Reference number(s)
676-D

Step Therapy Criteria
Antidiabetic Agents

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the counter (OTC) products are not included unless otherwise stated.

Amylin Analog:

Brand Name	**Generic Name**
SymlinPen	pramlintide acetate

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist:

Brand Name	**Generic Name**
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:

Brand Name	**Generic Name**
Mounjaro	tirzepatide

Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor:

Brand Name	Generic Name
Bexagliflozin	bexagliflozin
Brenzavvy	bexagliflozin
Farxiga	dapagliflozin
Invokana	canagliflozin
Jardiance	empagliflozin
Steglatro	ertugliflozin

SGLT2 Inhibitor / Metformin:

Brand Name	Generic Name
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 extended-release

SGLT2 Inhibitor / Dipeptidyl Peptidase-4 (DPP-4) Inhibitor:

Brand Name	Generic Name
Glyxambi	empagliflozin / linagliptin
Qtern	dapagliflozin / saxagliptin
Steglujan	ertugliflozin / sitagliptin

SGLT2 Inhibitor / DPP4 Inhibitor / Metformin:

Brand Name	Generic Name
Trijardy XR	empagliflozin / linagliptin / metformin HCl extended-release

Long Acting Insulin/GLP-1 Receptor Agonist:

Brand Name	Generic Name
Soliqua	insulin glargine / lixisenatide injection
Xultophy	insulin degludec / liraglutide injection

Indications

Amylin Analog:

SymlinPen

FDA-approved Indications

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:

Bydureon BCise

FDA-approved Indications

Bydureon BCise is 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.

Limitations of Use

- Bydureon BCise contains exenatide. Coadministration with other exenatide-containing products is not recommended.

Compendial Uses

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

Byetta

FDA-approved Indications

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 contains exenatide. Coadministration with other exenatide-containing products is not recommended.

Compendial Uses

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

Ozempic Injection

FDA-approved Indications

Ozempic injection 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.
- to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

Compendial Uses

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

Rybelsus, Ozempic Tablets

FDA-approved Indications

Rybelsus and Ozempic tablets are 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 (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.

Compendial Uses

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

Trulicity

FDA-approved Indications

Trulicity is indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age 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 who have established cardiovascular disease or multiple cardiovascular risk factors.

Compendial Uses

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus[29]

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

Victoza

FDA-approved Indications

Victoza is 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.
- 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 contains liraglutide. Coadministration with other liraglutide-containing products is not recommended.

Compendial Uses

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus[29]

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

GIP/GLP-1 Receptor Agonist:

Mounjaro

FDA-approved Indications

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

Compendial Uses

Metabolic dysfunction–associated steatotic liver disease (MASLD) in adults with type 2 diabetes[29]

Metabolic dysfunction–associated steatohepatitis (MASH) in adults with type 2 diabetes[29]

SGLT2 Inhibitor:

Bexagliflozin

FDA-approved Indications

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

Limitations of Use

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

Brenzavvy

FDA-approved Indications

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 for use to improve glycemic control in patients with type 1 diabetes mellitus.

Farxiga

FDA-approved Indications

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 visit 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 aged 10 years and older with type 2 diabetes mellitus.

Limitations of Use

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

FDA-approved Indications

Invokana (canagliflozin) is 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.
- 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 for use to improve glycemic control in patients with type 1 diabetes mellitus.

Invokana is not recommended for use to improve glycemic control in patients 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

FDA-approved Indications

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 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 adults 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 less than 30 mL/min/1.73 m^2. 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

greater than 45 mg of prednisone or equivalent for kidney disease. Jardiance is not expected to be effective in these populations.

Steglatro

FDA-approved Indications

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 for use to improve glycemic control in patients with type 1 diabetes mellitus.

SGLT2 Inhibitor / Metformin:

Invokamet, Invokamet XR

FDA-approved Indications

Invokamet is a combination of canagliflozin and metformin HCl immediate-release 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.

Invokamet XR is a combination of canagliflozin and metformin HCl extended-release 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.

Canagliflozin, when used as a component of Invokamet or Invokamet XR, is indicated 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).
- 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 or Invokamet XR are not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Segluromet

FDA-approved Indications

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 for use to improve glycemic control in patients with type 1 diabetes mellitus.

