North Dakota Medicaid Pharmacy Program Quarterly News

Published Quarterly by Health Information Designs, Inc. Summer 2009

Welcome to the Summer 2009 edition of the "North Dakota Medicaid Pharmacy Program Quarterly News," a pharmacy newsletter presented by the North Dakota Department of Human Services and published by Health Information Designs, Inc. This newsletter is published as part of a continuing effort to keep the Medicaid provider community informed of important changes in the North Dakota Medicaid Pharmacy Program.

The North Dakota Department of Human Services has contracted with Health Information Designs, Inc. (HID) to review and process prior authorizations (PAs) for medications. For a current list of medications requiring a PA, as well as the necessary forms and criteria, visit www.hidndmedicaid.com, or call HID at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup. This allows you to determine if a specific NDC is covered (effective date), reimbursement amount, MAC pricing, copay information, and any limitations (prior authorization or quantity limits).

The Summer 2009 newsletter provides information regarding clinical management of the new influenza A (H1N1) virus, follow-on drugs to market, and the Synagis registration guidelines for the 2009-2010 RSV season.

The North Dakota Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, or to make comments, please contact Health Information Designs, Inc. at (334) 502-3262, call toll free at 1-800-225-6998, or e-mail us at info@hidinc.com.

north dakota department of human services

Helpful Numbers

PA Help Desk	866-773-0695
To fax PAs	866-254-0761
To report adverse reactions (via Med Watch)	800-FDA-1088

Inside this issue:	Page

Visit HID's North Dakota Department of Human Services Prior Authorization Webpage, *www.hidndmedicaid.com.*

Clinical Guidelines for Treatment of H1N1

August 12, 2009 - WHO Reiterates Advice on Use of Flu Drugs for H1N1

Adults and children who are severely ill with H1N1 flu or at high risk of complications should be treated with antivirals, the World Health Organization (WHO) said on Wednesday. Otherwise healthy people with mild flu-like symptoms need not be given the drugs to combat swine flu.

Statistics

As of August 7, 2009, a total of 102,905 confirmed cases of H1N1 have been reported in all 35 countries in the Americas Region. A total of 1,274 deaths have been detected among the confirmed cases. In the United States, 353 deaths have been reported. Fifty-one (51) of these were reported since July 31.

Transmission

- The H1N1 virus is transmitted easily from person to person when speaking, or by sneezing and coughing.
- General incubation period is 1-4 days.
- Adults may be contagious from one day prior to the commencement of symptoms to up to 7 days after becoming sick.
- Children may be contagious for a period of up to 14 days after the appearance of symptoms.

Management Recommendations

- **Suspected/Probable Case -** stable patient with no pulmonary complications or additional chronic illness (excluding risk groups-immunosuppressed, CF patients, bronchopulmonary dysplasia, complex congenital cardiopathy, chronic pneumopathy and chronic renal insufficiency). Recommend surgical mask, home isolation, and symptomatic treatment. Watch for alert symptoms (dehydration, apparent respiratory difficulty, abdominal pain, purulent sputum, persistent vomiting, neurological deterioration, presence of criteria for hospitalization. Consider beginning antiviral treatment according to country situation and available resources.
- **Confirmed Case -** stable patient with no pulmonary complications or additional chronic illness, excluding risk groups. Recommend surgical mask, home isolation and symptomatic treatment. Consider antiviral treatment according to clinical criterion.

Recommendations for Ambulatory Management

- Analgesic/antipyretics (avoid aspirin, especially in children)
- Appropriate and abundant liquids (rehydration should be staggered in children)
- Rest and home isolation
- Infection control measures
- Follow-up of clinical evolution by primary care team, checking for worsening of symptoms

Antiviral Management*

The indications for use of antivirals include one of the following:

- Patient with rapid progression of illness
- Patient with criterion for admission to Intensive Care Unit (ICU)
- Patient with clinical diagnosis and X-ray of pneumonia, who needs hospitalization
- Chronic Obstructive Pulmonary Disease (COPD) or previous pulmonary pathology
- Complex congenital cardiopathy
- Chronic renal insufficiency
- Health worker with illness similar to influenza and exposure to probably or confirmed cases
- Pregnancy in 2nd or 3rd trimester
- Heart defect or previous cardiac pathology
- Immunosuppression therapy, transplant, or HIV/AIDS
- Patients with other underlying chronic diseases that present progression to deterioration
- Patients with social, personal, or familial circumstances for whom the illness implies a high risk for the patient or their surroundings.

