Subject: Medical Drug Dosage and Frequency

Background: In continuing efforts to ensure the safe and appropriate use of medications, Harvard Pilgrim applies industry standard maximum dosage and frequency guidelines to select drugs covered under the medical benefit in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based guidelines.

Dosing and frequency are based on U.S. Food and Drug Administration (FDA) approved maintenance drug dosage and frequency limits, manufacturer and clinical recommendations. Dosing limits, where applicable, are calculated using the Center for Disease Control’s (CDC) 75th percentile for body weight and body surface area.

Coverage for the drug must meet Harvard Pilgrim medical necessity criteria. For a complete list of the medical drugs requiring a prior authorization and the applicable criteria please refer to Medical Drug Program Prior Authorization List.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers the dosage, frequency and route of administration of a drug as reasonable and medically necessary for approved clinical indication(s) when documentation confirms the following:

- The drug dosage, frequency and route of administration is supported by ONE or more of the following for the treatment indication:
  - U.S. Food and Drug Administration (FDA) prescribing information
  - National Comprehensive Cancer Network® (NCCN) Drug & Biologics Compendium®
  - American Hospital Formulary Service Drug Information® (AHFS) Drug Information®
  - DRUGDEX® System

Note: Where applicable, maximum dosing limits using body weight and body surface area are calculated using the CDC 75th percentile as a proxy. Individual consideration will be available.

Exclusions:
Harvard Pilgrim Health Care (HPHC) considers drug dosage, frequency, and route of administration of a drug as not medically necessary outside the scope of drug dosage for covered clinical indications.

Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.
References:

Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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</thead>
<tbody>
<tr>
<td>9/20</td>
<td>Annual Review; no changes</td>
</tr>
<tr>
<td>10/19</td>
<td>Annual review; exclusion section added</td>
</tr>
<tr>
<td>3/18</td>
<td>Policy and Coverage Criteria and Background updated to add 75th percentile language</td>
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<tr>
<td>11/17</td>
<td>New policy</td>
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</tbody>
</table>

Approved by Medical Policy Committee: 9/22/20
Approved by Clinical Policy Operational Committee: 11/17, 3/18, 10/19; 10/20
Policy Effective Date: 10/09/20
Initiated: 11/17