# STEP THERAPY CRITERIA

**CATEGORY** **ANTIDIABETIC AGENTS**

**BRAND NAME***
**(generic)**

**AMYLIN ANALOG:**

**SYMLINPEN**
**(pramlintide acetate)**

**SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR:**

**BRENZAVVY**
**(bexagliflozin)**

**FARXIGA**
**(dapagliflozin)**

**INVOKANA**
**(canagliflozin)**

**JARDIANCE**
**(empagliflozin)**

**STEGLATRO**
**(ertugliflozin)**

**SGLT2 INHIBITOR / METFORMIN:**

**INVOKAMET**
**(canagliflozin / metformin HCl)**

**INVOKAMET XR**
**(canagliflozin /metformin HCl extended-release)**

**SEGLUROMET**
**(ertugliflozin / metformin HCl)**

**SYNJARDY**
**(empagliflozin / metformin HCl)**

**SYNJARDY XR**
**(empagliflozin / metformin HCl extended-release)**

**XIGDUO XR**
**(dapagliflozin / metformin HCl)**

**SGLT2 INHIBITOR / DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITOR:**

**GLYXAMBI**
**(empagliflozin / linagliptin)**

**QTERN**
**(dapagliflozin / saxagliptin)**

**STEGLUJAN**
**(ertugliflozin / sitagliptin)**

**SGLT2 INHIBITOR / DPP4 INHIBITOR / METFORMIN:**
**TRIJARDY XR**
**(empagliflozin / linagliptin / metformin HCl extended-release)**

***Status: Client Requested Criteria***
***Type: Initial Step Therapy; Post Step Therapy Prior Authorization*** ***Ref # C25493-D***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

## POLICY

### FDA APPROVED INDICATIONS

**AMYLIN ANALOG:**

**SymlinPen**

SymlinPen is indicated as an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and whose glycemic targets have not been met despite optimal insulin therapy.

**SGLT2 INHIBITOR:**

**Brenzavvy**

Brenzavvy (bexagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Brenzavvy is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

**Farxiga**

Farxiga (dapagliflozin) is indicated:

- to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
- to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure.
- to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age or older with type 2 diabetes mellitus.

Limitations of Use

- Farxiga is not indicated for the treatment of type 1 diabetes mellitus.
- Farxiga is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR <45 mL/min/1.73 $m^2$. Farxiga is likely to be ineffective in this setting based upon its mechanism of action.
- Farxiga is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease.

**Invokana**
Invokana (canagliflozin) is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD).
- to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria >300 mg/day.

Limitations of Use

- Invokana is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Invokana is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR <30 mL/min/1.73m$^2$. Invokana is likely to be ineffective in this setting based upon its mechanism of action.

**Jardiance**
Jardiance (empagliflozin) is 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 adult patients 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.

Limitation of Use

- Jardiance is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Jardiance is not recommended for use to improve glycemic control in patients with type 2 diabetes mellitus with an eGFR <30 mL/min/1.73 m2. Jardiance is likely to be ineffective in this setting based upon its mechanism of action.
- Jardiance is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or >45mg of prednisone or equivalent for kidney disease. Jardiance is not expected to be effective in these populations.

**Steglatro**
Steglatro (ertugliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Steglatro is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

**SGLT2 INHIBITOR/METFORMIN:**
**Invokamet, Invokamet XR**
Invokamet and Invokamet XR are a combination of canagliflozin and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Canagliflozin is indicated to reduce:

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

Limitations of Use

- Invokamet/Invokamet XR is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Canagliflozin is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR <30 mL/min/1.73m$^2$. Canagliflozin is likely to be ineffective in this setting based upon its mechanism of action.

**Segluromet**

Segluromet is a combination of ertugliflozin and metformin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Segluromet is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

**Synjardy, Synjardy XR**

- Synjardy is a combination of empagliflozin and metformin hydrochloride (HCl) 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 is a combination of empagliflozin and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    - Empagliflozin is indicated to reduce:
        - the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
        - the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
        - 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.

Limitation of Use

- Synjardy/Synjardy XR are not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Because of the metformin component, Synjardy/Synjardy XR is not recommended for use in patients with heart failure without type 2 diabetes mellitus.
- Empagliflozin, when used as a component of Synjardy/Synjardy XR, is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease. Empagliflozin is not expected to be effective in these populations.

**Xigduo XR**

Xigduo XR is a combination of dapagliflozin and metformin 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.

- Dapagliflozin is indicated to reduce:
    - the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
    - the risk of cardiovascular death,hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.

- the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Limitation of Use

- Xigduo XR is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Xigduo XR is limited to patients with type 2 diabetes mellitus for all indications because of the metformin HCl component.
- Xigduo XR is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Xigduo XR is not expected to be effective in these populations.

**SGLT2 INHIBITOR / DPP-4 INHIBITOR:**

**Glyxambi**

Glyxambi 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.

