Pharmacy Medical Necessity Guidelines: Sodium-Glucose Co-Transporter 2 Inhibitors
Effective: January 1, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td></td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit RX</td>
<td>Department to Review RXUM</td>
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</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 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. Jardiance (empagliflozin) is also approved to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

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</td>
<td>ST; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Canagliflozin-Metformin*</td>
<td>Invokamet</td>
<td>ST; Tier 2</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>Canagliflozin-Metformin Extended Release*</td>
<td>Invokamet XR</td>
<td>ST; Tier 2</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>Empagliflozin</td>
<td>Jardiance</td>
<td>ST; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Empagliflozin-Metformin</td>
<td>Synjardy</td>
<td>ST; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Empagliflozin-Metformin Extended Release</td>
<td>Synjardy XR</td>
<td>ST; Tier 2</td>
<td>10 mg/1,000 mg: 1 tablet/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>25 mg/1,000 mg: 1 tablet/day</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>5 mg/1,000 mg: 2 tablets/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/1,000 mg: 2 tablets/day</td>
</tr>
<tr>
<td>Dapagliflozin</td>
<td>Farxiga</td>
<td>PA; Tier 2</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td>Dapagliflozin-Metformin</td>
<td>Xigduo XR</td>
<td>PA; Tier 2</td>
<td>2.5 mg/1,000 mg: 2 tablets/day</td>
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<td>5 mg/1,000 mg: 2 tablets/day</td>
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</tr>
</tbody>
</table>

*Invokana (canagliflozin), Invokamet (canagliflozin/metformin), Invokamet XR (canagliflozin/metformin extended-release), Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), and Synjardy XR (empagliflozin/metformin extended-release) 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.

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

**Invokana, Invokamet, Invokamet XR, Jardiance, Synjardy, Synjardy 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

**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- or empagliflozin-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 Invokamet and Invokamet XR is limited to two tablets per day.
3. The coverage of Farxiga is limited to one tablet per day.
4. The coverage of Farxiga is limited to one tablet per day.
5. The coverage of Jardiance is limited to one tablet per day.
6. The coverage of Synjardy is limited to 2 tablets per day.
7. The coverage of Synjardy XR 10 mg/1,000 mg tablets and 25 mg/1,000 mg tablets is limited to 1 tablet per day.
8. The coverage of Synjardy XR 5 mg/1,000 mg tablets and 12.5 mg/1,000 mg tablets is limited to 2 tablets per day.
9. The coverage of Xigduo XR 2.5 mg/1,000 mg tablets, 5 mg/1,000 mg tablets, and 5 mg/500 mg tablets is limited to 2 tablets per day.
10. The coverage of Xigduo XR 10 mg/500 mg tablets and 10 mg/1,000 mg tablets is limited to 1 tablet per day.

CODES
None

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.
- January 1, 2016: Administrative change to rebranded template.
- January 12, 2016: No changes.
- January 10, 2017: Added criteria and quantity limit for Invokamet XR.
- May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- November 14, 2017: Jardiance, Synjardy, and Synjardy XR added to the Medical Necessity Guideline. Requirement for two additional antihyperglycemic agents besides metformin for canagliflozin-containing products. Updated Farxiga and Xigduo XR criteria to require a previous trial with metformin and either a canagliflozin- or empaglizoin-containing products. Added quantity limits for Jardiance, Synjardy, Synjardy XR, and Xigduo XR.

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 CareLink™ 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.