Pharmacy Medical Necessity Guidelines: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors

Effective: October 1, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

FDA-APPROVED INDICATIONS

The sodium-glucose cotransporter 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.
- Reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure
- Reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, CV death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

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.
- 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
- Reduce the risk of CV death and hospitalization for heart failure in adults with heart failure.
- Reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.

When used for the treatment of type 2 diabetes, canagliflozin, dapagliflozin, and empagliflozin are approved for use in patients 10 years of age and older.

The table below summarizes the FDA-approved indications for the different SGLT-2 inhibitors.

Medication Name	Adjunct to diet and exercise in T2DM	Reduce risk of **major adverse CV events*** in adults with T2DM & established CVD	Reduce risk of ESKD, doubling of SCr, CV death, and hospitalization for HF in adults with T2DM & diabetic nephropathy	Reduce risk **of CV death** in adult patients with T2DM & established CVD	Reduce risk of hospitalization for HF in patients with T2DM & **established CVD** *OR* **multiple CV risk factors**	Reduce risk of CV death, hospitalization for HF, and urgent HF visit in adults with HF	Reduce risk of sustained eGFR decline, ESKD CV death and hospitalization for HF in adults with CKD at risk of progression
Bexagliflozin	X						
Canagliflozin	X	X	X				
Dapagliflozin	X				X	X	X
Empagliflozin	X			X		X (NOT urgent HF)	X
Ertugliflozin	X						

*Major adverse CV events defined as CV death, nonfatal MI, nonfatal stroke

CKD = chronic kidney disease; CVD = cardiovascular disease; EF = ejection fraction; eGFR = estimated glomerular filtration rate; ESKD = end stage kidney disease; HF = heart failure; NYHA = New York Heart Association; SCr = serum creatinine; T2DM = type 2 diabetes mellitus

The American Diabetes Association guidelines for the treatment of type 2 diabetes recommend a glucagon-like peptide-1 (GLP-1) receptor antagonist or an SGLT-2 with proven CVD benefit in patients with established atherosclerotic cardiovascular disease (ASCVD). Additionally, an SGLT2 inhibitor with proven benefit in heart failure with reduced ejection fraction (HFrEF) is recommended in patients with heart failure. An SGLT2 inhibitor with evidence of reducing progression of chronic kidney disease is recommended in patients with diabetic kidney disease or albuminuria.

Tufts Health RITogether Preferred Drug List status for the SGLT-2 inhibitors is as follows:

Generic Name	Brand Name	PDL Status	Quantity Limitation
Bexagliflozin	Brenzavvy	PA	1 tablet/day
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#	Covered	1 tablet/day
Dapagliflozin-Metformin 10/1,1000 mg, 10/500 mg*	Xigduo XR tablets 10/1,1000 mg, 10/500 mg#	Covered	1 tablets/day
Dapagliflozin-Metformin 5/1,1000 mg, 5/500 mg*	Xigduo XR tablets 5/1,1000 mg, 5/500 mg#	Covered	2 tablets/day
Dapagliflozin-Metformin 2.5/1,000 mg	Xigduo XR tablets 2.5/1,000 mg	PA	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

*Generic dapagliflozin and dapagliflozin-metformin extended-release tablets are the preferred SGLT2s for RITogether members.

Brand name medications with AB-rated generics are non-covered. They are included in the table to serve as a reference. Requests for the brand-name products, with AB-rated generics, will also require review according to Brand Name criteria.

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 cotransporter 2 inhibitor for Members when the criteria are met and limitations do not apply:

Type 2 diabetes

1. The Member has a diagnosis of type 2 diabetes

AND

2. The Member has had an inadequate response, intolerance, or contraindication to metformin at the maximally tolerated dose

AND

3. **ONE** of the following:
    a. **BOTH** of the following:
        i. Member is less than 18 years of age
        ii. The request is for canagliflozin-, dapagliflozin-, or empagliflozin-containing product
    b. The Member meets **ONE** of the following:
        i. Invokana, Invokamet, Invokamet XR, Xigduo XR 2.5/1,000 mg, Jardiance, Synjardy, Synjardy XR: The Member has had an inadequate response or intolerance to generic dapagliflozin-containing product, or contraindication to dapagliflozin

ii. **Brenzavvy, Steglatro, Segluromet:** The Member has had an inadequate response, intolerance, or contraindication to at least one additional generic antihyperglycemic agent (e.g., sulfonylurea, pioglitazone, alogliptin)
iii. The Member has established cardiovascular disease (CVD) (e.g., ASCVD†, heart failure), diabetic nephropathy, or two or more cardiovascular risk factors and the request is for a medication with that indication

