Clinical Policy: Quantity Limit Override

Reference Number: CP.PMN.59
Effective Date: 05.01.14
Last Review Date: 11.20
Line of Business: Medicaid

Revision Log

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

Description
This policy establishes the criteria for overriding set quantity limits (QL).

FDA Approved Indication(s)
Varies by drug product.

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 QL edit exceptions are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Quantity Limit Exceptions (must meet all)**:**
Refer to Section IB for conditions eligible for continuity of care and Section IC for pain management

1. One of the following (a or b):
   a. Requested dose is supported by practice guidelines or peer-reviewed literature (e.g., phase 3 study or equivalent published in a reputable peer reviewed medical journal or text) for the relevant off-label use and/or regimen (*prescriber must submit supporting evidence*);
   b. Diagnosis of a rare condition/disease* for which FDA dosing guidelines indicate a higher quantity (dose or frequency) than the currently set QL;
   **Example: Proton pump inhibitors, which are commonly used for gastroesophageal reflux disease, have a QL of one dose per day; however, when there is a rare diagnosis such as Zollinger-Ellison syndrome, an override for two doses per day is allowed*
2. Member has been titrated up from the lower dose with partial improvement without adverse reactions (dose optimization is required; refer to the dose-optimization policy, CP.PMN.13).

Approval duration: 12 months

B. Continuity of Care (must meet all)**:**

1. State or health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology);
2. Therapy will be titrated to the currently set QL (refer to the dose-optimization policy, CP.PMN.13).

Approval duration: 3 months, or 12 months if subject to state continuity of care program

C. Opioid QL Exceptions

1. Refer to Opioid Analgesics policy, CP.PMN.97 or health plan specific opioid policy**.**

II. Continued Therapy

A. All Requests in Section I (must meet all)**:**

1. Currently receiving the requested quantity via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose optimization is required (refer to the dose-optimization policy, CP.PMN.13).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
QL: quantity limit

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

- Dose optimization is the consolidation of multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths. Requests for multiple units of a lower strength will be denied when the plan-approved QL for such medication is exceeded and higher strength units are commercially available to achieve the desired daily dose/regimen.

Request Example	Prescribed Regimen	Approvable Regimen
Request for Seroquel XR 800 mg/day	Seroquel XR 200 mg tablets, 4 tablets/day	Seroquel XR 400 mg tablets, 2 tablets/day
Request for aripiprazole 30 mg/day	Aripiprazole 15 mg tablets, 2 tablets/day	Aripiprazole 30 mg tablet, 1 tablet/day

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

1. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain – United States, 2016. MMWR Recomm Rep. 2016; 65(1): 1-49.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template.	08.15	08.15
Updated template; Added disease states to which continuity of care programs are applicable; Added reference section.	05.16	08.16
Converted to new integrated template; Changed continuity of care and pain management reference for additional information to CP.PMN.13 dose-optimization policy instead of CP.PMN.53 off-label policy; Removed hyperlipidemia/hypercholesterolemia, hypertension, depression, Parkinson's/dementia, glaucoma, hepatitis, and attention-deficit hyperactivity disorder (ADHD) from the list of continuity of care disease states.	10.16	11.16
Converted to new template. Updated verbiage.	08.07.17	11.17
4Q 2018 annual review: converted to new template; combined criteria sets for rare conditions and off-label use to apply more broadly; added oncology to list of possible continuation of care eligible conditions; referred off-label dosing to the off-label use policy; added reference to CP.PMN.97 for opioid requests; references reviewed and updated.	08.14.18	11.17
No significant changes; reference to opioid QL policy expanded to allow health plan specific policy to be used if available.	02.01.19	
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.12.19	11.19
4Q 2020 annual review: no significant changes; removed cross reference to the off-label use policy per PA Ops request; references reviewed and updated.	07.13.20	11.20

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.

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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.

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