STEP THERAPY CRITERIA

CATEGORY **ANTIDIABETIC AGENTS**

DRUG CLASS
BRAND NAME
(generic)

AMYLIN ANALOG:

SYMLINPEN
(pramlintide acetate)

GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONIST:

ADLYXIN
(lixisenatide)

BYDUREON
(exenatide extended-release)

BYDUREON BCISE
(exenatide extended-release)

BYETTA
(exenatide)

OZEMPIC
(semaglutide)

RYBELSUS
(semaglutide)

TRULICITY
(dulaglutide)

VICTOZA
(liraglutide)

GLUCOSE-DEPENDENT INSULINOTROPIC POLYPEPTIDE (GIP) RECEPTOR AND GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONIST:

MOUNJARO
(tirzepatide)

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)

LONG ACTING INSULIN/GLP-1 RECEPTOR AGONIST:
SOLIQUA
(insulin glargine / lixisenatide injection)

XULTOPHY
(insulin degludec / liraglutide injection)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization

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 who have failed to achieve desired glucose control despite optimal insulin therapy.

GLP-1 RECEPTOR AGONIST:
Adlyxin
Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Adlyxin should not be used in patients with type 1 diabetes mellitus.
- Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.

Bydureon/Bydureon BCise
Bydureon and Bydureon BCise are 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.
Limitations of Use
- Bydureon/Bydureon BCise are not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
- Bydureon/Bydureon BCise are not indicated for use in patients with type 1 diabetes mellitus.
- Bydureon/Bydureon BCise are extended-release formulations of exenatide and should not be used with other products containing the active ingredient exenatide.
- Bydureon/Bydureon BCise have not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Byetta
Byetta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Byetta is not indicated for use in patients with type 1 diabetes.
- Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Ozempic
Ozempic is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Rybelsus
Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Rybelsus is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus.

Trulicity
Trulicity is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use
- Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Trulicity should not be used in patients with type 1 diabetes mellitus.
- Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Victoza
Victoza is indicated:
- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
- Victoza should not be used in patients with type 1 diabetes mellitus.
- Victoza contains liraglutide and should not be coadministered with other liraglutide-containing products.

GIP/GLP-1 RECEPTOR AGONIST:
Mounjaro
Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

SGLT2 INHIBITOR:
Brenzavvy
Brenzavvy 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 in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Farxiga
Farxiga (dapagliflozin) is indicated:
- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- 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.
- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- 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.

Limitations of Use

- Farxiga is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients
- Farxiga is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 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. Farxiga is not expected to be effective in these populations.

Invokana

Invokana (canagliflozin) is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults 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 greater than 300 mg/day.

Limitations of Use

Invokana is not recommended 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 less than 30 mL/min/1.73m^2. Invokana is likely to be ineffective in this setting based upon its mechanism of action.

Jardiance

Jardiance is indicated:

- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
- 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 with type 2 diabetes mellitus,

Limitation of Use

Jardiance is not recommended 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 adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m2. Jardiance is likely to be ineffective in this setting based upon its mechanism of action.

Steglatro

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

Limitations of Use

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).

Canagliflozin is indicated 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 greater than 300 mg/day.

Limitations of Use
Invokamet/Invokamet XR is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Segluromet
Segluromet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Synjardy, Synjardy XR
Synjardy and Synjardy XR are 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.
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.

Xigduo XR
Xigduo XR is 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.

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.
Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes for all indications. 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.
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.

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

Steglujan
Steglujan is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use

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

LONG ACTING INSULIN / GLP-1 RECEPTOR AGONIST:
Soliqua
Soliqua 100/33 is a combination of insulin glargine and lixisenatide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use:
- Soliqua 100/33 has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Soliqua 100/33 is not recommended for use in combination with any other product containing a GLP-1 receptor agonist.
- Soliqua 100/33 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Soliqua 100/33 has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.
- Soliqua 100/33 has not been studied in combination with prandial insulin.

Xultophy
Xultophy 100/3.6 is a combination of insulin degludec and liraglutide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use:
- Xultophy 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rodent C-cell tumor findings to humans.
- Xultophy 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist.
- Xultophy 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Xultophy 100/3.6 has not been studied in combination with prandial insulin.

INITIAL STEP THERAPY*
**Include Rx and OTC products unless otherwise stated.*

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
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of type 2 diabetes mellitus **AND**
  - The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to metformin

    OR
    - The patient requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater

    OR
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide), Trulicity (dulaglutide), or Victoza (liraglutide) AND the patient has established cardiovascular disease

    OR
    - The request is for Invokana (canagliflozin) AND the patient has diabetic nephropathy with albuminuria greater than 300 mg per day

    OR
    - The request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin) AND the patient has multiple cardiovascular risk factors

    OR
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin) **AND**
      - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

    OR
    - The request is for Jardiance (empagliflozin) **AND**
      - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV) with an ejection fraction greater than 40 percent

    OR
    - The request is for Farxiga (dapagliflozin) **AND**
      - The patient has chronic kidney disease at risk of progression **AND**
        - The patient has an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m2

        OR
        - The patient has a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g

        OR
        - The patient has an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2 AND the request is for continuation of therapy

  OR
  - The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The patient has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy

    OR
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide), Trulicity (dulaglutide), or Victoza (liraglutide) AND the patient has established cardiovascular disease

    OR
    - The request is for Invokana (canagliflozin) AND the patient has diabetic nephropathy with albuminuria greater than 300 mg per day

OR

- The request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin) AND the patient has multiple cardiovascular risk factors

OR

- The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin) **AND**
  - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

OR

- The request is for Jardiance (empagliflozin) **AND**
  - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV) with an ejection fraction greater than 40 percent

OR

- The request is for Farxiga (dapagliflozin) **AND**
  - The patient has chronic kidney disease at risk of progression **AND**
    - The patient has an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m2

    OR
    - The patient has a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g

    OR
    - The patient has patient has an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2 AND the request is for continuation of therapy

OR

- The request is for SymlinPen (pramlintide acetate) AND the patient has a diagnosis of type 1 or type 2 diabetes mellitus **AND**
  - The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The patient has failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin

  OR
  - The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The patient has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy

OR

- The request is for Farxiga (dapagliflozin) **AND**
  - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

  OR
  - The patient has chronic kidney disease at risk of progression **AND**
    - The patient has an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m2

    OR
    - The patient has a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g

    OR
    - The patient has an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2 AND the request is for continuation of therapy in a patient with

OR

- The request is for Jardiance (empagliflozin) **AND**
  - The patient has a diagnosis of heart failure (New York Heart Association [NYHA] class II-IV)

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