Clinical Policy: Dose Optimization
Reference Number: ERX.PA.02
Effective Date: 06.01.18
Last Review Date: 05.18

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

Description
Dose optimization is a method to consolidate dosage units to the fewest units required to achieve the desired daily dose/regimen. This can reduce pill burden, simplify therapeutic regimens, improve treatment compliance, and reduce pharmacy spend.

FDA Approved Indication(s)
Not applicable

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 Envolve Pharmacy Solutions™ 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 C 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 commercially available to achieve the desired daily dose/regimen.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that exceptions to dose optimization are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Exceptions to Dose Optimization (must meet all):
      1. Member meets one of the following (a or b):
         a. Dose titration/tapering: Multiple lower strength units are requested for the purpose of dose titration or tapering;
         b. Other clinical reasons: Medical justification supports inability to use the higher strength units to achieve the desired dose/regimen;
      2. Dose does not exceed the FDA recommended regimen and maximum daily dose
   Approval duration:
   Dose titration/tapering: Duration of request or 60 days, whichever is less
   Other clinical reasons: Duration of request or 12 months, whichever is less

   B. Other diagnoses/indications: Not applicable

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. Documentation supports the continued need for dose titration or tapering;
            ii. If request is for a dose increase, new dose does not exceed the FDA recommended regimen and maximum daily dose;
         b. Other clinical reasons (i and ii):
            i. Member has previously met initial approval criteria;
            ii. Member remains on the same dose/regimen previously approved.
   Approval duration:
   Dose titration/tapering: Duration of request or 60 days, whichever is less
Other clinical reasons: Duration of request or 12 months, whichever is less

B. Other diagnoses/indications: Not applicable

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Examples of Dose Optimization

<table>
<thead>
<tr>
<th>Request Example</th>
<th>Prescribed Regimen</th>
<th>Approvable Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for Seroquel XR 800 mg/day</td>
<td>Seroquel XR 200 mg tablets, 4 tablets/day</td>
<td>Seroquel XR 400 mg tablets, 2 tablets/day</td>
</tr>
<tr>
<td>Request for aripiprazole 30 mg/day</td>
<td>Aripiprazole 15 mg tablets, 2 tablets/day</td>
<td>Aripiprazole 30 mg tablet, 1 tablet/day</td>
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</tbody>
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V. Dosage and Administration
Not applicable

VI. Product Availability
Not applicable

VII. References
Not applicable

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>06.01.18</td>
<td>05.18</td>
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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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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