

P.264 Approval Criteria**Farxiga**

- I. Generic Name:**
- a. Dapagliflozin (Farxiga®)
- II. Medication Class:**
- a. Sodium-glucose cotransporter 2 (SGLT2) inhibitor
- III. FDA Approved Uses:**
- a. Adults with type II diabetes mellitus (DM)
 - A. As an adjunct to diet and exercise to improve glycemic control
 - B. To reduce risk of hospitalization for heart failure in adults with type II DM and established cardiovascular disease or multiple cardiovascular risk factors
 - b. Heart failure with reduced ejection fraction
 - A. To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV)
- IV. Application of Criteria:**
- a. The following criteria applies to Illinois Medicaid.
- V. Criteria for Use:**
- a. Member must be 18 years of age or older
 - b. For Type II DM
 - A. Follow MeridianHealth Non-Preferred Policy M50.60
 - c. For Heart Failure (without type II DM):
 - A. Medication is prescribed by or in consultation with a cardiologist
 - B. Documented diagnosis of chronic heart failure class II, III, or IV with reduced LV ejection fraction $\leq 40\%$
 - C. Member is receiving standard HF therapy for 4 or more weeks including the following (1 *and* 2) at maximally tolerated doses unless otherwise contraindicated:
 1. Beta blocker (e.g. carvedilol, metoprolol)
 2. ACEi/ARB (e.g. lisinopril, losartan)
- VI. Required Medical Information:**
- a. Current clinical documents must be submitted
 - b. Charts showing compliance to previous therapy and office visits
- VII. Contraindications:**
- a. Known hypersensitivity to dapagliflozin
- VIII. Not Approved If:**

Farxiga

- a. Patient does not meet criteria
- b. Failure to provide the required medical information
- c. eGFR is less than 30 ml/min/1.73m²

IX. Length of Authorization:

- a. Initial: Up to 1 year
- b. Continuation: Up to 1 year

X. Dosing:

- a. Type II DM: 5 mg once daily and may increase up to 10 mg once daily
- b. Heart Failure: 10 mg once daily

XI. Criteria for continuation of therapy:

- a. Initial therapy tolerated
- b. Member is responding positively to therapy
- c. If request is for a dose increase, the new dose may not exceed the FDA-approved maximum recommended dose

XII. Criteria for discontinuation of therapy:

- a. Patient is noncompliant with medical or pharmacologic therapy
- b. No demonstrable of improvement in clinical condition has occurred after initiation of drug therapy

XIII. References:

- a. Farxiga (Dapagliflozin). Facts and Comparisons, 2020 Clinical Drug Information, LLC. Retrieved From: <https://fco.factsandcomparisons.com/lco/action/search?q=farxiga&t=name&va>
- b. Farxiga [Package Insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; May 2020.
- c. Wexler, DJ. Initial management of blood glucose in adults with type 2 diabetes mellitus. Topic 1779. Version 57.0, ©UpToDate Online. June 2020.
- d. Colucci, WS. Overview of the management of heart failure with reduced ejection fraction in adults. Topic 121085 Version 7.0, ©UpToDate Online. July 2020.

