Antidiabetic Agents

- **Amylin Analog Antidiabetics**
  - SymlinPen (Pramlintide)
- **Biguanide and Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Antidiabetic Combinations**
  - Janumet (Metformin; Sitagliptin)
  - Janumet XR (Metformin; Sitagliptin)
  - Jentadueto (Linagliptin; Metformin)
  - Jentadueto XR (Linagliptin; Metformin)
  - Kazano (Alogliptin; Metformin)
  - Kombiglyze XR (Metformin; Saxagliptin)
- **Biguanide, Dipeptidyl Peptidase-4 (DPP-4) Inhibitor, and Sodium Glucose Co-transporter 2 (SGLT2) Inhibitor Antidiabetic Combinations**
  - Qternmet XR (Dapagliflozin; Saxagliptin; Metformin)
  - Trijardy XR (Empagliflozin; Linagliptin; Metformin)
- **Biguanide and Sodium Glucose Co-transporter 2 (SGLT2) Inhibitors Antidiabetic Combinations**
  - Invokamet (Canagliflozin; Metformin)
  - Invokamet XR (Canagliflozin; Metformin)
  - Segluromet (Ertugliflozin; Metformin)
  - Synjardy (Empagliflozin; Metformin)
  - Synjardy XR (Empagliflozin; Metformin)
  - Xigduo XR (Dapagliflozin; Metformin)
- **Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Antidiabetics**
  - Januvia (Sitagliptin)
  - Nesina (Alogliptin)
  - Onglyza (Saxagliptin)
  - Tradjenta (Linagliptin)
- **Dipeptidyl Peptidase-4 (DDP-4) Inhibitor and Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitor Antidiabetic Combinations**
  - Glyxambi (Empagliflozin; Linagliptin)
  - Qtern (Dapagliflozin; Saxagliptin)
  - Steglujan (Ertugliflozin; Sitagliptin)

- **Dipeptidyl Peptidase-4 (DDP-4) Inhibitor and Thiazolidinedione (Glitazone) Antidiabetic Combinations**
    - Oseni (Alogliptin; Pioglitazone)
- Dual Glucose-dependent Insulinotropic Polypeptide (GIP) and GLP-1 Receptor Agonists
    - Mounjaro (Tirzepatide)
- **Incretin mimetics Antidiabetics**
    - Adlyxin (Lixisenatide)
    - Bydureon (Exenatide)
    - Bydureon BCise (Exenatide)
    - Byetta (Exenatide)
    - Ozempic (Semaglutide)
    - Rybelsus (Semaglutide)
    - Trulicity (Dulaglutide)
    - Victoza (Liraglutide)
- **Insulins and Analogs and Incretin Mimetic Combinations**
    - Soliqua (Insulin Glargine; Lixisenatide)
    - Xultophy (Insulin Degludec; Liraglutide)
- **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**
    - Farxiga (Dapagliflozin)
    - Invokana (Canagliflozin)
    - Jardiance (Empagliflozin)
    - Steglatro (Ertugliflozin)

Summary

Diabetes mellitus (commonly referred to as diabetes) is a chronic (long-term) medical condition characterized by high blood glucose (sugar). This may be because the pancreas (an organ in the belly) does not make enough insulin (a hormone), or because the body is not responding to insulin the way it should. Insulin helps glucose get into cells in the body, giving it energy. With diabetes, sugar builds up in the blood because the body stops responding to insulin, or because there is not enough of it. Diabetes is broadly grouped into two types:

- Type 1 diabetes - the pancreas makes no insulin, or a very small amount
- Type 2 diabetes - cells in the body do not respond to insulin the way it should; sometimes, the pancreas also does not make enough insulin

Diabetes is usually managed by eating healthy foods, getting plenty of exercise, and sometimes medicines. Medicines are used to either control blood sugar, or to lower the chance of problems that can happen in the future because of diabetes. These medications can be insulin itself, or medications that help the body make more insulin or help insulin do its job.

Table 1: Antidiabetic Agents

Classification	Drug#	FDA-Approved Indications
Amylin Analog Antidiabetics	SymlinPen (Pramlintide)	Adjunct 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.
Biguanide and Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Antidiabetic Combinations	Janumet (Metformin; Sitagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Janumet XR (Metformin; Sitagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Jentadueto (Linagliptin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Jentadueto XR (Linagliptin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Kazano (Alogliptin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

