Pharmacy Medical Necessity Guidelines: Inspra® (eplerenone)

Effective: November 13, 2018

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

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
  - CareLink® – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS**

Inspra (eplerenone) is indicated for improving survival of stable patients with left ventricular systolic dysfunction (left ventricular ejection fraction ≤40%) and congestive heart failure after an acute myocardial infarction (MI) with other agents. Inspra (eplerenone) is also indicated for hypertension, alone or combined with other agents.

Inspra (eplerenone) is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and MIs.

These benefits have been observed in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes.

**COVERAGE GUIDELINES**

**Note:** Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Group Plans</th>
<th>Tufts Health Plan Small Group and Individual Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step-1</strong></td>
<td></td>
<td></td>
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<tr>
<td>spironolactone</td>
<td>Covered</td>
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<tr>
<td>spironolactone/</td>
<td></td>
<td></td>
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<tr>
<td>hydrochlorothiazide</td>
<td></td>
<td></td>
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<tr>
<td><strong>Step-2</strong></td>
<td></td>
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<tr>
<td>eplerenone</td>
<td>Requires prior use of a drug on</td>
<td>Requires prior use of Step-1 or Step-2</td>
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<tr>
<td></td>
<td>Step-1 or Step-2</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Inspra</td>
<td></td>
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</tr>
</tbody>
</table>

**Automated Step Therapy Coverage Criteria**

The following stepped approach applies to coverage of Step-2 medications by the plan:

**Step 1:** Medications on Step-1 are covered without prior authorization.

**Step 2:** The plan may cover Inspra® (eplerenone) or eplerenone if the following criteria are met:
- The Member has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.
Coverage Criteria Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Service

The following stepped approach applies to eplerenone and Inspra (eplerenone):

1. Documented inability to tolerate the drug spironolactone (e.g., Aldactone®) because of clinically significant adverse effects

   OR

2. The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples.

Note: The plan may cover medications on Step-2 if a Member has received one of the noncovered medications, listed below in the limitations section, within the previous 180 days as evidenced by physician documented use, excluding the use of samples.

LIMITATIONS

1. Medications on Step-2 are not covered unless the above step therapy criteria are met.
2. Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
3. The plan does not authorize coverage of non-covered medications through this step therapy program. The plan does not cover the following medications for all Commercial formularies: Aldactone®, Aldactazide® and Carospir®. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.
4. The plan does not cover the following medication for the MA/RI EHB formularies: Inspra®. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.

CODES

None

REFERENCES


APPROVAL HISTORY

July 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 14, 2005: No changes
- May 9, 2006: No changes
- May 8, 2007: No changes
- May 13, 2008: No changes
- September 9, 2008: Added automated step therapy coverage guidelines for the Tufts Health Plan Commercial and the Generic Focused Formulary. Added limitation that medications on Step-2 are not covered unless the above step therapy criteria are met
• September 8, 2009: Added automated step therapy program for Tufts Health Plan Medicare Preferred MA-PD and PDP formularies (change from prior authorization) effective 1/1/2010.
• January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
• September 14, 2010: Effective January 1, 2011; Aldactone and Aldactazide will become not covered for Commercial and RI. Added Note: Tufts Health Plan may cover medications on Step-2 if a Member has received one of the following Non-covered medications within the previous 180 days: Aldactone Aldactazide.
• September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
• June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
• August 14, 2012: Removed reference to Tufts Health Plan Medicare Preferred MA-PD and PDP Formularies from coverage criteria. Added limitation that brand name Inspra is not covered on the Generic Focused Formulary. Added use of samples or vouchers/coupons for brand name medications limitation.
• June 11, 2013: No changes
• October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
• April 1, 2014: Administrative update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI formulary.
• June 10, 2014: No changes.
• March 10, 2015: For effective date April 1, 2015: Moved Inspra to not covered for the MA/RI EHB formularies.
• January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
• March 8, 2016: No changes
• March 14, 2017: No changes
• April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
• December 12, 2017: Administrative update, reflected the availability and coverage status of Carospir® suspension.
• November 13, 2018: No changes.

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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.