North Dakota Medicaid Pharmacy Program Quarterly News

Published Quarterly by Health Information Designs, LLC

Welcome to 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, LLC. 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, LLC (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).

This newsletter provides information regarding FDA guidance on zolpidem dosing.

The North Dakota Medicaid 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, LLC 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

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

Zolpidem Drug Safety Communication

The U.S. Food and Drug Administration has approved label changes for the popular sleep drug zolpidem in an effort to cut down on daytime drowsiness that could be a hazard while performing certain tasks, such as driving. Products affected are marketed as generics and under the brand names Ambien®, Ambien CR®, Edluar®, and Zolpimist®.

New data showed that zolpidem blood levels in some individuals may be high enough to lead to next-morning impairment. This occurs when a patient, whom has taken a medication for insomnia the night before, wakes up in the morning with the drug levels still high enough in their blood to impair activities that require alertness. This next-day impairment is not limited to medications containing zolpidem but to all sleep medications.

Drowsiness is the common side effect of these medications. Although the drug labels for these medications contain warnings that patients may still feel drowsy the day after taking them, it is still important to remind patients that they may feel fully awake the morning after use, but that their mental alertness may be impaired.

The FDA received data from driving simulation and laboratory studies that indicated that zolpidem levels above 50 ng/mL were capable of impairing driving to the extent of causing a motor vehicle accident. Pharmacokinetic trials of Ambien 10 mg (or bioequivalent zolpidem products) in 250 women and 250 men found that almost 15% of women and 3% of men had zolpidem concentrations that exceeded 50 ng/mL approximately 8 hours post-dosing. Three women had measurements that were ≥ 90 ng/mL at approximately 8 hours post-dosing. Approximately 5% of patients had blood levels ≥ 100 ng/mL. Studies of zolpidem extended-release 6.25 mg revealed 15% of women and 5% of men had zolpidem blood concentrations ≥ 50 ng/mL almost 8 hours post-dosing. Pharmacokinetic trials did not demonstrate a relationship between zolpidem blood level and patient's body weight or ethnicity.

Women appear to be more susceptible to next-morning impairment because they eliminate zolpidem from their bodies more slowly than men. Therefore, the FDA has told manufacturers that recommended doses for women should be cut in half, from 10 milligrams to 5 milligrams for immediate-release products (Ambien, Edluar and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).

This recommendation does not affect the product known as Intermezzo, an already lower dose marketed zolpidem product approved for middle-of-the-night awakenings. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men.

Lowering the nighttime dose means there will be less residual drug in the blood by the time the person wakes up. Extended-release forms of the drugs tend to stay in the body longer and therefore pose the highest risk for next morning impairment.

For all sleep medications, doctors should prescribe and patients should take the lowest effective dose.

Summary points

- Caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving.
- Inform patients that impairment from sleep drugs can be present despite feeling fully awake.
- The recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edluar, and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).
- Intermezzo's dosing remains the same.
- Prescribe the lowest dose that treats the patient's symptoms.

ND Medicaid Zolpidem Utilization		
01/01/13 - 12/31/13		
Label Name	**Rx Num**	**Total Reimb Amt**
ZOLPIDEM TART ER 12.5 MG TAB	128	$10,649.17
ZOLPIDEM TART ER 6.25 MG TAB	27	$2,468.28
ZOLPIDEM TARTRATE 10 MG TABLET	1384	$11,433.31
ZOLPIDEM TARTRATE 5 MG TABLET	2576	$16,363.09
Totals	**4115**	**$40,913.85**

References

U.S. Food and Drug Administration. (2013). Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Eldluar, and Zolpimist). Available from: http://www.fda.gov/drugs/drugsafety/ucm334033.htm.

U.S. Food and Drug Administration. (2013). FDA requiring lower recommended dose for certain sleep drugs containing zolpidem. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm334798.htm.

Health Information Designs, LLC 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.

Health Information Designs, LLC was founded in 1976 with a mission to improve patient care and contain costs for state Medicaid agencies by providing drug utilization review (DUR) services. In 1997, HID was acquired by HDI Solutions and subsequently has experienced strong and steady growth as a premium healthcare analytics and pharmacy support services provider. HID is the industry leader in providing comprehensive prescription drug monitoring programs. Currently, HID works with clients in 30 states, including 16 Medicaid agencies, 22 Boards of Pharmacy and state health agencies, and several private healthcare benefit management organizations. The work performed by HID has a daily impact on the healthcare of more than 115 million Americans.

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