Pharmacy Policy

Beta-Blockers

Policy Number: 9.164
Version Number: 10.0
Version Effective Date: 09/15/2016

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
☐ ________________

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of the specified beta blockers when appropriate criteria are met.

Description of Item or Service

Beta Blockers are used for a variety of conditions, including but not limited to heart failure, high blood pressure, glaucoma, and migraines. Beta-blockers differ in their duration of action, selective/non-selective activity at adrenergic receptors, and alpha blocking properties. These variations in activity allows for their use in very specific conditions. Most beta blockers are available in a generic formulation.

Bystolic® (nebivolol) is a long-acting cardio-selective β1 –adrenergic receptor antagonist indicated for the treatment of hypertension. Bystolic® has also been studied for the treatment of heart failure in elderly patients, but has not yet received FDA approval for this indication. The activity of Bystolic® at doses lower or equal to 10 mg in extensive metabolizers (majority of the population) is selective to β1–adrenergic receptors located in cardiac muscle. In poor metabolizers and at higher doses, Bystolic® acts by inhibiting both β1 and β2

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receptors. Bystolic® has been shown to have comparable efficacy to other cardio-selective beta-blockers for the treatment of hypertension. The mechanism of action for Bystolic® remains unclear; however possible factors may include the drug’s ability to (1) decrease heart rate, (2) decrease myocardial contractility, (3) decrease tonic sympathetic outflow to the periphery from cerebral vasomotor centers, (4) suppress renin activity and, (5) vasodilate and decrease peripheral vascular resistance. Unlike other beta-blockers, Bystolic® possesses a nitric-oxide (NO) vasodilatory effect, which may improve endothelial function for some patients.

Carvedilol belongs to the beta-blocker class of drugs, but is unique among them because it also possesses some alpha receptor blocking activity. The immediate-release version of carvedilol is generically available and is indicated for the treatment of hypertension, congestive heart failure, and left ventricular dysfunction following a myocardial infarction. The controlled-release version of carvedilol (Coreg CR®) became available in April 2007, and has the same indications as immediate-release carvedilol. Coreg® requires twice daily dosing, while Coreg CR® is dosed once daily. The two products are comparable in clinical efficacy.

Hemangeol™ (propranolol oral solution) is approved for the treatment of proliferating infantile hemangioma requiring systemic therapy. Infantile hemangiomas, or benign tumors of the vascular endothelium, are the most common tumors of childhood. While they are benign and self-limited, they can cause ulcerations or disfigurement. They may also compromise vital organ function. Hemangeol™ is contraindicated in premature infants with a corrected age less than 5 weeks; infants weighing less than 2 kilograms; known hypersensitivity to propranolol or any of its excipients; asthma or history of bronchospasm; heart rate less than 80 beats per minute, greater than first degree heart block, or decompensated heart failure; blood pressure less than 50/30 mmHg; and pheochromocytoma. Hemangeol™ was evaluated in a randomized, double-blind study evaluating four regimens (1.2 or 2.4 mg/kg/day twice daily for 3 or 6 months) in 460 infants between the ages of 35 days and 5 months at inclusion. All infants had a diagnosis of proliferating infantile hemangiomas requiring systemic therapy, except for life-threatening IH, function-threatening IH, and ulcerated IH with pain and lack of response to simple wound care measures. Significantly more patients in the Hemangeol™ treatment arm had complete or nearly complete resolution of their hemangioma at week 24 (60% vs. 4%, p<0.0001). Of those patients on Hemangeol™ 3.4 mg/kg/day for 6 months who were considered successes, 10% required retreatment for a recurrent hemangioma.

Sotylize™ (sotalol oral solution) is approved for the treatment of life-threatening ventricular arrhythmias and maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter. Sotylize™ is contraindicated in sinus bradycardia (< 50 beats per minute), sick sinus syndrome or 2nd or 3rd degree AV block (unless a functioning pacemaker is present); congenital or acquired QT syndromes; QT interval >450 ms; cardiogenic shock; uncontrolled heart failure; creatinine clearance less than 40 mL/minute; serum potassium < 4 mEq/L; bronchial asthma or related bronchospastic conditions; and hypersensitivity to sotalol.

Dutoprol™ is the combination of metoprolol succinate and hydrochlorothiazide in one tablet, and InnoPran XL® is the extended-release version of propranolol.

Metoprolol tartrate 37.5 mg and 75 mg tablets are branded generic versions of metoprolol tartrate. The 37.5 mg dose can be achieved by combining generic metoprolol tartrate 25 mg and 12.5 mg tablets.

