Clinical Guideline

Oscar Clinical Guideline: Non-Formulary Products Criteria (PG069, Ver. 7)

Non-Formulary Products Criteria

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 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 formulary alternatives. In most cases, the formulary alternatives must be used first as long as they are considered safe and effective for use by your provider. Qualifying exceptions to pre-requisite trial and failure with formulary 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 formulary alternative(s); ***or***
2. The member has a risk factor(s) for poor response to the formulary alternative(s); ***or***
3. The member is not a candidate for the formulary alternative(s) based on the member's condition(s), individual needs, treatment history, or accepted standards of medical practice.

For more information or to request an exception, please contact the Plan.

Definitions

"**Biosimilar**" refers to copies of biologic drugs. They are similar to an FDA-approved biologic, known as the reference product.

"**Brand Name Drug**" means the first version of a particular medication to be developed or a medication that is sold under a pharmaceutical manufacturer's own registered trade name or trademark. The original manufacturer is granted a patent, which allows it to be the only company to make and sell the new drug for a certain number of years.

"**Combination Product**" means co-packaged drugs or fixed-combination drugs.

1. "**Co-packaged drug**" is a product that contains two or more separate drugs in their final dosage forms that are intended to be used together for a common or related therapeutic purpose and that are contained in a single package or unit.
2. "**Fixed-combination drug**" means a drug in which two or more active ingredients are combined at a fixed dosage in a single dosage form.
   NOTE: Natural-source drugs are not included under the definition of "fixed-combination drug" unless those drugs are used as ingredients in combination with other ingredients in a single dosage form.

"**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:

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

"**FDA**" refers to the Federal Food and Drug Administration.

"**Formulary**" means the list of covered pharmaceutical products, developed in consultation with Physicians and pharmacists, approved for their quality and cost effectiveness.

"**Generic Drugs**" means prescription Drugs that have been determined by the Food and Drug Administration (FDA) to be equivalent to Brand Name Drugs, but are not made or sold under a registered trade name or trademark. Generic Drugs have the same active ingredients, meet the same FDA requirements for safety, purity, and potency and must be dispensed in the same dosage form (e.g., tablet, capsule, cream) as the Brand Name Drug.

Medical Necessity Criteria for Initial Authorization

The Plan considers the requested product medically necessary when **ALL** the following criteria are met:

1. The product is being used for an FDA-approved or compendia supported indication; ***AND***
2. The member meets **ALL** of the following:
    a. Is unable to use, or has adequately tried and failed **ALL** appropriate formulary alternative(s), when available, that are indicated and clinically appropriate for the diagnosis***; and***
    b. For a Brand-name product with a generic or biosimilar available - the member is unable to use, or has tried and failed the corresponding generic or biosimilar product from two or more (≥ 2) manufacturers, when available***; and***
    c. For a combination product - the member is unable to use, or has concurrently tried and failed the individual ingredients, when available, at therapeutic dosage (e.g., amount, frequency of administration, and duration of use) to treat the same sign or symptom of the disease or condition***; 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 dosage, frequency, duration of therapy, and site of administration that is supported by **ONE** 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 limit.

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

Medical Necessity Criteria for Reauthorization

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

1. The member continues to meet all Initial Authorization criteria***; AND***
2. Documentation shows the member is experiencing a positive clinical response or benefit from therapy, as evidenced by:
    a. Disease stability or disease improvement based on clinical monitoring appropriate for diagnosis; ***or***
    b. 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:
    a. Severe or life-threatening reaction requiring medical intervention***; or***
    b. Reaction that recurred despite dose reduction or other appropriate management***; or***
    c. 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.

Experimental or Investigational / Not Medically Necessary

The use of non-formulary products for any indication that is not supported by the FDA labeling or nationally recognized compendia is considered experimental, investigational or unproven, and therefore will not be considered medically necessary by the Plan.

Clinical Guideline Revision / History Information

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