Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**

Effective: January 1, 2027

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Jardiance (empagliflozin) is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated:

- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
- To 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.
- To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Empagliflozin Containing Combination Products: Glyxambi, Synjardy, Synjardy XR, Trijardy XR

Empagliflozin is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

Synjardy (empagliflozin and metformin hydrochloride) is a combination of empagliflozin and metformin hydrochloride (HCl) immediate-release indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Synjardy XR (empagliflozin and metformin HCl extended-release) is a combination of empagliflozin and metformin HCl extended-release indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Glyxambi (empagliflozin and linagliptin) is a combination of empagliflozin and linagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Trijardy XR (empagliflozin, linagliptin, metformin hydrochloride tablet, extended release) is a combination of empagliflozin, linagliptin, and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Clinical Guideline Coverage Criteria

The plan may authorize the coverage of empagliflozin for patients when the following criteria are met:

1. All of the following:
    a. The patient has a documented diagnosis of **both** of the following:
        i. Type 2 Diabetes Mellitus
        ii. Established cardiovascular disease

AND

    b. One of the following:
        i. For patients on background diabetic
        ii. For patients who are naïve to diabetic therapy, but require therapy
        iii. Patient is continuing Jardiance (empagliflozin) treatment, as documented by paid claims history or chart notes

AND

c. Patient is 18 years of age or older

AND

d. The Patient has symptomatic atherosclerotic cardiovascular disease characterized by at least **one** of the following, as documented in submitted chart notes:
   i. History of MI or stroke
   ii. Hospital admission for unstable angina
   iii. History of coronary revascularization procedure
   iv. History of peripheral revascularization procedure
   v. History of amputation secondary to peripheral vascular disease
   vi. Patient is symptomatic with documented hemodynamically-significant carotid or peripheral vascular disease

OR

2. **One** of the following:
   a. The patient has had trial and failure, inadequate response, intolerance, or contraindication to dapagliflozin or a dapagliflozin containing preferred generic alternative.
   b. The patient has an allergy to an ingredient in the generic dapagliflozin product that is not contained in the empagliflozin containing product as specified by prescriber and corroborated in submitted chart documentation
   c. For combination agents, one of the following:
      i. If the request is for **Synjardy IR or XR** (empagliflozin and metformin/ER), The patient has had trial and failure, inadequate response, intolerance, or contraindication to dapagliflozin in combination with metformin immediate release or extended release.
      ii. If the request is for **Glyxambi** (empagliflozin and linagliptin), The patient has had trial and failure, inadequate response, intolerance, or contraindication to dapagliflozin in combination with linagliptin or sitagliptin.
      iii. If the request is for **Trijardy XR** (empagliflozin, linagliptin, metformin hydrochloride tablet, extended release), The patient has had trial and failure, inadequate response, intolerance, or contraindication to dapagliflozin in combination with sitagliptin or linagliptin and metformin/ER.

Limitations

- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. GLYXAMBI® (empagliflozin/linagliptin) Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2026.
2. Jardiance® (empagliflozin) Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; current version.
3. TRIJARDY® XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets) Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2026.
4. Zinman B, Wanner C, Lachin JM, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *New England Journal of Medicine.* 2015;373(22):2117-2128.

Approval And Revision History

August E-Vote 2026: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August E-Vote 2026: Effective 1/1/27, added Glyxambi and Trijardy XR PA criteria to support state-specific benchmark requirements to cover select SGLT2 combination agents on select formularies (with PA).
- September E-Vote: Effective November 15, 2026, added criteria for all empagliflozin containing drugs, including combination agents. Effective 1/1/27, incorporated September E-Vote edits.

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.