*Treatment must begin in the first 48 hours of appearance of symptoms (ideally before 36 hours in children younger than 12 years) and be continued 24 to 48 hours after its resolution (maximum duration of therapy: 5 to 7 days)

Accessed online: http://www.who.int/csr/resources/publications/swineflu/clinical_managementH1N1_21_May_2009.pdf
Accessed online: http://www.reuters.com/article/healthNews/idUSTRE57B3IU20090812

Follow-on Drug Marketing

Follow-on or me-too products are drugs that are structurally similar to already known drugs. These follow-on drugs are the latest trend for drug companies looking to replace their drugs with expiring patents. The new formulations that are manufactured are generally metabolites, new salt forms, or isomers of the original product that offer very little if any benefit. The majority of the new products (around 75%) approved by the FDA are me-too drugs. As long as these agents exhibit that they are more effective than placebo, they are approved.

Examples of recent follow-on products to market include:

Old Drug	**Follow-on Drug**
Proventil/Ventolin	Xopenex
Provigil	Nuvigil
Zyrtec	Xyzal
Adderall XR	Vyvanse
Risperdal	Invega
Flonase	Veramyst
Prevacid	Kapidex
Effexor XR	Pristiq
Detrol LA	Toviaz

http://www.motherjones.com/politics/2004/09/truth-about-drug-companies
Follow-on drugs: therapeutic benefit or economic burden? Pharmacist's Letter/Prescribers Letter 2009;25(7):250710.

Synagis Registration

Palivizumab (hereby called by its trade name Synagis®) is FDA-approved for the prevention of respiratory syncytial virus (RSV) in selected infants and children. Synagis requires registration for reimbursement through the North Dakota Medicaid Program. The approval time frame for Synagis will begin October 19, 2009 and will be effective through April 21, 2010. Synagis should be administered monthly; per AAP guidelines, a total of up to five doses will be allowed per recipient from October 19 through April 21. For registration purposes, the recipient must meet AAP guidelines for gestational and chronological age.

Prescribers are to electronically submit requests for Synagis by filling out the Synagis registration form on the ND Medicaid/HID website. The website address is www.hidndmedicaid.com. Registration forms will be accepted beginning September 19 (for an October 19 effective date). Once registration is complete, each subsequent monthly dose will **NOT** require registration form resubmission.

The following provides instructions and additional information for completing the Synagis registration form. Questions regarding the Synagis registration process can be directed to Brendan Joyce at 1-701-328-4023 or bjoyce@nd.gov.

Additional Information

- The patient must meet the most current AAP guidelines unless otherwise stated.
- AAP guidelines recommend a total of 5 monthly doses for infants and young children with congenital heart disease or chronic lung disease of prematurity or preterm birth before 32 weeks' gestation (31 weeks, 6 days) to provide an optimal balance of benefit and cost, regardless of season onset and end.
- AAP guidelines recommend that patients younger than 3 months of age (ND Medicaid will allow up to 6 months of age) at the start of the RSV season, or who are born during the RSV season and who are likely to have an increased risk of exposure to RSV (at least one risk factor present) be considered for prophylaxis. Infants in this gestational age category should receive a maximum of 3 monthly doses with some only receiving 1 or 2 doses until they reach 3 months of age (ND Medicaid will allow up to 6 months of age).
- Approval may be given for up to 5 doses, up to 6 months of age or through the end of the RSV season (April 21), whichever comes first.

American Academy of Pediatrics. Respiratory Syncytial Virus. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009: 560-569.

Health Information Designs, Inc. (HID) is the most experienced and qualified provider of drug utilization review and pharmacy support services in the country. We specialize in helping our clients promote clinically appropriate and cost-effective prescribing, dispensing, and utilization of prescription drugs.

For 33 years, HID has worked to improve the quality and cost effectiveness of health care through clinically rational use of prescription medication. Our clients include public and private healthcare plans throughout the U.S. with a combined total of over 14 million covered lives.

Health Information Designs, Inc. was founded in 1976 and is incorporated as a C Corporation in the State of Delaware. HID's initial mission was to market drug utilization review (DUR) services nationally and since its founding, has provided DUR services for clients in approximately two-thirds of the United States. HID is headquartered in Auburn, Alabama, with regional offices in Arkansas, Maryland, and Mississippi.

HEALTH
INFORMATION DESIGNS
using medication information cost effectively

391 Industry Drive
Auburn, AL 36832
Tel: 800-748-0130
Fax: 800-748-0116

PRST STD

U.S.
Postage