North Dakota Medicaid Pharmacy Program Quarterly News

Published Quarterly by Health Information Designs, Inc. Spring 2010

Welcome to the Spring 2010 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 Spring 2010 newsletter provides information regarding safety concerns with proton pump inhibitors and Avandia prescribing information.

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	800-FDA-1088

Inside this issue:	Page

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

Proton Pump Inhibitors Safety Concerns and Utilization

Proton pump inhibitors (PPIs) were the third highest selling drug class in 2009 and the number of prescriptions dispensed increased by 5% from 2008. The FDA recently warned physicians and consumers about a possible increased risk for fractures of the hip, wrist, and spine with high doses or long-term use of PPIs. Because the PPIs are one of the most widely used classes of drugs and new studies are showing that there may be risks associated with long term use, this article will review the appropriate use of this class of medications.

PPIs are generally used short term to treat gastrointestinal and duodenal ulcers, mild gastroesophageal reflux disease (GERD) symptoms, and Helicobacter pylori. However, they may be used long-term for severe GERD, prevention of NSAID-induced ulcers, and for hypersecretory conditions (e.g., Zollinger-Ellison syndrome).

Rebound hypersecretion is observed in 60% to 90% of those who have taken PPIs for at least two to three months. It may last three months or more and may encourage the continued chronic use of PPIs to manage the symptoms. Patients who have taken PPIs for more than a few months without a clear indication should stop therapy.

Tapering of PPIs is an important concept in patients who have been on these meds for months at a time. Taper by first reducing the dose and then dose every other day for a week or longer. An antacid or histamine-2 (H2) blocker can be used for breakthrough symptoms if needed.

Patients who self-medicate with over-the-counter (OTC) PPIs should be reminded not to take a PPI for more than 14 days at a time and no more than three courses per year. If longer therapy is required, a physician should be contacted.

Along with the increased risk of fractures, infections are another safety concern with the use of PPIs. Even short-term use (under one week) has been shown to increase the incidence of infections. PPIs increase pH, which may allow more bacterial growth. Hospitalized patients on mechanical ventilators while taking a PPI are at greatest risk of developing hospital-acquired gram-negative pneumonias. An increase in Clostridium difficile infections and diarrhea may also be seen as a direct result of PPI usage.

PPIs have an overall good safety profile and are well tolerated, however they may be used longer than necessary or inappropriately. Patients should be evaluated to determine the appropriateness of PPI therapy, including indication and duration. Patients should also be reminded to contact their healthcare provider if their symptoms are not relieved or when using OTC PPIs for more than two weeks.

References

1. Proton pump inhibitors: appropriate use and safety concerns. Pharmacist's Letter/Prescriber's Letter 2010;26(7):260705.
2. Bartholow M. Top 200 prescription drugs of 2009. *Pharmacy Times*. May 11, 2010. http://www.pharmacytimes.com/issue/pharmacy/2010/May2010/RxFocusTopDrugs-0510. (Accessed July 7, 2010)
3. Proton pump inhibitors and risk of hip fracture. Pharmacist's Letter/Prescriber's Letter 2007;23(2):230202.

Proton Pump Utilization 05/26/09 - 05/25/10			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
ACIPHEX EC 20 MG TABLET	140	$25,368.24	$181.20
NEXIUM 40 MG CAPSULE	342	$56,783.54	$166.03
NEXIUM 20 MG CAPSULE	18	$2,897.93	$161.00
PREVACID 15 MG SOLUTAB	452	$65,414.77	$144.72
PREVACID 30 MG SOLUTAB	324	$46,305.76	$142.92
PREVACID 30 MG CAPSULE DR	529	$72,954.05	$137.91
PREVACID 15 MG CAPSULE DR	38	$4,741.68	$124.78
KAPIDEX DR 60 MG CAPSULE	3	$364.51	$121.50
PANTOPRAZOLE SOD DR 40 MG TAB	822	$90,835.16	$110.51
LANSOPRAZOLE DR 30 MG CAPSULE	273	$21,816.18	$79.91
PROTONIX DR 40 MG TABLET	122	$6,770.61	$55.50
PANTOPRAZOLE SOD DR 20 MG TAB	29	$1,556.58	$53.68
LANSOPRAZOLE DR 15 MG CAPSULE	17	$853.57	$50.21
PROTONIX DR 20 MG TABLET	1	$32.25	$32.25
OMEPRAZOLE DR 40 MG CAPSULE	36	$1,010.63	$28.07
OMEPRAZOLE DR 20 MG TABLET	336	$6,701.71	$19.95
PREVACID 24HR DR 15 MG CAPSULE	2	$39.24	$19.62
OMEPRAZOLE DR 10 MG CAPSULE	43	$821.45	$19.10
PRILOSEC OTC 20 MG TABLET	432	$7,779.21	$18.01
OMEPRAZOLE DR 20 MG CAPSULE	9,776	$174,785.15	$17.88
PRILOSEC DR 20 MG CAPSULE	2	$27.26	$13.63
Total	**13,735**	**$587,832.22**	

Avandia Prescribing Information

In 2007, the FDA reviewed information about rosiglitazone and cardiovascular risk ultimately deciding that rosiglitazone could remain on the market with a black box warning about cardiovascular risk in the approved labeling. On July 13 and 14, 2010, an FDA advisory committee met once again to decide the fate of rosiglitazone, based on newer information regarding the cardiovascular safety of the drug. Prior to the meeting in 2010, two articles regarding the safety of rosiglitazone were published. The first article concluded that the currently available literature demonstrates an increased risk for myocardial infarction, although not for cardiovascular or all-cause mortality resulting in an unfavorable benefit to risk ratio for rosiglitazone. The second article concluded that compared with pioglitazone, rosiglitazone was associated with an increased risk of stroke, heart failure, and all-cause mortality and an increased risk of the composite of acute myocardial infarction, stroke, heart failure, or all-cause mortality in patients 65 years or older.

Following testimony, 33 voting panelists of the Endocrine and Metabolic Advisory Committee were asked to vote on recommendations for Avandia's future availability in the US. Twelve of the thirty-three panelists voted to withdraw rosiglitazone from the market and 20 of the 33 voted to leave the drug on the market (with some recommending stronger warnings and added restrictions). Although the FDA is not required to follow the advisory committee recommendations, it usually does.

Until the FDA announces its decision, the previous FDA recommendation for healthcare professionals should be followed:

- Follow recommendations in the drug label when prescribing rosiglitazone. This includes a boxed warning stating that:

    1. Use of rosiglitazone in patients with established NYHA Class III or IV heart failure is contraindicated. Further, rosiglitazone is not recommended in patients with symptomatic heart failure.

    2. Rosiglitazone causes or exacerbates congestive heart failure in some patients. Healthcare professionals should monitor for the signs and symptoms of heart failure (including excessive, rapid weight gain, difficulty breathing, and/or swelling) after starting treatment and after dose increases of rosiglitazone. If heart failure signs and symptoms occur, heart failure should be managed appropriately and discontinuation or dose reduction of rosiglitazone must be considered.

- Discuss with patients the risks of rosiglitazone treatment, taking into account the clinical utility of rosiglitazone, the risks/benefits of other antidiabetic medications, and the risks associated with poorly controlled blood glucose.

- Discuss with patients the importance of adhering to their diabetes medication regimen.

- Report any adverse events associated with the use of rosiglitazone to FDA's MedWatch program.

References

1. Cardiovascular Safety of Rosiglitazone (Avandaia)-2010 Update. Pharmacist's Letter 2010;26 (8):260801.

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