Original Effective Date: 04/28/2021
Current Effective Date: 12/01/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 04/2026
Policy Number: C21116-A

Antidiabetic Agents

PRODUCTS AFFECTED

bexagliflozin, BRENZAVVY (bexagliflozin), dapagliflozin, dapagliflozin-metformin, FARXIGA (dapagliflozin), GLYXAMBI (empagliflozin/linagliptin), INVOKAMET (canagliflozin/metformin), INVOKAMET XR (canagliflozin/metformin HCL extended-release), INVOKANA (canagliflozin), JARDIANCE (empagliflozin), QTERN (dapagliflozin/saxagliptin), SEGLUROMET (ertugliflozin/metformin), STEGLATRO (ertugliflozin), STEGLUJAN (ertugliflozin/sitagliptin), SYNJARDY (empagliflozin/metformin HCl), SYNJARDY XR (empagliflozin/metformin extended-release), XIGDUO XR (dapagliflozin/metformin HCl)

ADLYXIN (lixisenatide), BYDUREON (exenatide), BYETTA (exenatide), liraglutide, OZEMPIC (semaglutide), RYBELSUS (semaglutide), SOLIQUA (insulin glargine-lixisenatide), TRULICITY (dulaglutide), VICTOZA (liraglutide), XULTOPHY (insulin degludec-liraglutide)

alogliptin, alogliptin/metformin, alogliptin/pioglitazone, JANUMET (sitagliptin/metformin), JANUMET XR (sitagliptin/metformin extended-release), JANUVIA (sitagliptin), JENTADUETO (linagliptin/metformin), JENTADUETO XR (linagliptin/metformin extended-release), KAZANO (alogliptin/metformin), KOMBIGLYZE XR (saxagliptin/metformin extended-release), NESINA (alogliptin), ONGLYZA (saxagliptin), OSENI (alogliptin/pioglitazone), saxagliptin, saxagliptin-metformin, sitagliptin, sitagliptin-metformin, TRADJENTA (linagliptin), Zituvimet (sitagliptin free base), Zituvimet XR (sitagliptin free base-metformin), Zituvio (sitagliptin)

TRIJARDY XR (empagliflozin/linagliptin/metformin extended-release)

MOUNJARO (tirzepatide)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes.
Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Type 2 diabetes mellitus, Heart failure, Chronic Kidney Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. STEP THERAPY FOR FORMULARY DRUGS:
1. The requested medication is being used for treatment of type 2 diabetes mellitus
   MOLINA REVIEWER NOTE: Includes medications with indication of type 2 diabetes mellitus AND cardiovascular disease or chronic kidney disease
   OR
   The requested medication is being used for an FDA-approved indication other than type 2 diabetes mellitus – SEE CONDITION SPECIFIC CRITERIA BELOW
   AND
2. (a) Documentation or prescriber attestation that metformin has been ineffective in the treatment of the member's disease or medical condition OR based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of metformin, is likely to be ineffective or adversely affect the drug's effectiveness or member compliance
   OR
   (b) Documentation or prescriber attestation that metformin has caused or based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of metformin, is likely to cause a clinically significant adverse reaction or other harm to the member and which the requested drug is not as likely to cause
   MOLINA REVIEWER NOTE: FOR CA/FL/KY/WA MARKETPLACE: Approval letter or other coverage documentation showing the formulary drug we require step therapy for was covered for the member by their previous insurer will also meet this criteria.

B. TYPE 2 DIABETES MELLITUS:
1. Documentation of diagnosis of type 2 diabetes mellitus
   MOLINA REVIEWER NOTE: Includes medications with indication of type 2 diabetes mellitus AND cardiovascular disease or chronic kidney disease
   AND
2. Documentation of an inadequate treatment response, contraindication or serious side effects to 3 consecutive months of metformin. Inadequate response is defined as not achieving adequate glycemic control after 3 continuous months of receiving maximal daily doses despite current treatment. (See Appendix 1)
   AND
3. Documentation of member individualized goals for therapy (e.g., A1c, weight management, maintain blood glucose within target range, prevent or reduce hospitalization due to hyper-or hypo-glycemic events, etc. See Appendix 3.)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA

labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to GLP-1 agonists or combinations include: Hypersensitivity to requested product, or any component of the formulation; history of or family history of medullary thyroid carcinoma (MTC); patients with multiple endocrine neoplasia syndrome type 2 (MEN2). Contraindications to Alogliptin, Saxagliptin, Linagliptin, Sitagliptin include: Hypersensitivity (e.g., anaphylaxis, angioedema, exfoliative skin conditions) to the requested product or any component of the formulation. Contraindications to SGLT2 inhibitors include severe renal impairment (see individual agent for eGFR limit), ESRD or dialysis, history of serious hypersensitivity to drug or components of the formulations.]
AND

5. FOR NON-FORMULARY/NON-PREFERRED SINGLE AGENTS: Documented inadequate response, serious side effects, or contraindication to ALL FORMULARY/PREFERRED agents within the same therapeutic class [Failure is defined as not achieving expected A1C lowering while adherent to therapy]
OR
6. FOR COMBINATION PRODUCTS:
(a) Documented inadequate response, serious side effects, or contraindication to ALL FORMULARY/PREFERRED COMBINATION agents with MATCHING THERAPEUTIC CLASS [Failure is defined as not achieving expected A1C lowering while adherent to therapy]
OR
(b) Documented inadequate response, serious side effects, or contraindication to ALL MATCHING CLASS (SGLT2/GLP1/DPP4 CLASS) FORMULARY SINGLE AGENTS within the requested combination product [Failure is defined as not achieving expected A1C lowering while adherent to therapy]