Synjardy, Synjardy XR

FDA-approved Indications

Synjardy is a combination of empagliflozin and metformin hydrochloride (HCl) immediate-release 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 HCl extended-release indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Empagliflozin, when used as a component of Synjardy/Synjardy XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of:

- Cardiovascular (CV) death in adults with established CV disease.
- CV death and hospitalization for heart failure in adults with heart failure.
- Sustained decline in eGFR, end-stage kidney disease, CV death, and hospitalization in adults with chronic kidney disease at risk of progression.

Limitation of Use

- Synjardy and Synjardy XR are 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.
- Because of the metformin HCl component, the use of Synjardy or Synjardy XR is limited to patients with type 2 diabetes mellitus for all indications.
- Empagliflozin, when used as a component of Synjardy or 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

FDA-approved Indications

Xigduo XR is a combination of dapagliflozin and metformin hydrochloride (HCl) extended-release, 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, when used as a component of Xigduo XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of:

- Sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in patients with chronic kidney disease at risk of progression.
- Hospitalization for heart failure in patients with type 2 diabetes mellitus and either established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
- Cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in patients with heart failure.

Limitation of Use

- Xigduo XR is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
- Because of the metformin component, the use of Xigduo XR is limited to patients with type 2 diabetes mellitus 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

FDA-approved Indications

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 use to improve glycemic control in 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 less than 30 ml/min/1.73m^2. Glyxambi is likely to be ineffective in this setting based upon its mechanism of action.

Qtern

FDA-approved Indications

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 use to improve glycemic control in patients with type 1 diabetes mellitus.

Steglujan

FDA-approved Indications

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 for use to improve glycemic control in patients with type 1 diabetes mellitus.
- 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

FDA-approved Indications

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 use to improve glycemic control in 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

FDA-approved Indications

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 contains lixisenatide. Coadministration with any other product containing lixisenatide or another glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- Soliqua 100/33 is not recommended for the treatment of diabetic ketoacidosis.
- Soliqua 100/33 has not been studied in combination with prandial insulin.

Xultophy

FDA-approved Indications

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 contains liraglutide. Coadministration with other products containing liraglutide or another glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- Xultophy 100/3.6 is not recommended 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 Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)-Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists:

If the patient has filled a prescription for at least a 30-day supply of metformin when the date of a metformin fill is AT LEAST 10 days prior to the claim for a GLP-1 receptor agonist or a GIP-GLP-1 receptor agonist 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.

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

Chronic Kidney Disease

Authorization may be granted when the patient has a diagnosis of chronic kidney disease at risk of progression when the following criteria is met:

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

Heart Failure

Authorization may be granted for a diagnosis of heart failure when the following criteria is met:

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

Type 1 or 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 1 or type 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 the following criteria is met:
    - The patient has failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin.

Type 2 Diabetes Mellitus

Authorization may be granted 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 ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist or Glucose-Dependent Insulinotropic Polypeptide (GIP)-Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist [Note:

Examples of GLP-1 Agonists are Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity, Victoza. An example of a GIP/GLP-1 Agonist is Mounjaro.], then ONE of the following criteria is met:

- The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] and the following criteria is met:
    - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL.

- 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 a diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD) or metabolic dysfunction-associated steatohepatitis (MASH) and the following criteria is met:
        - The request is for Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide) injection, Rybelsus (semaglutide), Ozempic (semaglutide) tablets, Trulicity (dulaglutide), Victoza (liraglutide) or Mounjaro (tirzepatide).
    - The patient has established cardiovascular disease and the following criteria is met:
        - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide) injection, Trulicity (dulaglutide), or Victoza (liraglutide).
    - The patient has a diagnosis of diabetic nephropathy with albuminuria greater than 300 mg per day and the following criteria is met:
        - The request is for Invokana (canagliflozin).
    - The patient has multiple cardiovascular risk factors and the following criteria is met:
        - The request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin).
    - The patient is at high risk of major cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) and the following criteria is met:
        - The request is for Rybelsus (semaglutide) or Ozempic (semaglutide) tablets.
    - The patient has a diagnosis of heart failure and the following criteria is met:
        - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin).
    - The patient has a diagnosis of chronic kidney disease at risk of progression and the following criteria is met:
        - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin).

- The patient has a diagnosis of chronic kidney disease AND the following criteria is met:
  - The request is for Ozempic (semaglutide) injection.
- The patient has a diagnosis of advanced chronic kidney disease (CKD) (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2) and the following criteria is met:
  - The request is for Trulicity (dulaglutide) or Victoza (liraglutide).

