Medica

# UTILIZATION MANAGEMENT POLICY

TITLE: RARE DISEASES: ACCESS TO OUT-OF-NETWORK DIAGNOSIS, MONITORING, AND TREATMENT

**EFFECTIVE DATE**: January 01, 2024

THIS POLICY APPLIES TO MINNESOTA MEMBERS COVERED BY THE FOLLOWING:

- COMMERCIAL PRODUCTS:
  - LARGE GROUP PLANS
  - SMALL GROUP PLANS
  - SELF-INSURED (NON-ERISA).
- INDIVIDUAL (IFB) PRODUCTS
- GOVERNMENT PROGRAM PRODUCTS
  - MEDICAID
  - MINNESOTACARE
  - DUAL PRODUCTS.

FOR OTHER PRODUCTS, PROVIDERS ARE DIRECTED TO CALL THE MEDICA PROVIDER SERVICE CENTER (SEE BELOW), AND MEMBERS CAN CONTACT THE CUSTOMER SERVICE NUMBER LISTED ON THEIR MEMBER IDENTIFICATION CARD

**IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**

*These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between policy requirements and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.*

*Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.*

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

I. Definitions
   A. **Rare disease or condition** is defined as any disease or condition that affects fewer than 200,000 persons in the United States and is a chronic, serious, life-altering, or life-threatening disease/condition.

II. Beginning with dates of service 01/01/2024, the State of Minnesota has created new requirements ("the law") for health plan companies and managed care plans related to access, coverage, and reimbursement for diagnosis, monitoring, and treatment of a rare disease or condition. Further details can be found within Minnesota law 62Q.451:
   A. Minnesota Provision 62Q: https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/70/2023-05-23%2016:05:22+00:00/pdf#page=65.
   B. Minnesota Provision 256B: https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/70/2023-05-23%2016:05:22+00:00/pdf#page=30.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for out-of-network (OON) access to diagnosis, monitoring, and treatment for rare diseases. Please see the prior authorization list for product specific prior authorization requirements.
2. Notification of member's intent to receive services outside the member's contracted network (i.e., OON services) **is required.**
3. Emergency services **do not require** prior authorization.
4. Coverage may vary according to the terms of the member's plan document.
5. Medical Assistance and MinnesotaCare providers must still meet all applicable requirements under Minnesota's medical assistance program.
6. A rare disease or condition ***does not include*** an infectious disease that:
   a. Has widely available and known protocols for diagnosis and treatment, and
   b. That is commonly treated in a primary care setting, even if it affects less than 200,000 persons in the United States.
7. The law ***prohibits*** a health plan from engaging in **all of the following** practices:
   a. Restricting the choice of an enrollee as to where the enrollee receives services from a licensed health care provider related to the diagnosis, monitoring, and treatment of a rare disease or condition. This prohibition includes any restrictions through (1) prior authorization, (2) preauthorization, (3) prior approval, (4) precertification process, (5) increased fees, or (6) other methods.
   b. Denying coverage for a service on the basis it was provided by, referred for, or ordered by an out-of-network provider.
   c. Applying different prior authorization requirements based on a provider's network participation status.
8. The law ***does not require*** a health plan company to provide coverage for a procedure or treatment, laboratory or clinical testing, or medication that is not covered under the member's health plan.
9. The law stipulates that a health plan may require use of a specialty pharmacy, as defined in section 62W.02, subdivision 20: https://www.revisor.mn.gov/statutes/cite/62W.02.
10. Under the law, the health plan must apply the in-network benefit level (i.e., cost-sharing) for the diagnosis, treatment, and monitoring of a rare disease or condition ***regardless of*** the provider's network participation status.
11. Once a patient with a disease or condition that meets the rare disease or condition criteria is definitively ***diagnosed with a disease or condition that does not meet*** the rare disease medical necessity criteria (with notification of the diagnosis provided to both the health plan and the enrollee or a parent or guardian of a minor enrollee) any services provided or referred for by an out-of-network provider related to the diagnosis:
    a. Requires that coverage must be continued to be covered at the in-network benefit level for up to 60 days, *and*
    b. After this 60-day period, subsequent services provided or referred for by an out-of-network provider related to the diagnosis are no longer covered at the in-network benefit level.
12. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
13. If it appears that the Medical Necessity Criteria and Benefit Considerations criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

I. Indications

NOTE: Emergency services **do not require** prior authorization.

NOTE: This policy **does not apply** to an infectious disease that: (1) has widely available and established protocols for diagnosis and treatment and (2) is commonly treated in a primary care setting, even if it affects less than 200,000 persons in the United States.

NOTE: A health plan company ***is not required*** to provide coverage for a procedure or treatment, laboratory or clinical testing, or medication that is not covered under the member's health plan.

**NOTE:** ***Medical Director review is required*** for determining access to out-of-network diagnosis, monitoring, and treatment of a rare disease.

A. Access to diagnosis, monitoring, and treatment of a rare disease is considered medically necessary when documentation in the medical record indicates that **one of the following** criteria are met:
   1. The disease/condition is labeled as a rare disease or condition on the Genetic and Rare Diseases Information Center list created by the National Institutes of Health and available at: https://rarediseases.info.nih.gov/diseases?category=&page=1&letter=&search=.
   2. The disease/condition affects fewer than 200,000 persons in the United States and is classified as chronic, serious, life-altering, or life-threatening.
   3. The disease/condition affects more than 200,000 persons in the United States and a drug proposed for treatment has been designated as a drug for a rare disease or condition pursuant to United States Code, title 21, section 360bb.
   4. The medical record indicates **all of the following** criteria are met:
      a. Documentation of **one of the following**:
         1) A developmental delay through standardized assessment
         2) Developmental regression
         3) Failure to thrive
         4) Progressive multisystem involvement.
      b. Two or more clinical consultations received from a primary care provider or specialty provider that are specific to the individual's presenting complaint.
      c. Laboratory or clinical testing resulted in **one of the following**:
         1) Failure to provide a definitive diagnosis.
         2) Conflicting diagnoses.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/search.aspx

MINNESOTA HEALTH CARE PROGRAMS (MHCP)

- For MHCP members, refer to https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_000094#
- No MHCP policy found as of 10/20/2023.

DOCUMENT HISTORY

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| Original Effective Date | January 1, 2024 |
| MPC Endorsement Date(s) | |
| Administrative Updates | |