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 Health and Human Services and published by Kepro. 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 Health and Human Services has contracted with Kepro 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 Kepro 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 about preferred Remicade biosimilars and Smart Therapy.

The North Dakota Medicaid Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, please contact Kepro at 1-800-225-6998, or e-mail us at ND_Info@kepro.com.

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Helpful Numbers

PA Help Desk	866-733-0695
To fax PAs	855-207-0250
To report adverse reactions	800-FDA-1088

Inside this issue:

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

Preferred Remicade Biosimilars

A biosimilar is a biologic that is highly similar to an existing FDA-approved biologic agent, known as the reference product. They are made with the same types of living sources, administered the same, have the same dosing, the same listed side effects, and the same treatment benefits as the reference product. Switching from the reference product to a biosimilar may be considered the same as switching from lot-to-lot of a reference product. As such, biosimilars have no clinically meaningful differences to the reference product.

The FDA assesses the manufacturers of the biosimilars to ensure strategies are in place to promote consistency in safety, efficacy, and quality. Such strategies involve inspecting manufacturing facilities and reviewing manufacturer, provider, and patient safety reports.

As of January 1st, 2023, ND Medicaid prefers biosimilars Avsola (Q5121) and Renflexis (Q5104) without requiring prior authorization (PA). All other agents, Remicade (J1745), Inflectra (Q5103), and infliximab (J1745) will require PA. Grandfathering will not be granted for Remicade, Inflectra, or infliximab.

When requesting authorization for the non-preferred products, please refer to the most recent preferred drug list for current criteria located at http://www.hidesigns.com/ndmedicaid/pdl/ and utilize the Medical Service Authorization PA form found at https://www.nd.gov/eforms/Doc/sfn00511.pdf.

References:

1. *Curriculum Materials for Health Care Degree Programs | Biosimilars.* (2022, Dec 13). U.S. Food and Drug Administration. Accessed from: https://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars
2. *Overview of Biosimilar Products.* U.S. Food and Drug Administration. Accessed from: https://www.fda.gov/media/151058/download
3. *Biosimilar Regulatory Review and Approval.* U.S. Food and Drug Administration. Accessed from: https://www.fda.gov/media/151061/downloadhttps://www.fda.gov/media/151058/download
4. *Interchangeable Biological Products.* U.S. Food and Drug Administration. Accessed from: https://www.fda.gov/media/151094/download

SMART Therapy

For safety, GINA (Global Initiative for Asthma) no longer recommends treatment of asthma with SABA alone. All asthma treatment regimens should include an ICS (inhaled corticosteroid)-containing controller treatment. For mild asthma, as-needed ICS-formoterol is the preferred reliever medication for as needed symptom relief. In Steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment. This approach is termed SMART (Single Maintenance and Reliever Therapy). When adherence with a daily ICS is poor, patients rely on their SABA alone. In mild asthma, treatment with as-needed-only low dose ICS-formoterol reduces the risk of severe exacerbations by about two-thirds versus a SABA alone.

Formoterol is a rapid, long-acting beta-2 agonist (LABA) and can be used as a reliever medication in place of a SABA. Currently, this combination of an ICS-formoterol is available in two agents, budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera), with budesonide/formoterol being recommended as first-treatment by the asthma guidelines. Patients prescribed ICS-non-formoterol maintenance medication should continue to use SABA as their reliever medication.

ND Medicaid accommodates SMART therapy by allowing 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org
2. Lin J, Zhou X, Wang C, Liu C, Cai S, Huang M. Symbicort® Maintenance and Reliever Therapy (SMART) and the evolution of asthma management within the GINA guidelines. Expert Rev Respir Med. 2018 Mar;12(3):191-202. doi: 10.1080/17476348.2018.1429921. Epub 2018 Feb 5. PMID: 29400090.