Continuation of Therapy

Chronic Kidney Disease

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Heart Failure

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Type 1 or 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 1 or type 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 the following criteria is met:
  - The patient has demonstrated a reduction in A1C since starting this therapy.

Type 2 Diabetes Mellitus

Authorization may be granted 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 when ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist or Glucose-Dependent Insulinotropic Polypeptide (GIP)-Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist [Note: Examples of GLP-1 Agonists are Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity, Victoza. An example of a GIP/GLP-1 Agonist is Mounjaro.], then ONE of the following criteria is met:
  - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]

  - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] and the following criteria is met:
    - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL.
- The patient meets ONE of the following criteria:
  - The patient has demonstrated a reduction in A1C since starting this therapy.
  - The patient has a diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD) or metabolic dysfunction-associated steatohepatitis (MASH) and the following criteria is met:
    - The request is for Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide) injection, Rybelsus (semaglutide), Ozempic (semaglutide) tablets, Trulicity (dulaglutide), Victoza (liraglutide) or Mounjaro (tirzepatide).
  - The patient has established cardiovascular disease and the following criteria is met:
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide) injection, Trulicity (dulaglutide), or Victoza (liraglutide).
  - The patient has a diagnosis of diabetic nephropathy with albuminuria greater than 300 mg per day and the following criteria is met:
    - The request is for Invokana (canagliflozin).
  - The patient has multiple cardiovascular risk factors and the following criteria is met:
    - The request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin).
  - The patient is at high risk of major cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) and the following criteria is met:
    - The request is for Rybelsus (semaglutide) or Ozempic (semaglutide) tablets.
  - The patient has a diagnosis of heart failure and the following criteria is met:
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin).
  - The patient has a diagnosis of chronic kidney disease at risk of progression and the following criteria is met:
    - The request is for Farxiga (dapagliflozin) or Jardiance (empagliflozin).
  - The patient has a diagnosis of chronic kidney disease and the following criteria is met:
    - The request is for Ozempic (semaglutide) injection.
  - The patient has a diagnosis of advanced chronic kidney disease (CKD) (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2) and the following criteria is met:
    - The request is for Trulicity (dulaglutide) or Victoza (liraglutide).

Reference number(s)
676-D

Duration of Approval (DOA)

- 676-D: DOA: 36 months

References

1. Bexagliflozin [package insert]. Marlborough, MA: TheracosBio, LLC; April 2024.
2. Brenzavvy [package insert]. Marlborough, MA: TherascoBio, LLC.; February 2024.
3. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2025.
4. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2025.
5. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2024.
6. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
7. Invokamet, Invokamet XR [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
8. Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
9. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2023.
10. Mounjaro [package insert]. Indianapolis, IN: Eli Lilly and Company.; May 2025.
11. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2025.
12. Qtern [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024.
13. Rybelsus and Ozempic Tablets [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2026.
14. Segluromet [package insert]. Rahway, NJ: Merck Sharpe & Dohme LLC.; December 2024.
15. Soliqua [package insert]. Morristown, NJ: sanofi-aventis U.S. LLC; May 2025.
16. Steglatro [package insert]. Rahway, NJ: Merck Sharpe & Dohme LLC.; December 2024.
17. Steglujan [package insert]. Rahway, NJ: Merck Sharpe & Dohme LLC.; December 2024.
18. SymlinPen [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019.
19. Synjardy, Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2025.
20. Trijardy XR [package Insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
21. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2025.
22. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; May 2025.
23. Xigduo XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2024.
24. Xultophy [package insert]. Plainsboro, NJ: Novo Nordisk U.S. LLC; May 2025.
25. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed March 2025.
26. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/2025).
27. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. Endocrine Practice 28 (2022) 923-1049.

28. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.
29. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2025. Diabetes Care. 2025:48(Suppl. 1):S1-S352.
30. Heidenreich PA, Bozkurt B, Aguilar D et. al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2022;79:e263-e421.
31. Kittleson MM, Panjrath GS, Amancherla K et. al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* 2023;81(18):1835-1878.
32. Maddox TM, Januzzi JL Jr, Allen LA, et. al. 2024 ACC expert consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol* 2024;83(15):1444-1488.
33. Samson SL, Vellanki P, Blonde L et. al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. Endocrine Practice 2023;29(5):P305-340.