†ASCVD defined as:
- Coronary heart disease (CHD) (myocardial infarction, angina, coronary artery disease)
- Cerebrovascular disease (e.g., transient ischemic attack, ischemic stroke)
- Peripheral artery disease
- Aortic atherosclerotic disease

*Cardiovascular risk factors include (but not limited to):
- Dyslipidemia
- Hypertension
- Current tobacco use
- Obesity/overweight
- Family history of premature ASCVD
- Chronic kidney disease
- Metabolic syndrome
- Presence of albuminuria

Chronic Kidney Disease

1. The Member has a diagnosis of chronic kidney disease (CKD) at risk of progression

AND

2. The request is for a dapagliflozin- or empagliflozin-containing product

AND

3. The Member is stable on an angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril, benazepril) or an angiotensin II receptor blocker (ARB) (e.g., candesartan, irbesartan, losartan, valsartan), or a clinical rationale why the Member cannot take an ACE inhibitor or ARB is provided

Heart Failure

1. The Member has a diagnosis of heart failure

AND

2. The request is for a dapagliflozin- or empagliflozin-containing product

AND

3. **Heart failure with reduced ejection fraction (HFrEF) only:** The member will be taking the requested medication with standard therapy for HFrEF (e.g., ACE inhibitor, ARB, beta blocker) OR documentation that treatment with standard HFrEF therapy is not appropriate for the member.