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The Plan may authorize coverage of Bystolic®, Coreg CR®, Dutroprol™, Hemangeol™, InnoPran XL®, Metoprolol 37.5mg & 75mg and Sotylize™ meeting the following clinical criteria:

**Medications** | **Approval Criteria**
--- | ---
**Automatic Approval**: An automatic approval will be generated at the point of sale when the following criteria are met:

**Bystolic®**

1. Pharmacy claims indicating that *any two* of the following generic cardio-selective beta-blocker agents have been filled in the past 120 days:
   - Acebutolol
   - Atenolol
   - Betaxolol
   - Bisoprolol
   - Metoprolol

**Dutroprol™**

1. Pharmacy claims indicating concurrent use of the following agents for at least 30 days in the past 120 days:
   - Metoprolol succinate
   - Hydrochlorothiazide

**Prior Authorization**: A prior authorization request will be required for beta blockers listed below when the above criteria for automatic approval (where applicable) are not met. These requests will be approved when the following criteria met:

**Bystolic® (Duration of Approval – up to 2 years)**

1. Documentation of the following:
   1. An inadequate response or intolerance to a trial of any two of the cardio-selective beta blocker medications such as: acebutolol, atenolol, bexalol, bisoprolol, and metoprolol.
<table>
<thead>
<tr>
<th>Medications</th>
<th>Approval Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coreg CR® (Duration of Approval – up to 2 years)</td>
<td>Documentation of the following: 1. An inadequate response or intolerance to a trial of generic carvedilol immediate release AND at least one other beta-blocker</td>
</tr>
<tr>
<td>Dutoprol™ (Duration of Approval – up to 2 years)</td>
<td>Documentation of the following: 1. Inadequate response to a beta blocker in combination with a thiazide diuretic (e.g., hydrochlorothiazide, chlorthalidone); OR 2. Member requires treatment with a long-acting beta-blocker and hydrochlorothiazide AND has difficulty adhering to medications</td>
</tr>
<tr>
<td>Hemangeol™ (Duration of approval – 1 year)</td>
<td>Documentation of the following: 1. Diagnosis of proliferating infantile hemangioma requiring systemic therapy; AND 2. Member was not born prematurely with a corrected age of less than 5 weeks; AND 3. Member weighs more than 2 kilograms; AND 4. Member does not have any contraindications to treatment (e.g., history of pheochromocytoma, blood pressure less than 50/30 mmHg, etc.)</td>
</tr>
<tr>
<td>InnoPran XL® (Duration of approval – 2 years)</td>
<td>Documentation of the following: 1. An intolerance to a trial of generic extended release propranolol; AND 2. An inadequate response, intolerance or contraindication to two other covered long-acting beta blockers besides propranolol ER</td>
</tr>
<tr>
<td>Metoprolol tartrate 37.5 mg tablet</td>
<td>Documentation of the following: 1. An intolerance to a trial of generic metoprolol tartrate 25 mg tablets AND metoprolol tartrate 50 mg tablets</td>
</tr>
<tr>
<td>Metoprolol tartrate 75 mg tablet</td>
<td>Documentation of the following: 1. An intolerance to a trial of generic metoprolol tartrate 50 mg tablets AND metoprolol tartrate 100 mg tablets</td>
</tr>
<tr>
<td>Sotylize™</td>
<td>Documentation of the following:</td>
</tr>
</tbody>
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<table>
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<tr>
<th>Medications</th>
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</tr>
</thead>
</table>
| (Duration of Approval – 2 years) | 1. Inadequate response or intolerance to generic sotalol tablets; **OR**
| | 2. Member has difficulty swallowing tablets |

**Limitations**

The Plan will not approve coverage of Bystolic®, Coreg CR®, Dutoprol™, Hemangeol™, Innopran XL®, and Sotylize™ in the following instances:

1. When the above criteria are not met.

**Clinical Background Information and References**


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
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</thead>
<tbody>
<tr>
<td>05/12/2011</td>
<td>05/12/2011</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
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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>
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<tr>
<td>05/14/2009</td>
<td>P&amp;T Annual Review, no changes required.</td>
<td>09/01/2009</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>05/13/2010</td>
<td>P&amp;T Annual Review, no changes required. Added approval duration in the language</td>
<td>09/01/2010</td>
<td>P&amp;T Committee</td>
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<tr>
<td>05/12/2011</td>
<td>P&amp;T Annual Review, merged with Coreg® CR policy (previously a separate policy), criteria added for Nexiclon XR™ tablets and suspension.</td>
<td>09/01/2011</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>05/10/2012</td>
<td>P&amp;T Annual Review, removed Nexiclon XR™ tablets and suspension due to product discontinuation.</td>
<td>09/01/2012</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>05/09/2013</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>09/01/2013</td>
<td>P&amp;T Committee</td>
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<tr>
<td>12/13/2013</td>
<td>Policy applied to ConnectorCare / Qualified Health Plan (QHP)</td>
<td>04/01/2014</td>
<td>P&amp;T Committee</td>
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<tr>
<td>05/08/2014</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>09/01/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>05/14/2015</td>
<td>P&amp;T Annual Review, changed name of policy from “Bystolic®, Coreg CR®” to “Beta Blockers”; added approval criteria for Dutoprol™, Hemangeol™, InnoPran XL®, and Sotylize™. Applied policy to NH Medicaid</td>
<td>09/01/2015 (BMCHP) and 10/01/2015 (Well Sense)</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>05/12/2016</td>
<td>P&amp;T Annual Review, added Metoprolol</td>
<td>09/15/2016</td>
<td>P&amp;T Committee</td>
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Policy Revisions History

| tartrate 37.5 mg and 75 mg tablets to the policy | NH DHHS |

Next Review Date

05/11/2017

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy

Reference to Applicable Laws and Regulations, If Any

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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Beta Blockers

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