Clinical Policy: Quantity Limit Override and Dose Optimization

Reference Number: CP.PMN.59
Effective Date: 05.01.14
Last Review Date: 11.25
Line of Business: Medicaid, HIM

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) and dose optimization.

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 dose optimization is implemented when clinically appropriate. Prescribers are required to consolidate multiple units of lower strength to the fewest units required to achieve the desired daily dose/regimen based on commercially available dosage strengths (see *Appendix D* for examples). 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.

It is the policy of health plans affiliated with Centene Corporation® that QL and dose optimization exceptions are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

For members in **Nevada, medical management techniques, including quantity management, beyond step therapy is not allowed for medication-assisted treatment (MAT)/withdrawal, HIV, and hepatitis C drugs*

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, b, c, or d):
   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*
   c. Request is for epinephrine in the treatment of allergic reactions, one of the following (i or ii):

i. Provider submits documentation supporting the use of previous Auvi-Q, EpiPen, EpiPen Jr, or Neffy fills, including the date(s) of use, and that immediate medical or hospital care was received in conjunction with administration of Auvi-Q, EpiPen, EpiPen Jr, or Neffy;
ii. Provider submits documentation supporting that the most recent fill for Auvi-Q, EpiPen, EpiPen Jr, or Neffy has expired, including the expiration date;

d. For other acute therapies (e.g., albuterol for asthma), medical justification supports a higher quantity than the currently set QL (provider must submit documentation regarding current or planned use of maintenance therapies);

2. For requests other than epinephrine in the treatment of allergic reactions, both of the following (a and b):
   a. Member has been titrated up from the lower dose with partial improvement without adverse reactions;
   b. Dose optimization is required, unless one of the following applies (i or ii):
      i. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
      ii. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen.

Approval duration:
Epinephrine – one Auvi-Q 2-pack, one EpiPen 2-Pak, one EpiPen Jr 2-Pak, or one Neffy 2-pack
Acute therapies – 3 months
All other requests – 12 months (*60 days if dose optimization exception is requested due to dose titration*)

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, psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology, depression, transplant);
2. Therapy will be titrated to the currently set QL;
3. Dose optimization is required, unless one of the following applies (a or b):
   a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
   b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen.

Approval duration: 3 months (*60 days if dose optimization exception is requested due to dose titration*), or 12 months if subject to state continuity of care program

C. Dose Optimization Exceptions (must meet all)**:**
1. One of the following (a or b):
   a. Dose titration: Multiple lower strength units are requested for the purpose of dose titration;
   b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;

2. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA-recommended regimen and maximum daily dose;
   b. For QL exceptions, refer to Section IA above.

Approval duration:
Dose titration – Duration of request or 60 days, whichever is less
Other clinical reasons – Duration of request or 12 months, whichever is less

II. Continued Therapy*

For members in **Nevada, medical management techniques, including quantity management, beyond step therapy is not allowed for medication-assisted treatment (MAT)/withdrawal, HIV, and hepatitis C drugs*

A. Requests for Epinephrine or Acute Therapies

1. Continuation of therapy will not be granted. Member must be evaluated against the initial approval criteria.

Approval duration: Not applicable

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

1. Member meets one of the following (a, b, or c):
   a. Currently receiving medication via Centene benefit;
   b. Member has previously met initial approval criteria;
   c. State or health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology, depression, transplant) with documentation that supports that member has received this medication for at least 30 days (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Dose optimization is required, unless one of the following applies (a or b):
   a. Documentation supports the continued need for dose titration;
   b. Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
4. For dose optimization exception requests only: If request is for a dose increase, new dose does not exceed the FDA-recommended regimen and maximum daily dose.

Approval duration: 12 months (*60 days if dose optimization exception is requested due to dose titration*)

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. This can reduce pill burden, simplify therapeutic regimens, improve treatment compliance, and reduce pharmacy spend. 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

Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes.	07.22.21	11.21
Added dose optimization criteria (CP.PMN.13 retired).	04.26.22	08.22
4Q 2022 annual review: no significant changes. Template changes applied to continued therapy section.	08.02.22	11.22
Revised continuity of care verbiage to state: 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) with documentation that supports that member has received this medication for at least 30 days.	03.14.23	
Added HIM line of business.	06.15.23	08.23
4Q 2023 annual review: in section ID for dose optimization, added reference to Section IA for QL exception requests.	08.02.23	11.23
Added disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439.	05.28.24	
4Q 2024 annual review: added depression and transplant to list of continuity of care programs per current Centene standard approach.	07.29.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2025 annual review: added quantity limit exception criteria specific to acute therapies, with requirements for epinephrine (adopted from CP.PMN.144 that will be retired) and other acute therapies; removed criteria set for opioid QL exceptions as section I.A. will be applied; references reviewed and updated.	08.21.25	11.25
For quantity limit exceptions (Section I.A.), clarified requirements for dose titration and optimization do not apply to requests for epinephrine in the treatment of allergic reactions.	02.11.26	

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.