	Kombiglyze XR (Metformin; Saxagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Biguanide, Dipeptidyl Peptidase-4 (DPP-4) Inhibitor, and Sodium Glucose Co-transporter 2 (SGLT2) Inhibitor Antidiabetic Combinations	Qternmet XR (Dapagliflozin; Saxagliptin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. NOTE: FDA approved May 2019; anticipated availability is currently unknown.
	Trijardy XR (Empagliflozin; Linagliptin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. NOTE: Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
Biguanide and Sodium Glucose Co-transporter 2 (SGLT2) Inhibitors Antidiabetic Combinations	Invokamet (Canagliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Invokamet XR (Canagliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Segluromet (Ertugliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Synjardy (Empagliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Synjardy XR (Empagliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Xigduo XR (Dapagliflozin; Metformin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Antidiabetics	Januvia (Sitagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, as monotherapy or combination therapy.
	Nesina (Alogliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

	Onglyza (Saxagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus as monotherapy or combination therapy.
	Tradjenta (Linagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes as monotherapy or in combination with other antidiabetic agents.
Dipeptidyl Peptidase-4 (DDP-4) Inhibitor and Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitor Antidiabetic Combinations	Glyxambi (Empagliflozin; Linagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Note: Empagliflozin is indicated for risk reduction of cardiovascular mortality in adults with type 2 diabetes mellitus and established cardiovascular disease.
	Qtern (Dapagliflozin; Saxagliptin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Steglujan (Ertugliflozin; Sitagliptin)	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.
Dipeptidyl Peptidase-4 (DDP-4) Inhibitor and Thiazolidinedione (Glitazone) Antidiabetic Combinations	Oseni (Alogliptin; Pioglitazone)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dual Glucose-dependent Insulinotropic Polypeptide (GIP) and GLP-1 Receptor Agonists	Mounjaro (Tirzepatide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Incretin mimetics Antidiabetics	Adlyxin (Lixisenatide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Bydureon (Exenatide)	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus

	Bydureon BCise (Exenatide)	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
	Byetta (Exenatide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
	Ozempic (Semaglutide)	Diabetes mellitus, type 2, treatment: ● 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.
	Rybelsus (Semaglutide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
	Trulicity (Dulaglutide)	Diabetes mellitus, type 2, treatment: ● As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; ● risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.
	Victoza (Liraglutide)	Diabetes mellitus, type 2, treatment: ● As an adjunct to diet and exercise to improve glycemic control in children ≥10 years of age, adolescents, and adults with type 2 diabetes mellitus; ● risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
Insulins and Analogs and Incretin Mimetic Combinations	Soliqua (Insulin Glargine; Lixisenatide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
	Xultophy (Insulin Degludec; Liraglutide)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Sodium-Glucose Co-Transporter	Farxiga (Dapagliflozin)	● Chronic kidney disease: To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular

2 (SGLT2) Inhibitors		death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of use: Dapagliflozin is not recommended in patients with polycystic kidney disease, or in those who currently require or with a recent history of immunosuppressive therapy for kidney disease. ● Diabetes mellitus, type 2, treatment: ○ As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; ○ risk reduction of hospitalization for heart failure in patients with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors. ● Heart failure with reduced ejection fraction: To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II to IV).
	Invokana (Canagliflozin)	Diabetes mellitus, type 2, treatment: ● As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; ● risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease; ● risk reduction of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with urinary albumin excretion >300 mg/day.
	Jardiance (Empagliflozin)	1. Diabetes mellitus, type 2, treatment: ○ As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; ○ risk reduction of cardiovascular mortality in adults with type 2 diabetes mellitus and established cardiovascular disease. 2. Heart failure: Risk reduction of cardiovascular mortality and hospitalization for heart failure in adults with heart failure.
	Steglatro (Ertugliflozin)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

[#] *include both brand and generic and all dosage forms and strengths unless otherwise stated*
NOTE: The Plan requires that members be unable to use, or have tried and failed preferred medication(s) first. Requests for non-formulary medications are subject to Medical Necessity Criteria for Non-Formulary Drugs (PG069).

Definitions

"Insulin" is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body's sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

"Type 1 Diabetes" is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as "insulin-dependent" because these patients require insulin daily to maintain their blood glucose at acceptable levels.

"Type 2 Diabetes" is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are "insulin-requiring".

"Blood Glucose" is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL). When blood sugar is too high for long periods of time, complications can occur as a result of blood vessel damage.

"Hemoglobin A1c (HbA1c)" is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as "A1C" or "glycosylated hemoglobin". A1C should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control. A1C test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Hypoglycemia" is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

Medical Necessity Criteria for Authorization

The Plan considers Antidiabetic Agents medically necessary when ALL the following criteria are met for the applicable indication or agent listed below:

For Type 2 Diabetes Mellitus:

Medical Necessity Criteria for Authorization

The Plan considers Antidiabetic Agents* medically necessary when ALL the following criteria are met:

