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

Effective: January 14, 2020

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

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

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.

Dapagliflozin is also approved to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

Canagliflozin is also approved to reduce the risk of major adverse CV events (CV death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes and established CVD. Additionally, canagliflozin is approved to reduce the risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for heart failure in adults with type 2 diabetes and diabetic nephropathy and albuminuria > 300 mg/day.

Empagliflozin is also approved to reduce the risk of CV death in adult patients with type 2 diabetes mellitus and established CVD.

Tufts Health RITogether Preferred Drug List status:

Generic Name	Brand Name	PDL Status	Quantity Limitation
Canagliflozin	Invokana tablets	PA	100 mg: 2 tablets/day 300 mg: 1 tablet/day
Canagliflozin-Metformin	Invokamet tablets	PA	2 tablets/day
Canagliflozin-Metformin Extended Release	Invokamet XR tablets	PA	2 tablets/day
Dapagliflozin	Farxiga tablets	PA	1 tablet/day
Dapagliflozin-Metformin	Xigduo XR tablets	PA	10/1,000, 10/500 mg: 1 tablets/day; 2.5/1,000 mg, 5/1,000, 5/500 mg: 2 tablets/day
Empagliflozin	Jardiance	PA	1 tablet/day
Empagliflozin-Metformin	Synjardy	PA	2 tablet/day
Empagliflozin-Metformin Extended-Release	Synjardy XR	PA	10/1,000 mg: 1 tablet/day 25 mg/1,000 mg: 1 tablet/day 5 mg/1,000 mg: 2 tablets/day 12.5 mg/1,000 mg: 2 tablets/day
Ertugliflozin*	Steglatro	PA	N/A

Ertugliflozin-Metformin*	Segluromet	PA	N/A

*Steglatro (ertugliflozin) and Segluromet (ertugliflozin/metformin) are the preferred SGLT2s for RITogether members.

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 Segluromet or Steglatro

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 at least one additional generic antihyperglycemic agents

For Farxiga, Invokana, Invokamet, Invokamet XR, Jardiance, Synjardy, Synjardy XR, 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 one other generic antihyperglycemic agents AND an ertugliflozin-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 Jardiance is limited to one tablet per day.
5. The coverage of Synjardy is limited to 2 tablets per day.
6. 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.
7. 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.
8. The coverage of Xigduo XR 2.5/1,000 mg tablets, 10/1,000 tablets, and 10/500 mg tablets is limited to 2 tablets per day.
9. The coverage of Xigduo XR 5/1,000 tablets and 5/500 mg tablets is limited to 1 tablet per day

CODES

None

REFERENCES

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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.
3. September 16, 2015: Approval duration approved for life of plan.
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. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
8. November 14, 2017: No changes.
9. December 11, 2018: Effective 4/1/19, Steglatro and Segluromet are the preferred SGLT2 inhibitors. Steglatro, Segluromet, Jardiance, Synjardy, and Synjardy XR added to the Medical Necessity Guideline. Invokana, Invokamet, and Invokamet XR moved from first line SGLT2 inhibitors to second line. Added quantity limits for Xigduo XR, Jardiance, Synjardy, Synjardy XR. Removed step therapy language from the background section. Administrative changes made to template.
10. February 12, 2019: Administrative update, removed "Step Therapy" notation for Steglatro and Segluromet from the overview section of the MNG. Updated the quantity limits for Xigduo XR.
11. January 14, 2020: 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.