- Empagliflozin is indicated to reduce:
  - the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
  - the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
  - 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.

Limitations of Use

- Glyxambi is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Glyxambi has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi.
- Glyxambi is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR <30 ml/min/1.73m2. Glyxambi is likely to be ineffective in this setting based upon its mechanism of action.

**Qtern**

Qtern is a combination of dapagliflozin and saxagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Dapagliflozin is indicated to reduce:
  - the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
  - the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
  - the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Limitations of Use

- Qtern is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Qtern should only be used in patients who tolerate dapagliflozin 10mg.

**Steglujan**

Steglujan is a combination of ertugliflozin and sitagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Steglujan is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Steglujan has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

**SGLT2 INHIBITOR / DPP-4 INHIBITOR / METFORMIN:**
**Trijardy XR**
Trijardy XR 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.

- Empagliflozin is indicated to reduce:
    - the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
    - the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

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.Limitations of Use

- Trijardy XR is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Trijardy XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy XR.

**SCREEN OUT LOGIC***
**Includes Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 30-day supply of Entresto (sacubitril/valsartan) within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested sodium-glucose cotransporter 2 (SGLT2) inhibitor or SGLT2 inhibitor combination drug will be paid under that prescription benefit.

If the patient does not meet the initial screen out logic or is requesting a drug under these criteria that is not an SGLT2 inhibitor or SGLT2 inhibitor combination drug, then the claim will proceed to the initial step therapy criteria outlined in this policy.

**INITIAL STEP THERAPY***
*Includes Rx and OTC products unless otherwise

**INITIAL STEP THERAPY For AMYLIN ANALOGS (SymlinPen):**
If the patient has filled a prescription for at least a 30-day supply of a rapid-acting insulin or short-acting insulin or pre-mixed insulin [e.g., insulin aspart (Novolog), insulin glulisine (Apidra), insulin lispro (Humalog), insulin regular R (Afrezza, Humulin R, Novolin R)] within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**INITIAL STEP THERAPY For ALL OTHER TARGET DRUGS:**
If the patient has filled a prescription for at least a 30-day supply of metformin within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a

message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**COVERAGE CRITERIA**

**Type 2 Diabetes Mellitus**

The requested drug will be covered with prior authorization for a diagnosis of type 2 diabetes mellitus when the patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months when the patient meets **ONE** of the following criteria:

- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
- The patient requires combination therapy and has an A1c of 7.5 percent or greater
- The patient has established cardiovascular disease and
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), or Jardiance (empagliflozin)
- The patient has a diagnosis of diabetic nephropathy with albuminuria greater than 300mg per day and
    - The request is for Invokana (canagliflozin)
- The patient has multiple cardiovascular risk factors and
    - The request is for Farxiga (dapagliflozin)
- The patient has a diagnosis of heart failure and
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)
- The patient has a diagnosis of chronic kidney disease at the risk of progression and
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)

**Type 1 or 2 Diabetes Mellitus**

The requested drug will be covered with prior authorization for a diagnosis of type 1 or 2 diabetes mellitus when **ALL** of the following criteria are met:

- The request is for SymlinPen (pramlintide acetate)
- The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months and failed to achieve desired glucose control despite receiving optimal insulin therapy including mealtime insulin

**Chronic Kidney Disease**

The requested drug will be covered with prior authorization for a diagnosis of chronic kidney disease at risk of progression when the following criteria are met:

- The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)

**Heart Failure**

The requested drug will be covered with prior authorization for a diagnosis of heart failure at risk of progression when the following criteria are met:

- The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)

**CONTINUATION OF THERAPY**

**Type 2 Diabetes Mellitus**

The requested drug will be covered with prior authorization for a diagnosis of type 2 diabetes mellitus when the patient has been receiving a stable maintenance dose of the requested drug for at least 3 months, and the patient meets **ONE** of the following criteria:

- The patient has demonstrated a reduction in A1c since starting this therapy
- The patient has established cardiovascular disease and
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), or Jardiance (empagliflozin)
- The patient has a diagnosis of diabetic nephropathy with albuminuria greater than 300mg per day and
    - The request is for Invokana (canagliflozin)
- The patient has multiple cardiovascular risk factors and
    - The request is for Farxiga (dapagliflozin)
- The patient has a diagnosis of heart failure and
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)
- The patient has a diagnosis of chronic kidney disease at the risk of progression and
    - The request is for Farxiga (dapagliflozin or Jardiance (empagliflozin)

**Type 1 or 2 Diabetes Mellitus**

The requested drug will be covered with prior authorization for a diagnosis of type 1 or 2 diabetes mellitus when **ALL** of the following criteria are met:

- The request is for SymlinPen (pramlintide acetate)
- The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months and has demonstrated a reduction in A1c since starting this therapy

**Chronic Kidney Disease**
All patients requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

**Heart Failure**
All patients requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Duration of Approval (DOA):

- C25493-D: DOA: 12 months

## REFERENCES


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