vaccine administration by commercial community vaccinators as long as it's as part of a contractual relationship.

Reimbursement to private providers by private health insurance plans is at the discretion of each plan, but the CDC said

it expects private plans will do so. Coverage for H1N1 vaccine administration is already guaranteed from Medicare, the Veterans Administration, TRICARE, and the Indian Health Service. Reimbursement levels are the same as for administration of seasonal flu vaccine, about \$20.

The CDC's information page also listed the various codes that are used to receive reimbursement for vaccine administration. ■

FDA Approves Gardasil Use in Males Aged 9-26

The Food and Drug Administration has approved the Gardasil vaccine for boys and men aged 9-26 years to prevent genital warts associated with the human papillomavirus, according to a statement from the vaccine's manufacturer, Merck & Co. An FDA press officer confirmed the approval.

The human papillomavirus (HPV) vaccine offers protection against four strains of the virus (types 6, 11, 16, and 18) that have been associated with the most disease, including cervical cancer in women (types 16 and 18) and genital warts in both women and men (types 6 and 11), according to the statement.

In an Oct. 21 vote, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) declined to recommend routine use of Gardasil in males aged 9-26 years, letting physicians decide whether to use the vaccine. The vaccine was approved in 2006 for young women and girls aged 9-26 years, and it is part of the CDC's adolescent vaccination schedule.

Gardasil is not recommended for pregnant women or for individuals with hypersensitivity to yeast, according to the vaccine's safety information.

—Heidi Splete



Introducing Zipsor. Tough love for acute pain.

It is important to carefully consider the potential benefits and risks of Zipsor prior to initiating therapy. Zipsor should be used at the lowest effective dose for the shortest duration consistent with individual patient treatment goals. The only approved dosing regimen for Zipsor is 25 mg four times a day.

See accompanying Brief Summary for additional Prescribing Information. For complete Prescribing Information, please see adjacent pages.

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Risk

- Nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk [see Warnings and Precautions].
- Zipsor is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery [see Contraindications].

Gastrointestinal Risk

NSAIDs increase the risk of serious gastrointestinal (GI) adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events [see Warnings and Precautions].

*NPRS = Numeric Pain Rating Scale.

†Zipsor (25 mg) was evaluated in multicenter, randomized, double-blind, placebo-controlled, parallel group studies. The baseline pain intensity ranged from 4-10 on the NPRS in both groups.

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