Clinical Guideline

Oscar Clinical Guideline: Quantity Limit Exception Criteria (PG200, Ver. 1)

Quantity Limit Exception 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

This policy applies to all prescription medications with quantity limits for members enrolled in the Plan's pharmacy benefit. The purpose of this policy is to establish evidence-based criteria for prior authorization of medication quantities exceeding the Plan's limits and/or established Plan Clinical Guidelines. The goal is to ensure appropriate utilization of medications based on FDA-approved dosing, nationally recognized compendia, clinical practice guidelines, and peer-reviewed medical literature while promoting safe, effective, and cost-effective use of prescription drugs.

The Plan has established quantity limits for certain products, drugs, and biologicals to restrict the amount of medication that can be dispensed during a specific time period. These limits are designed to promote adherence to recommended dosing schedules, and prevent stockpiling or diversion of medications. However, the Plan recognizes that, in some cases, members may require higher quantities of medication due to individual clinical circumstances, such as variations in weight, metabolism, disease severity, or treatment response.

Requests for quantity limit exceptions will be evaluated on a case-by-case basis, taking into account factors such as the member's diagnosis, prescribed dosage regimen, previous treatment history, and the prescriber's clinical rationale for exceeding the established limit. The Plan will also consider the available evidence from FDA-approved labeling, nationally recognized compendia, clinical practice guidelines, and peer-reviewed literature to support the decision. Special considerations will be given to requests involving off-label use, dose optimization during medication initiation or titration, or use in specific patient populations to ensure the requested quantity is appropriate and medically necessary.

NOTE: *If the requested medication requires a drug-specific prior authorization in addition to a quantity limit exception, the drug-specific prior authorization must be requested and approved before the quantity limit exception request can be considered. The approval of a quantity limit exception does not override the need for any other applicable prior authorization requirements.*

Definitions

"**Clinical Practice Guidelines**" are evidence-based recommendations developed by expert panels or professional associations to guide healthcare providers in making decisions about appropriate diagnostic, therapeutic, or preventive interventions for specific clinical circumstances.

"**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. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

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

"**FDA-approved Labeling**" is the official description of a drug product, including its intended uses, dosage, route of administration, and other information, as approved by the U.S. Food and Drug Administration (FDA).

"**Medical Necessity**" refers to healthcare services or supplies that are determined by the plan to be necessary, appropriate, and consistent with generally accepted standards of care for the diagnosis, treatment, or prevention of a medical condition.

"**Peer-reviewed Medical Literature**" refers to scientific or medical publications that have undergone a rigorous evaluation process by independent experts in the field to assess the quality, validity, and significance of the research before publication.

"**Quantity Limit**" refers to a restriction on the amount or quantity of medication that can be dispensed during a specific time period.

"**Quantity Limit Exception**" is a request to dispense a medication at a quantity or dosage that exceeds the plan's established quantity limit for a given time period.

Medical Necessity Criteria for Initial Authorization

The Plan considers medication **quantities exceeding established Plan limits** medically necessary when **ALL** of the following criteria are met:

1. The member has a documented diagnosis for the requested medication that is supported by **ONE** of the following:
    a. FDA-approved labeling***; or***
    b. Nationally recognized compendia (e.g., American Hospital Formulary Service Drug Information, Clinical Pharmacology, Micromedex DrugDex, National Comprehensive Cancer Network Drugs and Biologics Compendium)***; or***
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; ***or***
    d. Peer-reviewed medical literature from a major scientific or medical publication; ***AND***
2. The prescribed dose, frequency, and duration of therapy are consistent with **ONE** of the following:
    a. FDA-approved labeling; ***or***
    b. Nationally recognized compendia; ***or***
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; ***or***
    d. Peer-reviewed medical literature from a major scientific or medical publication; ***AND***
3. The prescribed dosage (i.e., dose and/or frequency) cannot be achieved using a different dose, dosage form, or strength that is covered within the Plan's limits; ***AND***
4. The prescriber provides compelling clinical rationale for exceeding the established quantity limit that is supported by at least **ONE** of the following:

a. The member has tried and failed an adequate trial (e.g. ≥ 3 months) of the medication at the Plan's quantity limit, as evidenced by paid claims, pharmacy records, or chart notes; ***or***

b. The member requires a higher dose due to well-documented clinical circumstances[ɳ], such as variations in weight, metabolism, body size, or disease severity that necessitate doses beyond the established limit per recognized treatment guidelines; ***or***

