Pharmacy Medical Necessity Guidelines: Sodium-Glucose Co-Transporter 2 Inhibitors

Effective: January 12, 2016

Prior Authorization Required  ✓  Type of Review – Care Management
Not Covered  ✓  Type of Review – Clinical Review
Pharmacy (RX) or Medical (MED) Benefit RX  Department to Review RXUM

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 Rite 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

FDA-APPROVED INDICATIONS
The sodium-glucose co-transporter 2 inhibitors (SGLT2s) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Tufts Health Together Preferred Drug List status:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>PDL Status</th>
<th>Quantity Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canagliflozin*</td>
<td>Invokana tablets</td>
<td>ST; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Canagliflozin-Metformin*</td>
<td>Invokamet tablets</td>
<td>ST; Tier 2</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>Dapagliflozin</td>
<td>Farxiga tablets</td>
<td>PA; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Dapagliflozin-Metformin</td>
<td>Xigduo XR tablets</td>
<td>PA; Tier 2</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) are the preferred SGLT2s for Together members and may process as a step therapy medication at the point-of-sale if the Member has previous prescription claims for a 30-day supply of metformin and at least two alternative antidiabetic agents within the last six months.

SGLT2 Inhibitors not included in the PDL or within the SGLT2 medical necessity guideline are considered non-covered.

COVERAGE GUIDELINES
The plan may authorize coverage of a sodium-glucose co-transporter 2 inhibitor for Members when the criteria are met and limitations do not apply:

**For Invokana or Invokamet.**
1. The member is stable on the requested medication
   **OR**
2. The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with metformin and with at least two other antihyperglycemic agents

**For Farxiga or Xigduo XR.**
1. The member is stable on the requested medication
   **OR**
2. The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with metformin and with at least two other antihyperglycemic agents, one of which must be a canagliflozin-containing product

LIMITATIONS
1. The coverage of Invokana is limited to two tablets per day of the 100 mg strength, and one tablet per day of the 300 mg strength.
2. The coverage of Farxiga is limited to one tablet per day.
3. Requests for quantities that exceed the quantity limit will also be reviewed according to the Drugs with Quantity Limitation criteria.

REFERENCES


APPROVAL HISTORY

December 12, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- June 12, 2014: No changes.
- March 10, 2015: Xigduo XR added; approval duration limited to one year.
- September 16, 2015: Approval duration approved for life of plan.
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.