North Dakota Medicaid Pharmacy Program Quarterly Newsletter

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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 (HID). 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 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.hidesigns.com/ndmedicaid, or call HID at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup, which 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 an overview of a recent FDA update to the prescribing information for montelukast (all generics and brand name Singulair) and covers updates to North Dakota Medicaid's preferred diabetic testing supplies list.

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

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Helpful Numbers

PA Help Desk	866-773-0695
To fax PAs	855-207-0250
To report adverse reactions	800-FDA-1088

Inside this issue:

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

FDA Label Update for Montelukast

Potential Risk of Serious Mental Health Effects with Montelukast

In a news release from March 04, 2020, U.S. Food and Drug Administration (FDA) announced that they would require a new boxed warning for montelukast (Singulair), a leukotriene modifier with FDA-approved indications for the treatment of asthma and allergic rhinitis. The new warning was put in place to advise health care providers to avoid prescribing montelukast for patients with mild symptoms, particularly those with allergic rhinitis. In addition to the boxed warning, the FDA is also requiring a new Medication Guide containing this warning to be given to patients with each new montelukast prescription.

Ever since an update from the FDA in 2008, the prescribing information for montelukast has contained a warning about the risk of neuropsychiatric events associated with the drug, including suicidal thoughts or actions. The decision to strengthen this warning to a boxed warning was made after reviewing case reports, data from the FDA's Sentinel System, and observational and animal studies in the published literature. While the FDA acknowledged that the new data regarding the risk of mental health side effects with montelukast are limited, they ultimately determined that montelukast should not be the first choice treatment (particularly when allergic rhinitis symptoms are mild) due to these potential risks, as well as the wide availability of other available drug therapies with extensive histories showing safety and efficacy. Additionally, the FDA was concerned that many health care professionals and patients are not currently aware of montelukast's risks of mental health side effects despite the previously existing warnings.

Wording from the Boxed Warning

To ensure that this update is communicated to as many providers as possible, a copy of the wording from the boxed warning on the prescribing information for Singulair can be found below (references to other parts of the prescribing information have been removed):

> Serious neuropsychiatric (NP) events have been reported with the use of SINGULAIR. The types of events reported were highly variable, and included, but were not limited to, agitation, aggression, depression, sleep disturbances, suicidal thoughts and behavior (including suicide). The mechanisms underlying NP events associated with SINGULAIR use are currently not well understood.
>
> Because of the risk of NP events, the benefits of SINGULAIR may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with alternative therapies. Reserve use of SINGULAIR for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. In patients with asthma or exercise-induced bronchoconstriction, consider the benefits and risks before prescribing SINGULAIR.
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> Discuss the benefits and risks of SINGULAIR with patients and caregivers when prescribing SINGULAIR. Advise patients and/or caregivers to be alert for changes in behavior or new NP symptoms when taking SINGULAIR. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, advise patients to discontinue SINGULAIR and contact a healthcare provider immediately.

Please be advised that all patients that are prescribed montelukast should be counseled on these risks and urged to report any new neurologic or psychiatric symptoms that they experience while on the medication to their provider. To ensure that the FDA can continue to evaluate safety risks of

this medication, health care providers and patients should report experienced side effects from montelukast to the FDA's MedWatch program, which can be found at www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

References:

1. FDA Requires Stronger Warning About Risk of Neuropsychiatric Events Associated with Asthma and Allergy Medication Singulair and Generic Montelukast [Press Release]. The U.S. Food and Drug Administration. March 04, 2020. Retrieved from https://www.fda.gov/news-events/press-announcements/fda-requires-stronger-warning-about-risk-neuropsychiatric-events-associated-asthma-and-allergy
2. Singulair (montelukast) [prescribing information]. Whitehouse Station, NJ: Merck and Co, Inc; April 2020.

Updates on Coverage Rules for Montelukast

North Dakota Medicaid has updated coverage rules on utilization of montelukast to require use of the appropriate strength/dosing, based on dosing recommendations in the prescribing information for montelukast. Per the prescribing information, the recommended dose of montelukast for the treatment of asthma and allergic rhinitis (seasonal or perennial) is based on age as follows:

- **Diagnosis of Asthma:**
  - **Younger than 6 months:** Safety and effectiveness have not been established
  - **6 to 23 months of age**: 4 mg once daily (1 packet of oral granules)
  - **2 to 5 years of age:** 4 mg once daily (1 chewable tablet)
  - **6 to 14 years of age:** 5 mg once daily (1 chewable tablet)
  - **15 years of age and older:** 10 mg once daily
- **Diagnosis of Allergic Rhinitis (seasonal or perennial):**
  - **Younger than 2 years of age:** Safety and effectiveness have not been established
  - **2 to 5 years of age:** 4 mg once daily (1 chewable tablet)
  - **6 to 14 years of age:** 5 mg once daily (1 chewable tablet)
  - **15 years of age and older:** 10 mg once daily

With this new coverage rule, pharmacy claims for dosage strengths that are not recommended for the patient's age will reject at the pharmacy with a message to use the appropriate dose for the patient's age. Requests for coverage for dosage strengths that are not recommended for the patient's age may be made by submitting a prior authorization request using the "General PA Form" available from the "PA Forms" page of Health Information Designs' North Dakota Department of Human Services Prior Authorization website, which is available at http://www.hidesigns.com/ndmedicaid. Prior authorization requests will be reviewed based on the providers clinical justification for use of a non-recommended dose of montelukast (please include any clinical justification on the request form and attach any supporting documentation to the request).

Please be advised that pharmacy claims for the recommended dose/strength of montelukast for the patient's age are automatically covered (no prior authorization required).

References:

1. Singulair (montelukast) [prescribing information]. Whitehouse Station, NJ: Merck and Co, Inc; April 2020.