Pharmacy Medical Necessity Guidelines: Antihypertensive Medications

Effective: July 17, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Not Covered</td>
<td>√</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Department to Review</td>
</tr>
<tr>
<td>RX</td>
<td>RXUM</td>
</tr>
</tbody>
</table>

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIt Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
- RXUM: 617.673.0988

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Medications in the guideline are indicated for the treatment of hypertension either alone or in combination with other antihypertensive agents.

In addition to the diagnosis of hypertension, the following medications have additional cardiovascular indications:

- **Candesartan** - Treatment of heart failure to reduce the risk of death from cardiovascular causes and reduce heart failure hospitalizations
- **Irbesartan** - Treatment of diabetic nephropathy in patients with an elevated serum creatinine and in patients with type 2 diabetes and a history of hypertension
- **Telmisartan** - For reduction of the risk of myocardial infarction (MI), stroke, or death from cardiovascular causes in patients 55 years and older at high risk of developing major cardiovascular events who are unable to take angiotensin-converting enzyme (ACE) inhibitors.
- **Valsartan** - For the treatment of heart failure (New York Heart Association [NYHA] class II to IV) and to reduce cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following MI.
- **Coreg CR** - For the treatment of mild to severe chronic heart failure and left ventricular dysfunction following myocardial infarction in clinically stable patients
- **Cardizem LA and Matzim LA** - For the management of chronic stable angina
- **Inspra** - To improve survival of stable patients with left ventricular systolic dysfunction and clinical evidence of congestive heart failure (CHF) after an acute myocardial infarction.

Nimodipine is only indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their postictus neurological condition (ie, Hunt and Hess grades I to V). It is not indicated for hypertension.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Reference Brand Name*</th>
<th>Utilization Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiotensin II Receptor Blocker (ARB)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azilsartan medoxomil tablet</td>
<td>Edarbi</td>
<td>PA</td>
</tr>
<tr>
<td>Candesartan cilexetil tablet</td>
<td>Atacand</td>
<td>PA</td>
</tr>
<tr>
<td>Eprosartan mesylate tablet</td>
<td>Teveten</td>
<td>PA</td>
</tr>
<tr>
<td>Irbesartan tablet</td>
<td>Avapro</td>
<td>ST</td>
</tr>
<tr>
<td>Olmesartan medoxomil tablet</td>
<td>Benicar</td>
<td>ST</td>
</tr>
<tr>
<td>Telmisartan tablet</td>
<td>Micardis</td>
<td>PA</td>
</tr>
<tr>
<td>Valsartan tablet</td>
<td>Diovan</td>
<td>ST</td>
</tr>
</tbody>
</table>

**Beta-blockers:**
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Reference Brand Name*</th>
<th>Utilization Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoprolol tartrate 37.5 and 75 mg</td>
<td>Metoprolol tartrate</td>
<td>PA</td>
</tr>
<tr>
<td>Nebivolol HCl tablet</td>
<td>Bystolic</td>
<td>ST; QL (1 unit/day)</td>
</tr>
<tr>
<td>Carvedilol phosphate capsule SR 24HR</td>
<td>Coreg CR</td>
<td>ST</td>
</tr>
<tr>
<td><strong>Calcium Channel Blockers:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diltiazem HCl coated beads tablet 24HR</td>
<td>Cardizem LA, Matzim LA</td>
<td>PA</td>
</tr>
<tr>
<td>Isradipine capsule</td>
<td>Dynacirc</td>
<td>PA</td>
</tr>
<tr>
<td>Nimodipine</td>
<td>Nymalize</td>
<td>PA</td>
</tr>
<tr>
<td><strong>Direct Renin Inhibitors:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aliskiren fumarate tablet</td>
<td>Tekturna</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td><strong>Selective Aldosterone Receptor Antagonist:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eplerenone tablet</td>
<td>Inspira</td>
<td>PA; QL (2 units/day)</td>
</tr>
<tr>
<td><strong>Combinations Products:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aliskiren/amldipine tablet</td>
<td>Tekamlo</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Aliskiren/amldipine/hydrochlorothiazide tablet</td>
<td>Amturnide</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Aliskiren/hydrochlorothiazide tablet</td>
<td>Tekturna HCT</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Amlodipine besylate/olmesartan tablet</td>
<td>Azor</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Amlodipine besylate/valsartan tablet</td>
<td>Exforge</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Amlodipine/valsartan/hydrochlorothiazide tablet</td>
<td>Exforge-HCT</td>
<td>PA; QL (1 unit/day)</td>
</tr>
<tr>
<td>Irbesartan/hydrochlorothiazide tablet</td>
<td>Avalide</td>
<td>ST</td>
</tr>
<tr>
<td>Olmesartan medoxomil/hydrochlorothiazide tablet</td>
<td>Benicar HCT</td>
<td>ST</td>
</tr>
</tbody>
</table>

*Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

ST: Prior authorization required if step therapy criteria are not met at the point-of-sale. Reference the Tufts Health Public Plans Preferred Drug Lists (PDLs) for a list of preferred products within each therapeutic class that are covered without restriction.

**COVERAGE GUIDELINES**

The plan may authorize coverage of an antihypertensive medication for Members when **all** of the following criteria are met:

**Bystolic**
1. The Member is stable on the requested medication  
   OR  
2. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with two alternative beta-blockers (e.g., metoprolol, bisoprolol)

**Coreg CR**
1. The Member is stable on the requested medication  
   OR  
2. The provider indicates clinical inappropriateness of therapy with immediate-release carvedilol

**Eplerenone**
1. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with another aldosterone antagonist (e.g., spironolactone)

**Metoprolol 37.5 and 75 mg**
1. Provider documentation of clinical inappropriateness of therapy with generic metoprolol tartrate 25, 50, and 100 mg tablets

**Tekturna**
1. The Member has been stable on the medication for a duration of at least 3 months
   OR
2. The Member failed a course of therapy, or the provider indicates clinical inappropriateness of therapy with at least three alternative antihypertensive medications, one of which must be an angiotensin converting enzyme inhibitor (ACE-I) (e.g., lisinopril, captopril, benazepril, fosinopril) and one of which must be an angiotensin II receptor blocker (ARB) (e.g., losartan)

**Angiotensin II Receptor Blocker (ARB)**
1. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with losartan or losartan/HCTZ

**Calcium Channel Blocker**
1. The Member is diagnosed with or is at risk for having subarachnoid hemorrhage or stroke*
   OR
2. The Member failed a course of therapy with two of the preferred calcium channel blockers (e.g., amlodipine, diltiazem, felodipine, nifedipine, verapamil)

**Combination medication**
1. The Member is stable on the requested medication or on the individual ingredients
   AND
2. The provider indicates concern with the use of the individual medications

*Diagnoses indicating at risk for stroke may include, but is not limited to, hypertensive crisis, cerebral vasculitis, acute onset headache syndromes, cerebral vasoconstriction

**LIMITATIONS**
1. The coverage of Amturnide, Azor, Bystolic, Exforge, Exforge HCT, Tekamlo, Tekturna, and Tekturna HCT is limited to one tablet per day.
2. The coverage of eplerenone is limited to two tablets per day.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

**CODES**
None

**REFERENCES**
1. Atacand (candesartan) [prescribing information]. Wilmington, DE: AstraZeneca LP; February 2016.
3. Bystolic (nebivolol) [prescribing information]. St. Louis, MO: Forest Laboratories; October 2016.
6. Dynacric CR (isradipine) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline; February 2009.
7. Edarbi (azilsartan medoxomil) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; October 2016.
10. Teveten (eprosartan) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2014.
11. Micardis (telmisartan) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; December 2014.
14. Nymalize (nimodipine) [prescribing information]. Atlanta, GA: Arbor; September 2013.
15. Tekturna (aliskiren) [prescribing information]. Boston, MA: Noden Pharma USA, Inc; November 2016.

**APPROVAL HISTORY**

April 14, 2015: Consolidated individual antihypertensive medication criteria; modified approval duration

Subsequent endorsement date(s) and changes made:
- September 16, 2015: Approval duration approved for life of plan
- January 1, 2016: Administrative change to rebranded template
- April 12, 2016: Added brand metoprolol 37.5 and 75 mg tablets. Removed Limitation #3 “Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria.”
- July 11, 2017: Removed penbutolol from Medical Necessity Guideline due to product discontinuation. Reflected generic availability of Inspra. Clarified eplerenone approval criteria to require clinical inappropriateness with another aldosterone antagonist. Provided examples of therapeutic trial options for Bystolic and Coreg CR.

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.