Clinical Policy: Dose Optimization
Reference Number: CP.PMN.13
Effective Date: 05/16
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
~~For the purpose of this policy,~~ D~~d~~ose ~~-~~ optimization is ~~defined as~~ a method to consolidate ~~tablets/capsules~~dosage units to the ~~-~~ fewest~~least amount of~~ unit~~(~~s~~)~~ required to achieve the desired daily dose/regimen ~~in accordance with FDA approved recommendation~~. This can ~~A few advantages of dose optimization include~~ reduce~~d~~ pill burden ~~to members~~, simplify~~ied~~ therapeutic regimens, improve~~d~~ treatment compliance, and ~~reduction~~ reduce~~in~~ pharmacy spend. ~~When plan approved quantity limit is exceeded for a specific medication, this policy would guide the approval/denial of such request by ensuring that the prescribed treatment is optimal.~~

FDA approved indication
N/A

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) 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 ~~will b~~are~~e~~ required to consolidate multiple units of lower strength to the ~~least~~fewest ~~amount of~~ units required to achieve the desired daily dose/regimen based on commercially available dosage strengths (see appendix B for examples). Requests for multiple units of a lower strength will be denied when the plan approved quantity limit for such medication is exceeded and higher strength units are~~is~~ commercially available to achieve the desired daily dose/regimen.

It is the policy of health plans affiliated with Centene Corporation® that exceptions to dose optimization are~~will be implemented when clinically appropriate~~ **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

~~**A. Implementation of Dose Optimization** (must meet all)~~**:**

~~1. Request for multiple units of a lower strength will be denied when the plan approved quantity limit for such medication is exceeded and higher strength unit is commercially available to achieve the desired daily dose/regimen~~

~~2. Prescribers will be required to consolidate multiple units of lower strength to the least amount of units required to achieve the desired daily dose based on commercially available dosage strength~~

~~*Examples:*~~

~~*a) Request for Seroquel XR 800mg/day*~~

~~*Prescribed regimen = Seroquel XR 200mg tablets, 4 tablets/day*~~
~~↓~~
~~*Approvable regimen = Seroquel XR 400mg tablets, 2 tablets/day*~~
~~*a) Request for Aripiprazole 30mg/day*~~
~~*Prescribed regimen = Aripiprazole 15mg tablets, 2 tablets/day*~~
~~↓~~
~~*Approvable regimen = Aripiprazole 30mg tablet, 1 tablet/day*~~

~~1. Requested must comply with FDA approved usage recommendation with regards to **regimen and maximum daily dose***~~
~~*Examples:*~~
~~*a) Request **NOT** in compliance with FDA recommended **regimen***~~
~~*Prescribed regimen: Bystolic 5 mg twice daily, 2 tablets/day*~~
~~↓~~
~~*Approvable regimen: Bystolic 10 mg once daily, 1 tablet/day*~~
~~*a) Request **NOT** in compliance with FDA recommended **maximum dose***~~

~~*Prescribed regimen: Uloric 80mg twice daily, 2 tablets/day*~~
~~↓~~
~~*Approvable regimen: Uloric 80mg once daily, 1 tablet/day*~~
~~**Approval duration: [XX (months)]**~~

~~W.~~A. **Exceptions to Dose Optimization** (must meet all)**:**
1. Member meets one of the following (a or b):
   ~~1.~~a. Dose titration/tapering: ~~a short term approval may be granted for~~ multiple lower strength units are requested ~~when it is used~~ for the purpose of dose titration or tapering;
   a. Other clinical reasons: ~~approval may be granted at the discretion of the utilization management reviewer, if the prescriber provides a~~ documented clinical rationale supports~~for~~ ~~why~~ member inability~~is unable~~ to use the higher strength unit~~(~~s~~)~~ to achieve the desired dose/regimen;
2. Dose does not exceed FDA recommended regimen and maximum daily dose.~~.~~

Approval duration:
Dose titration/tapering: ~~duration of request or~~ 60 days or duration of request,~~(~~ whichever is less~~)~~
Other clinical reasons: ~~duration of request or~~ 12 months or duration of request, ~~(~~whichever is less~~)~~

II. Continued Therapy

A. Exceptions to Dose Optimization (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Dose titration/tapering (i and ii):
      i. ~~prescriber submits d~~Documentation ~~supporting~~ supports the continued need for dose titration or tapering;
      ~~1.~~ii. If request is for a dose increase, new dose does not exceed FDA recommended regimen and maximum daily dose;

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b. Other clinical reasons (i and ii):
i. Member has previously met initial approval criteria ~~for the desired medication~~ ;
ii. Member ~~and~~ remains on the same dose/regimen previously approved.

~~1. .~~

Approval duration:
Dose titration/tapering: ~~duration of request or~~ 60 days or duration of request, ~~(~~whichever is less~~)~~
Other clinical reasons: ~~duration of request or~~ 12 months or duration of request, ~~(~~whichever is less~~)~~

III. Diagnoses/Indications for which coverage is NOT authorized:
A. N/A

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
N/A: not applicable

Appendix B: Examples of Dose Optimization

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

Appendix C: Examples of Exceeding FDA Recommended Regimen/Maximum Dose

Request Example	Prescribed Regimen	Approvable Regimen
Request exceeding FDA recommended regimen	Bystolic 5 mg twice daily, 2 tablets/day	Bystolic 10 mg once daily, 1 tablet/day
Request exceeding FDA recommended maximum dose	Uloric 80 mg twice daily, 2 tablets/day	Uloric 80 mg once daily, 1 tablet/day

V. Dosage and Administration
N/A

VI. Product Availability
N/A

VII. Workflow Document
N/A

VIII. References
1. N/A

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/16	05/16
~~No clinical changes to criteria~~ - Converted to new template	03~~1~~/17	05/17

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.

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.