Clinical Policy: Quantity Limit Overrides

Reference Number: NH.PMN.59
Effective Date: 05.14
Last Review Date: 02.19 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Quantity limits (QL) are concurrent pharmacy edits on individual drugs that restrict the utilization to what is deemed appropriate and safe based on standard FDA and manufacturer dosing guidelines. Quantity limits encompassed both the medically accepted frequency of dosing per day and the maximum daily dose. Certain quantity limits also contain an aspect of dose optimization. Dose optimization quantity limits are applied when multiple strengths of a drug care readily available on the market (and the use of lower strengths can be consolidated with a high strength dosage form). Most quantity limits are applied with a daily dose edit, however, in certain circumstances where daily dose is not convenient, a quantity per period of time (e.g. 30 days) is implemented.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Quantity Limit Overrides are **medically necessary** when the following criteria are met:

I. Approval Criteria

- **A. Rare conditions/diseases:** FDA dosing guidelines indicates a higher quantity (dose or frequency) for a specific disease state than currently implemented (e.g. proton pump inhibitors are commonly used for GERD therefore the QL is one per day, however when there is a rare diagnosis such as Zollinger-Ellison syndrome or other similar acid reflux conditions an override for two doses per day will be allowed).
- **B. Continuity of care:** For members currently on regimens with quantities above set limits, a (one-time) 3-month titration period to the standard limit will be allowed. Only drug classes in which continuity of care programs are applied are eligible (i.e. anticonvulsants).
- **C. Pain management:** For opioid analgesics where maximum daily doses do not exist quantity limits can be overridden for the following:
    1. Diagnosis of cancer, sickle cell anemia, or terminally ill/end of life care, OR
    2. The member has signed a pain management treatment plan specific to his/her care with a single qualified prescriber AND the prescriber has provided his plan of action (which may include historical titration

schedule to the current dose and/or titration schedule to decrease the dose to be within the QL).

D. **Off Label Use:** The prescriber can provide documentation that quantities above the set standard have been proven safe and effective, for a specific disease state, in a defined regimen. Documentation must be in the form of a Phase 3 study (or equivalent), published in a reputable peer reviewed medical journal or clinical practice guidelines or text or if dose has been demonstrated to be safe and effective for the patient based on prior clinical experience. (For additional requirements, please reference the off label use policy CP.PMN.53).

Approval duration: 3-12 Months depending on the criteria for approval and disease state the quantity limit is requested for.

Revision Log	
Revision	**Date**
Added if dose has been demonstrated to be safe and effective for the patient based on prior clinical experience.	07.15
Annual Review, No changes	08.16
Annual Review, No changes	07.17
Annual Review, No Changes	07.18
Updated template	02.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.