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

Effective: February 18, 2019

Prior Authorization Required: √
Type of Review – Care Management

Not Covered
Type of Review – Clinical Review: √

Pharmacy (RX) or Medical (MED) Benefit
Department to Review: RX

Fax Numbers:
RXUM: 617.673.0988

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
- CareLinkSM – 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

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

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>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>Steglatro</td>
<td>ST;Tier 2</td>
</tr>
<tr>
<td>Ertugliflozin-Metformin</td>
<td>Segluromet</td>
<td>ST;Tier 2</td>
</tr>
</tbody>
</table>

Tufts Health Together members may fill a prescription for Steglatro or Segluromet as a step therapy medication at the point-of-sale if the Member has previous prescription claims for a supply of metformin in the last 180 days.

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:

Steglatro or Segluromet
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

LIMITATIONS
None

CODES
None

REFERENCES

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

Subsequent endorsement date(s) and changes made:
1. June 12, 2014: No changes.
2. March 10, 2015: Xigduo XR added; approval duration limited to one year.
4. January 1, 2016: Administrative change to rebranded template.
5. January 12, 2016: No changes.
6. January 10, 2017: Added criteria and quantity limit for Invokamet XR.
7. May 9, 2017: Administrative update, Adding Tufts Health RITtogether to the template.
8. 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 removed. 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.
9. September 18, 2018: Effective 1/1/19, added Steglatro and Segluromet to the MNG. Removed Farxiga, Invokana, Invokamet, Invokamet XR, Jardiance, Synjardy, Synjardy XR, and Xigduo XR from the MNG to reflect Not Covered status.
10. February 12, 2019: Administrative changes made to template. Clarified information on step therapy at the point of sale in the Overview section of the MNG.
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.