[ɳ]*e.g., for topical products, the requested quantity is needed for treatment of a larger affected surface area*

c. The member has a diagnosis that requires a higher FDA-approved or compendia-supported dose or longer duration of therapy than accommodated by the Plan's quantity limit; ***AND (if applicable)***

Additional Considerations (i.e., Additional Criteria for Special Circumstances):

5. **For requests exceeding the FDA-approved dosing, frequency or duration of therapy**, the prescriber provides additional clinical evidence (e.g., evidence-based guideline or peer-reviewed literature) supporting the safety and effectiveness of the higher dose for the member's specific diagnosis and clinical circumstances; ***AND***
6. **For requests to optimize dosing during medication initiation or titration**, **ALL** of the following:
    a. The requested quantity is necessary to achieve the initial or target therapeutic dose and/or frequency per FDA-approved labeling or recognized compendia; ***and***
    b. The dose optimization cannot be achieved using commercially available dosage strengths and/or package sizes within the Plan's standard quantity limit; ***and***
    c. The prescriber has submitted a dose titration schedule outlining the starting dose, titration amounts and intervals, and goal maintenance dose, along with the anticipated duration of the titration period.

If the above medical necessity criteria for initial authorization are met, the requested medication may be approved for up to 12 months (or 3 months for dose optimization).

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if the member meets **ALL** of the following criteria:

1. The member continues to have a documented diagnosis for the requested medication that is supported by **ONE** of the following:
    a. FDA-approved labeling; ***or***

b. Nationally recognized compendia; ***or***
c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; ***or***
d. Peer-reviewed medical literature from a major scientific or medical publication; ***AND***

2. The prescribed dose, frequency, and duration of therapy continue to be consistent with **ONE** of the following:
    a. FDA-approved labeling; ***or***
    b. Nationally recognized compendia; ***or***
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; ***or***
    d. Peer-reviewed medical literature from a major scientific or medical publication; ***AND***
3. The member has demonstrated a positive clinical response to therapy at the requested dose and quantity, as evidenced by **ONE** of the following:
    a. Improvement or stabilization of signs and symptoms of the underlying condition; ***or***
    b. Improvement or stabilization of functional status; ***or***
    c. Disease remission or lack of disease progression; ***AND***
4. The prescriber provides a rationale for continuing treatment at the requested dose and quantity that exceeds the Plan's established limit, considering the member's clinical status, response to therapy, and any relevant factors such as:
    a. Changes in the member's weight, metabolism, or disease severity that necessitate a higher dose; ***or***
    b. Continued need for a higher dose to maintain therapeutic efficacy or prevent disease progression; ***or***
    c. Inadequate response or loss of efficacy at the Plan's quantity limit; ***AND***
5. The member has not experienced any treatment-limiting adverse effects or drug toxicity that would preclude continued use of the requested medication at the prescribed dose and quantity.

Experimental or Investigational / Not Medically Necessary

The use of the requested medication for any indication other than those specifically listed in this policy or supported by the FDA-approved labeling, nationally recognized compendia, or peer-reviewed medical literature is considered experimental, investigational, or unproven and therefore not medically necessary. Non-covered indications include, but are not limited to, the following:

- Use in combination with other medications or therapies not supported by the FDA-approved labeling, nationally recognized compendia, or peer-reviewed medical literature.

- Use for a non-FDA-approved indication or an indication not supported by nationally recognized compendia or peer-reviewed medical literature.
- Use of a dosage form, strength, or route of administration not approved by the FDA or supported by nationally recognized compendia or peer-reviewed medical literature.
- Use in a patient population or clinical scenario not adequately represented in the supporting evidence (e.g., pediatric use when safety and efficacy have not been established).
- Use for the purpose of weight loss, cosmetic improvement, or performance enhancement, unless specifically addressed in the member's benefit plan documents.

References

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4. National Institutes of Health. (April 2023). *Glossary of Common Terms.* https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms
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7. U.S. Preventive Services Task Force. (n.d.). STANDARDS FOR GUIDELINE DEVELOPMENT. https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/standards-guideline-dev%20%281%29.pdf

Clinical Guideline Revision / History Information

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