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# North Dakota Medicaid Pharmacy Program Quarterly News

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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](http://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 new treatment options for managing hypercholesterolemia and guidelines for the treatment of irritable bowel syndrome (IBS).

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](mailto:info@hidinc.com).



### 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](http://www.hidndmedicaid.com).

## **New Treatment Options for Managing Hypercholesterolemia**

Proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors are a new group of injectable medications to lower lipid levels in patients with heterozygous familial hypercholesterolemia (HeFH), patients without familial hypercholesterolemia but with elevated LDL-C and high cardiovascular risk on statin therapy, or patients who are intolerant of statins due to muscle-related adverse effects. These medications bind PCSK9 in the hepatocyte and prevent association with LDL receptors. This mechanism allows the recycling of LDL receptors to the surface of hepatocytes facilitating the process of LDL-C uptake into the cell. PCSK9 inhibitors are intended to be used with or without statins, based on the patient's individual response to statin therapy. The mechanism of action of PCSK9 inhibitors works independent to that of the HMG-CoA reductase inhibitors. Furthermore, current Phase III trials of both medications are using injectable dosing every 2 weeks or every 4 weeks as opposed to the daily administration of statin therapy.

PCSK9 inhibitors have not been shown to retain the muscular adverse effects that statins are known to cause. However, further adverse events are still pending larger trials. Alirocumab and evolocumab, the first PCSK9 inhibitors to market, have demonstrated a benefit in reducing various measures of cholesterol, although, the benefit on cardiovascular morbidity and mortality has not yet been determined. PCSK9 inhibitors are generally well tolerated, with few clinically significant adverse drug reactions.

The ACC/AHA guidelines do not address the place in therapy of PCSK9 inhibitors. The recommendation for physicians is to limit prescribing to the very high risk, hard-to-treat patients approved by the FDA and otherwise follow current guidelines, which recommend lifestyle change, and if needed, statins for most patients who have or are at risk of heart disease. Statins are available as low-cost generics and are well tolerated in most patients and their effectiveness is supported by strong evidence.

## **Irritable Bowel Syndrome**

The original guidelines for IBS were written in 2008 and have been unchanged until February 2015. Beginning with pharmacological therapy, it is now recommended that tricyclic antidepressants be used as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. This use is strictly related to the analgesic effect of TCAs. At the time of this guidelines original publication, TCAs did not have UK marketing authorization for indications such as this. Recent studies have shown statistically significant improvement in terms of bowel habits, pain score, number of patients with less pain, and global symptoms in patients taking antidepressants. SSRIs are recommended if TCAs have failed to show efficacy. Patients prescribed these medications should be started at a low dose and follow up at 4 weeks and 6 to 12 month intervals, thereafter.

The original guidelines recommended the use of exclusion diets in IBS. The evidence still supports this recommendation; however, the committee added that the use of such diets should only be undertaken with the help of a specialist. The new recommendation states that patient's should be referred to a dietician if diet continues to be considered a major factor in a person's symptoms; if they are following general lifestyle/dietary advice.

To review, it is recommended that antispasmodics along with dietary and lifestyle changes be considered in IBS patients. Laxatives should be considered for the treatment of constipation in IBS but patients should be discouraged from using lactulose. Loperamide is the antimotility agent of choice for patients experiencing diarrhea with IBS. Patients should be advised on how to adjust their doses of laxative or antimotility agents according to clinical response. Finally, new recommendations suggest considering TCAs in patients who fail laxatives, loperamide or antispasmodics. SSRIs are only to be considered if TCAs are ineffective.



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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