LIMITATIONS

1. The coverage of Brenzavvy is limited to one tablet per day.
2. 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.
3. The coverage of Invokamet and Invokamet XR is limited to two tablets 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 2.5/1,000 mg tablets, 10/1,000 tablets, and 10/500 mg tablets is limited to 2 tablets per day.
10. The coverage of Xigduo XR 5/1,000 tablets and 5/500 mg tablets is limited to 1 tablet per day
11. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. American Diabetes Association. Standards of medical care in diabetes – 2025. *Diabetes Care*. 2024; 48(Supp. 1): S1-S352.
2. Bailey C, Gross J, et al. Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with metformin: a randomized, double-blind, placebo controlled trial. Lancet. 2010 June. 375: 2223-2233.
3. Brenzavvy (bexagliflozin) [package insert]. Marlborough, MA: TheracosBio, LLC; February 2024.
4. Farxiga (dapagliflozin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024
5. Ferrannini E, Tang W, et al. Dapagliflozin monotherapy in type 2 diabetic patients with inadequate Glycemic control by diet and exercise. Dabetes Care. 2010 October. 33(10):2217-2224.
6. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(8):e895-e1032.
7. Henry R, Murray A, Marmolejo M, et al. Dapagliflozin, metformin XR, or both: initial pharmacotherapy for type 2 diabetes, a randomized controlled trial. The International Journal of Clinical Practice. 2012 May. 66(5):446-456.
8. Invokamet/Invokamet XR (canagliflozin/metformin, canagliflozin/metformin extended-release) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
9. Invokana (canagliflozin) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
10. Jabbour S, Hardy E, et al. Dapagliflozin is effective as add on therapy to sitagliptin with or without metformin: A 24 week multicenter, randomized, double blind, placebo controlled study. Diabetes Care. 2013 October. 10:1-11.
11. Jardiance (empagliflozin) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; October 2025.
12. Kohan D, Fioretto P, et al. Long term study of patients with type 2 diabetes and moderate renal impairment shows that dapagliflozin reduces weight and blood pressure but does not improve glycemic control. Kidney International. 2013 September. 10: 1-9.
13. McDonagh TA, Metra M, Adam M, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart Journ*. 2021;42:3599-3726.
14. McMurray JV, DeMets DL, Inzucchi SE, et al. A trial to evaluate the effect of the sodium-glucose co-transporter 2 inhibitor dapagliflozin on morbidity and mortality in patients with heart failure and reduced left ventricular ejection fraction (DAPA-HF). *Eur J Heart Fail*. 2019;21(4):665-675.
15. National Institute for Health and Clinical Excellence. Diabetes (type 2) - canagliflozin. In progress. URL: http://guidance.nice.org.uk/TA/WaveR/160. Available from Internet. Accessed 2014 Feb 5.
16. National Institute for Health and Clinical Excellence. Diabetes (type 2) - dapagliflozin. URL: http://publications.nice.org.uk/dapagliflozin-in-combination-therapy-for-treating-type-2-diabetes-ta288/guidance. Available from Internet. Accessed 2014 Feb 5 .
17. Nauck M, Rohwedder K, et al. Dapagliflozin vs. glipizide as Add-on therapy in patients with type 2 diabetes who have inadequate glycemic control with metformin. Diabetes Care. 2011 September. 34: 2015-2022.
18. Rosenstock J, Salsali A, et al. Effects of dapagliflozin, an SGLT2 inhibitor, on HBA1C, body weight, and hypoglycemia risk in patients with type 2 diabetes inadequately controlled on pioglitazone monotherapy. Diabetes Care. 2012 July. 35:1473-1478.
19. Segluromet (ertugliflozin and metformin) [package insert]. Rahway, NJ: Merck & Co; June 2024.
20. Steglatro (ertugliflozin) [package insert]. Rahway, NJ: Merck & Co; June 2024.
21. Synjardy/Synjardy XR (empagliflozin/metformin, empagliflozin/metformin extended-release) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; October 2025.
22. Strojek K, Yoon K, et al. Effect of dapagliflozin in patients with type 2 diabetes who have inadequate glycaemic control with Glimepiride: a randomized, 24-week, double blind, placebo controlled trial. Diabetes, Obesity and Metabolism. 2011 June. 13:928-938.
23. Wilding J, Woo V, et al. Long term efficacy of dapagliflozin in patients with type2 diabetes mellitus receiving high doses of insulin. Annals of Internal medicine. 2012 September. 156:405-415.
24. Xigduo XR (dapagliflozin and metformin extended-release) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: Effective August 1, 2023, updated approval criteria for heart failure to remove HFrEF requirement for dapagliflozin to account for expanded indication.
2. October 10, 2023: Effective November 1, 2023, added Brenzavvy to the MNG and updated criteria for Invokana, Invokamet, Invokamet XR, Farxiga, Xigduo XR, Jardiance, Synjardy, Synjardy XR for the treatment of type 2 diabetes to include Brenzavvy as a previous treatment option.
3. October 8, 2024: Administrative update to fax number.
4. December 9, 2025: Effective February 1, 2026, updated Overview section with expanded indication for the following drugs: empagliflozin for reduction of risk of sustained decline in eGFR, ESRD, CV death, and hospitalization in adults with CKD at risk of progression; canagliflozin and dapagliflozin for pediatric patients 10 years of age or older for the treatment of type 2 diabetes. Updated approval criteria for type 2 diabetes to include use in pediatric patients based on expanded indication for canagliflozin-, dapagliflozin-, or empagliflozin-products. Updated approval criteria for chronic kidney disease to include that request can be for empagliflozin-containing product based on expanded indication.
5. September 15, 2026: Effective October 1, 2026, updated Preferred Drug List status table within the Overview section to list dapagliflozin and dapagliflozin/metformin extended-release (10/1,000 mg, 10/500 mg, 5/1,000 mg, 5/500 mg) as covered medications without prior authorization and to indicate that generic dapagliflozin and dapagliflozin/metformin extended-release are preferred SGLT2s instead of Steglatro and Steglurometa. Also updated Drug list and Limitations section to note that requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name Criteria. Updated coverage criteria for Type 2 Diabetes to require trial with generic dapagliflozin-containing product for Invokana, Invokamet, Invokamet XR, Xigduo XR 2.5/1,000 mg, Jardiance, Synjardy, Synjardy XR instead of trial with bexagliflozin or ertugliflozin-containing product AND at least one generic antihyperglycemic agent.

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.

Provider Services