

Sodium-Glucose Co-Transporter 2 Inhibitors (SGLT2) PA Criteria

1. Does the patient have a diagnosis of diabetes mellitus, type 2?
 - a. If Yes, Go to question #2.
 - b. If No, Category 3 denial.
Category 3: Not a covered benefit. SGLT2s are only FDA approved for the treatment of type 2 diabetes.

2. Is the patient newly diagnosed?
 - a. If Yes, Forward to Medical Director for medical appropriateness.
Category 5: Not medically appropriate. An appropriate trial period of lifestyle modifications and other anti-diabetic agents (metformin, pioglitazone, sulfonylureas, DPP-4s, basal insulin, and GLP-1s) required for newly diagnosed patients prior to consideration of SGLT2s.
 - b. If No, Go to question #3.

3. Does the patient have a history of genital fungal infections, urinary tract infections, severe renal impairment (eGFR < 30 mL/minute/1.73 m²), end-stage renal disease, or is the patient on dialysis?
 - a. If Yes, Forward to Medical Director for medical appropriateness.
Category 5: Not medically appropriate. The above listed conditions represent contraindications to use of SGLT2s.
 - b. If No, Go to question #4.

4. Is the patient currently taking metformin, pioglitazone, a sulfonylurea, a DPP-4, basal insulin, and a GLP-1?
 - a. If Yes, Go to question #6.
 - b. If No, Go to question #5.

5. Has the patient tried and failed metformin, pioglitazone, sulfonylureas, DPP-4s, basal insulin, and GLP-1s, or does the patient have contraindications to these treatments?
 - a. If Yes, Go to question #6.
 - b. If No, Forward to Medical Director for medical appropriateness.
Category 5: Not medically appropriate. Provider submitted documentation does not indicate that patient has tried and failed, or has a contraindication to, preferred treatment alternatives.

6. Review fill history for patient. Has patient shown compliance to current diabetes medications (80% or greater adherence)?
 - a. If Yes, Go to question #7.
 - b. If No, Forward to Medical Director for medical appropriateness.
Category 5: Not medically appropriate. Approval requires patient compliance.

7. Is the request for a formulary SGLT2 agent? Formulary SGLT2 agents are the canagliflozin (Invokana) and empagliflozin (Jardiance).
 - a. If Yes, Go to question #9.
 - b. If No, Go to questions #8.

8. Has the patient tried and failed formulary SGLT2 agents? Formulary SGLT2 agents are the canagliflozin (Invokana) and empagliflozin (Jardiance).
 - a. If Yes, Go to question #9.
 - b. If No, Category 15 denial.

Category 15: Not a covered benefit. Provider submitted documentation does not indicate that the patient has tried and failed formulary alternatives canagliflozin (Invokana) and empagliflozin (Jardiance).

9. Is the medication dosing within the FDA approved dosing parameters for the medication? * Dosing adjustment due to renal or hepatic impairment may be necessary.
- a. If Yes, **Approve**.
 - b. If No, Category 3 denial.
Category 3: Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established.

*** Contraindications to traditional anti-diabetic medications:**

- Metformin contraindications: hypersensitivity to metformin, renal disease or renal dysfunction, acute or chronic metabolic acidosis, and increased risk of lactic acidosis (e.g. CHF, advanced age, impaired hepatic function).
- Pioglitazone contraindications: hypersensitivity to pioglitazone, CHF, bladder cancer, edema, high risk of fractures, impaired hepatic function, and anemia.
- Sulfonylurea contraindications: hypersensitivity to sulfonylureas, high risk of hypoglycemia, and diabetic ketoacidosis.

*** FDA approved medication dosing:**

- Canagliflozin (Invokana): 100 mg to 300 mg once daily
- Dapagliflozin (Farxiga): 5 mg to 10 mg once daily
- Empagliflozin (Jardiance): 10 mg to 25 mg once daily

Guide to Denial Categories	Reason for Denial
Category 1	The condition is not on a funded line
Category 3	The use of the medication is considered experimental/ investigational (usually applies to off-label use of a medication)
Category 5	Not medically appropriate
Category 15	Formulary medications have not been exhausted