Clinical Guideline

Oscar Clinical Guideline: Medical Necessity Prior Authorization Criteria for Formulary Products (PG076, Ver. 8)

Medical Necessity Prior Authorization Criteria for Formulary Products

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan has developed this pharmacy policy to promote clinically appropriate, safe and cost-effective use of Formulary prescription products when a product-specific prior authorization clinical guideline is not available or applicable. The Plan's pharmacy formularies cover drugs and products that are approved by the U.S. Food and Drug Administration (FDA) and are broadly used and accepted by healthcare professionals to treat different conditions. The purpose of this medical necessity criteria is to ensure the member is using the requested product for an appropriate diagnosis and has tried or is unable to try available preferred alternatives (if available). In most cases, the preferred alternatives must be used first as long as they are considered safe and effective for use. Qualifying exceptions to pre-requisite trial and failure with preferred alternatives (if available) may include, but are not limited to the following:

1. The member has a documented trial and failure, inadequate response, intolerance, or contraindication to the preferred alternative(s); *or*
2. The member has a risk factor(s) for poor response to the preferred alternative(s); *or*
3. The member is not a candidate for the preferred alternative(s) based on the member's condition(s), individual needs, treatment history, or accepted standards of medical practice.

Definitions

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information.
2. Clinical pharmacology.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium.
4. Thomson Micromedex DrugDex.
5. United States Pharmacopeia-National Formulary (USP-NF).

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"FDA" refers to the federal Food and Drug Administration.

"Formulary" refers to the list of medications and products available to members with or without Prior Authorization.

"Medical Necessity" means evidence based criteria that justifies clinical use.

"Member" means an individual enrolled in a health plan offered by Oscar.

"Therapeutic class" refers to a group of drugs that can be used to effectively treat a particular health condition.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial General Medical Necessity Criteria

The Plan considers the requested Formulary Product medically necessary when ALL the following criteria are met:

1. The product is being used for a FDA-approved or compendia-supported indication; *AND*
2. The member is unable to use, or has adequately tried and failed ALL appropriate preferred formulary alternative(s), when available and when applicable, that are indicated and clinically appropriate for the diagnosis[s]*; AND*
3. Documentation has been provided detailing:
    a. The member's diagnosis, including any testing to confirm*; and*
    b. Past medication trials, including drug names, strength/dose/frequency, duration, response, and reason for failure or discontinuation*; AND*
4. The product being requested meets BOTH of the following:
    a. Is being used at the age, dosage, frequency, duration of therapy, and site of administration that is supported by ONE (1) of the following:
        i. FDA-approved labeling (product information)*; or*
        ii. Compendia of current literature*; or*
        iii. Peer-reviewed medical literature*; and*
    b. IF the requested dosage exceeds the Plan's quantity limit AND the prescribed dosage cannot be achieved using a different dose or formulation that is within the Plan's quantity limit.

If the above prior authorization criteria are met, the requested medication may be approved for up to 12-months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent General Medical Necessity Criteria

Renewals of prior authorizations will be reviewed on a case-by-case basis to determine if continued use of the requested formulary medication is medically necessary by meeting ALL the following criteria:

1. The member continues to meet the above applicable Initial General Medical Necessity Criteria; *AND*
2. Documentation shows the member is experiencing a positive clinical response or benefit from therapy, as evidenced by:

1. Disease stability or disease improvement based on clinical monitoring appropriate for diagnosis*; or*
2. Documented improvement in sign(s) and/or symptom(s) being treated; *AND*

3. The member does not have evidence of any clinically significant adverse drug reaction or unacceptable toxicity from the requested product that may exclude continued use, such as:
    1. Severe or life-threatening reaction requiring medical intervention*; or*
    2. Reaction that recurred despite dose reduction or other appropriate management*; or*
    3. Reaction that resulted in treatment discontinuation.

If the above prior authorization criteria are met, the requested medication may be approved for up to 12-months.[s]

Experimental / Investigational, or unproven[s]

The use of any Formulary product for any indication that is not supported by the FDA labeling, nationally recognized compendia, or peer-reviewed medical literature is considered experimental, investigational or unproven.

Clinical Guideline Revision / History Information

Original Date: 11/05/2020 Reviewed/Revised: 12/01/2021, 9/15/2022, 01/21/2023, 12/14/2023, 12/19/2024, 03/02/2026, 08/03/2026