**not inclusive of SymlinPen (please refer to SymlinPen drug-specific criteria sub-section below)*

1. The member has a diagnosis of type 2 diabetes mellitus***; AND***
2. The member has ONE of the following:
    a. is unable to use, or has adequately tried and failed metformin***; or***
    b. requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater***; or***
    c. has established cardiovascular disease, AND the request is for ONE of the following:
        i. Farxiga (dapagliflozin)***; or***
        ii. Invokana (canagliflozin)***; or***
        iii. Jardiance (empagliflozin)***; or***
        iv. Ozempic (semaglutide)***; or***
        v. Trulicity (dulaglutide)***; or***
        vi. Victoza (liraglutide)***; or***
    d. has diabetic nephropathy with albuminuria greater than 300 mg per day, AND the request is for Invokana (canagliflozin)***; or***
    e. has multiple cardiovascular risk factors, AND the request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin)***; or***

f. has New York Heart Association (NYHA) Class II-IV heart failure and ONE of the following:
    i. reduced ejection fraction (HFrEF), defined as heart failure with left ventricular ejection fraction (LVEF) ≤ 40%, AND the request is for Farxiga (dapagliflozin)***; or***
    ii. the request is for Jardiance (empagliflozin)***; or***
g. has chronic kidney disease at risk of progression, AND BOTH of the following:
    i. The request is for Farxiga (dapagliflozin)***; and***
    ii. The member has ONE of the following:
        1. an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m^2 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g***; or***
        2. an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m^2 AND this is a continuation of therapy***; or***
h. has been receiving the requested drug for at least 3 months, AND one of the following:
    i. has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy***; or***
    ii. has established cardiovascular disease, AND the request is for ONE of the following:
        1. Farxiga (dapagliflozin)***; or***
        2. Invokana (canagliflozin)***; or***
        3. Jardiance (empagliflozin)***; or***
        4. Ozempic (semaglutide)***; or***
        5. Trulicity (dulaglutide)***; or***
        6. Victoza (liraglutide)***; or***
    iii. has diabetic nephropathy with albuminuria greater than 300 mg per day, AND the request is for Invokana (canagliflozin)***; or***
    iv. has multiple cardiovascular risk factors, AND the request is for Trulicity (dulaglutide) or Farxiga (dapagliflozin)***; or***
    v. has New York Heart Association (NYHA) Class II-IV heart failure and ONE of the following:
        1. reduced ejection fraction (HFrEF), defined as heart failure with left ventricular ejection fraction (LVEF) ≤ 40%, AND the request is for Farxiga (dapagliflozin)***; or***
        2. the request is for Jardiance (empagliflozin)***; or***
    vi. has chronic kidney disease at risk of progression, AND BOTH of the following:
        1. The request is for Farxiga (dapagliflozin)***; and***

2. The member has ONE of the following:
    a. an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m^2 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g***; or***
    b. an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m^2 AND this is a continuation of therapy.

If the above prior authorization criteria are met, the requested drug will be approved for 12 months.

For Chronic Kidney Disease:

Medical Necessity Criteria for Authorization

The Plan considers Farxiga (dapagliflozin) medically necessary when BOTH of the following criteria are met:

1. The member has chronic kidney disease at risk of progression***; AND***
2. The member has ONE of the following:
    a. an estimated glomerular filtration rate (eGFR) of 25 to 75 mL/min/1.73m^2 AND a urine albumin creatinine ratio (UACR) between 200 and 5000 mg/g***; or***
    b. an estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73m^2 AND this is a continuation of therapy

If the above prior authorization criteria are met, the requested drug will be approved for 12 months.

For Heart Failure:

Medical Necessity Criteria for Authorization

The Plan considers Farxiga (dapagliflozin) or Jardiance (Empagliflozin) medically necessary when BOTH of the following criteria is met:

1. The member has New York Heart Association (NYHA) Class II-IV heart failure***; AND***
2. The request meets ONE of the following:
    a. The member has heart failure with reduced ejection fraction (HFrEF), defined as heart failure with left ventricular ejection fraction (LVEF) ≤ 40% AND the request is for Farxiga (dapagliflozin)***; or***
    b. The request is for Jardiance (empagliflozin).

If the above prior authorization criteria are met, the requested drug will be approved for 12 months.

For SymlinPen (Pramlintide):

Medical Necessity Criteria for Authorization

The Plan considers SymlinPen (Pramlintide) medically necessary when ALL the following criteria are met:

1. The member has a diagnosis of type 1 diabetes mellitus or type 2 diabetes mellitus***; AND***
2. The member has ONE of the following:
    a. failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin***; or***
    b. has been receiving SymlinPen (Pramlintide) for at least 3 months AND has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy

If the above prior authorization criteria are met, the requested drug will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Antidiabetic Agents for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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50. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2021.
51. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; December 2021.
52. Xigduo XR (dapagliflozin and metformin) [prescribing information]. Wilmington, DE: AstraZeneca; April 2022.

53. Xultophy (insulin degludec and liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2019.

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