Pharmacy Policy

Mandatory Generic Substitution Program

Policy Number: 9.002  
Version Number: 12.0  
Version Effective Date: 03/01/2017

Product Applicability

☐ All Plan* Products

- Well Sense Health Plan
  - New Hampshire Medicaid
  - NH Health Protection Program
- Boston Medical Center HealthNet Plan
  - MassHealth
  - Qualified Health Plans/ConnectorCare/Employer Choice Direct
  - Senior Care Options

Policy Summary

The Plan will authorize coverage of brand-name medications with AB-rated generic equivalents when appropriate criteria are met.

Description of Item or Service

In the state of Massachusetts, therapeutic substitution of the AB rated generic version of a brand name medication is mandatory, unless the prescribing physician specifies that they would like the brand name medication to be dispensed by writing on the prescription, “No Substitution”.

In the state of New Hampshire, if the prescribing practitioner handwrites “brand necessary”, “brand medically necessary” or “medically necessary” on the face of each paper prescription, or uses electronic indications when transmitted electronically or gives instructions when transmitted orally that the brand name drug product is medically necessary” (NH State Law RSA: 318:47-d), a prior authorization will be required. The therapeutic substitution of the A rated generic version of a brand name medication is mandatory. AB rated generic medications are considered to be therapeutically equivalent to their branded versions.

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Policy

The Plan may authorize coverage of brand-name medications with AB-rated generic equivalents for members meeting the following criteria:

Prior Authorization – (Duration of Approval: Non-maintenance drugs – up to one year, Maintenance drugs – up to unlimited)

A prior authorization request will be required for all prescriptions where the prescriber has indicated that he or she would like the brand name version of a generically available medication dispensed by writing, “No substitution” on the prescription. Requests will be approved when all of the following criteria are met:

Documentation of the following:
1. An allergy to one of the inactive ingredient(s) found in the generic version(s) of the medication that is not found in the brand name medication AND;
2. An inadequate response or intolerance to a trial of at least two other covered alternatives (one if less than two available) within the same therapeutic class as the requested medication.

Limitations

The Plan will not approve coverage of brand-name medications with AB-rated generic equivalents in the following instances:

- When the criteria above has not been met.

Clinical Background Information and References

1. Food and Drug Administration [homepage on the internet]. Therapeutic Equivalence Code, CDER Data Standards
3. He-W 570.01 Definitions.
4. He-W 570.09 Certification of Prescriptions
5. New Hampshire State Law Chapter 318; 318:47-d

<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/07/2003</td>
<td>04/07/2004</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
</tr>
</tbody>
</table>

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/08/2007</td>
<td>P&amp;T annual review; Coumadin®, Dilantin®, Synthroid®, Neoral®, Sandimmune®, and Orapred® no longer exempt from criteria</td>
<td>03/08/2008</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/13/2008</td>
<td>P&amp;T annual review; “Brand Name Necessary, dispense as Written” changed to “No substitution”</td>
<td>03/13/2009</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/12/2009</td>
<td>P&amp;T annual review, no changes required</td>
<td>03/12/2010</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/11/2010</td>
<td>P&amp;T annual review, updated language to include “all available” generic versions</td>
<td>03/11/2011</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/14/2011</td>
<td>Policy applied to Commercial</td>
<td>11/14/2011</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/10/2011</td>
<td>P&amp;T annual review, changed requirement of allergy from all, to “a” available generic version(s), added requirement of 2 alternatives within the same therapeutic class.</td>
<td>09/08/2008</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>08/22/2012</td>
<td>Policy applied to NH Medicaid for non-PDL drugs</td>
<td>12/01/2013</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>11/08/2012</td>
<td>P&amp;T annual review, modified criteria to include inadequate response or intolerance to alternatives, removed other clinical rationale for use.</td>
<td>03/08/2013</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>11/14/2013</td>
<td>P&amp;T annual review, no changes required</td>
<td>03/12/2010</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>12/26/2013</td>
<td>Policy applied to ConnectorCare/Qualified Health Plan (QHP)</td>
<td>04/26/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/13/2014</td>
<td>P&amp;T annual review, minimal criteria language revision</td>
<td>03/02/2015</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>05/29/2015</td>
<td>Policy applied to NH Medicaid to include PDL drugs</td>
<td>10/01/2015</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>11/12/2015</td>
<td>P&amp;T Annual Review, no criteria changes required</td>
<td>03/01/2016</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>11/10/2016</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>03/01/2017</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
</tbody>
</table>

### Next Review Date

11/09/2017

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3 of 4
Other Applicable Policies

N/A

Reference to Applicable Laws and Regulations, If Any

N/A

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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