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)

SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR:

FARXIGA (dapagliflozin)

INVOKANA (canagliflozin)

JARDIANCE (empagliflozin)

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STEGLATRO (ertugliflozin)

SGLT2 INHIBITOR / METFORMIN:

INVOKAMET

(canagliflozin / metformin HCI)

INVOKAMET XR

(canagliflozin /metformin HCI extended-release)

SEGLUROMET

(ertugliflozin / metformin HCI)

SYNJARDY

(empagliflozin / metformin HCI)

SYNJARDY XR

(empagliflozin / metformin HCl extended-release)

XIGDUO XR

(dapagliflozin / metformin HCI)

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

GLYXAMBI

(empagliflozin / linagliptin)

QTERN

(dapagliflozin / saxagliptin)

STEGLUJAN

(ertugliflozin / sitagliptin)

SGLT2 INHIBITOR / DPP4 INHIBITOR / METFORMIN:

QTERNMET XR

(dapagliflozin / saxagliptin / metformin HCl extended-release)

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 is not indicated for use 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 (exenatide) 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.

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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.

SGLT2 INHIBITOR:

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 m². 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).

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• 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

Jardiance

Jardiance 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 cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.
- to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction

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. <u>Limitations of Use</u>

Steglatro is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SGLT2 INHIBITOR / METFORMIN:

Invokamet, Invokamet XR

Invokamet and Invokamet XR are a combination of canagliflozin and metformin hydrochloride (HCI) 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 who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.

Limitations of Use

Segluromet is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Synjardy, Synjardy XR

Synjardy and Synjardy XR are a combination of empagliflozin and metformin hydrochloride 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.

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Limitation of Use

Xigduo XR is not recommended for patients with type 1 diabetes mellitus or diabetic ketoacidosis.

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 (dapagliflozin and saxagliptin) 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 indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Steglujan

Steglujan is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.

Limitations of Use

Steglujan is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. 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:

Qternmet XR

Qternmet XR (dapagliflozin, saxagliptin, and metformin hydrochloride) extended-release tablets is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

Qternmet XR is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Qternmet XR initiation is intended only for patients currently taking 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

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- 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 premixed 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

- o The patient has been receiving the requested drug for at least 3 months AND
 - The patient has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy
 - 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

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- The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin) AND
 - the patient has 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 Farxiga (dapagliflozin) AND
 - o 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 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g
 - The request is for continuation of therapy in a patient with an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2

OR

 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 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 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 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g
 OR
 - The request is for continuation of therapy in a patient with an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2

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 been receiving the requested drug for at least 3 months AND has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy
- The patient has failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin

OR

- The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin)
 - the patient has 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 Farxiga (dapagliflozin) AND
 - the patient has chronic kidney disease at risk of progression AND

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- The patient has an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m2
 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g
 OR
- The request is for continuation of therapy in a patient with an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m2

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