C. REDUCE RISK OF HOSPITALIZATION FOR HEART FAILURE- FARXIGA/JARDIANCE/XIGDUO XR ONLY:

1. (a) Documentation member has a diagnosis of heart failure consistent with individual product FDA label
OR
(b) Documentation member has: (i) a diagnosis of Type 2 diabetes AND (ii) at high risk for cardiovascular events [(a) established cardiovascular disease OR (b) age ≥55 years in men/≥60 years in women AND ONE of the following: dyslipidemia, hypertension or current tobacco use]
AND
2. Documentation that member is concurrently receiving guideline-directed medical therapy (Heidenreich 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; Kittleson, Gurusher Panjrath, et al., 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction)
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Farxiga (dapagliflozin) include: history of serious hypersensitivity reaction to Farxiga, and patients on dialysis. Contraindications to Jardiance (empagliflozin) include: Hypersensitivity to empagliflozin or any of the excipients in Jardiance, and patients on dialysis. Contraindications to Xigduo XR (dapagliflozin and metformin) include: severe renal impairment (eGFR below 30 mL/min/1.73m2), end stage renal disease or dialysis, history of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin, and metabolic acidosis, including diabetic ketoacidosis.]

D. CHRONIC KIDNEY DISEASE – FARXIGA ONLY:

1. Documented diagnosis of chronic kidney disease (CKD)
AND
2. Documentation member has an eGFR of 25-75 mL/min/1.73m^2 or CKD stage 2, 3, or 4
AND

3. Member has no previous use of dialysis
   AND
4. Documentation of concurrent use or FDA labeled contraindication of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Farxiga (dapagliflozin) include: history of serious hypersensitivity reaction to Farxiga, and patients on dialysis.]

E. OFF-LABEL USE: See Exclusions/Discontinuation

CONTINUATION OF THERAPY:

A. STEP THERAPY FOR FORMULARY DRUGS: N/A

B. TYPE 2 DIABETES MELLITUS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by improvement in hemoglobin A1c OR member has reached individualized goals

C. REDUCE RISK OF HOSPITALIZATION FOR HEART FAILURE- FARXIGA/JARDIANCE/XIGDUO XR ONLY:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms

D. CHRONIC KIDNEY DISEASE – FARXIGA ONLY

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by stabilization of eGFR, or decline of eGFR <50% from pre-treatment
   AND
4. Documentation the member has not progressed to end stage renal disease (ESRD) requiring dialysis
   AND
5. Documentation of concurrent use or FDA labeled contraindication of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)

DURATION OF APPROVAL:
Step Therapy: Initial Authorization: 12 months, Continuation of Therapy: N/A
All other indications: Initial Authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
Victoza, Bydureon BCise, Trulicity, Jardiance, Synjardy: 10 years of age and older
Farxiga, Invokana, Xigduo XR for type 2 diabetes only: 10 years of age and older
All others: 18 years of age and older

QUANTITY:
Bydureon: 4 pens per 28 days
Byetta: 1 pen per month (30 days)
Ozempic: 3 mL per 28 days
Rybelsus: 1 tablet per day of any strength
Trulicity: 2mL per 28 days
Victoza: 9mL per 30 days
Soliqua: 5 pens per 30 days
Xultophy: 5 pens per 30 days
Mounjaro: maximum of 15mg/week, 4 pens per 28 days
All others: Formulary limit (if applicable) and maximum quantity limits per FDA label

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Subcutaneous

DRUG CLASS:
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors, Dipeptidyl Peptidase-4 Inhibitor-Biguanide Combinations, DPP-4 Inhibitor-Thiazolidinedione Combinations, Incretin Mimetic Agents (GIP & GLP-1 Receptor Agonists), Incretin Mimetic Agents (GLP-1 Receptor Agonists), Insulin-Incretin Mimetic Combinations, Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors, SGLT2 Inhibitor - DPP-4 Inhibitor - Biguanide Combination, SGLT2 Inhibitor - DPP-4 Inhibitor Combinations, Sodium-Glucose Co-Transporter 2 Inhibitor-Biguanide Combination

FDA-APPROVED USES:
Adlyxin (lixisenatide), Soliqua (insulin glargine and lixisenatide), Xultophy (insulin degludec and liraglutide):

- 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. Not for treatment of type 1 diabetes. Has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.
Limitations of use (Soliqua): Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. Not recommended for use in combination with any other product containing a GLP-1 receptor agonist. Not for treatment of type 1 diabetes mellitus

or diabetic ketoacidosis. Not recommended for use in patients with gastroparesis. Has not been studied in combination with prandial insulin.
Limitations of use (Xultophy): Not recommended as first-line therapy for patients inadequately controlled on diet and exercise. Not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist. Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Has not been studied in combination with prandial insulin.

Brenzavvy (bexagliflozin) is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

Bydureon (exenatide) 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: Not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise. Not indicated to treat type 1 diabetes mellitus. Bydureon BCise is an extended-release formulation of exenatide and should not be used with other exenatide-containing products. Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

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: Should not be used for the treatment of type 1 diabetes. Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

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 with reduced ejection fraction (NYHA class II-IV).
- 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: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. 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 m2. Farxiga is likely to be ineffective in this setting based upon its mechanism of action. 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 the treatment of kidney disease. Farxiga is not expected to be effective in these populations.

Glyxambi (empagliflozin/linagliptin), Trijardy XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets):

- 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: 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. Additional limitation of use for Glyxambi: 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.

Invokamet (canagliflozin/metformin), Invokamet XR (canagliflozin/metformin extended-release):

- 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 in adults with type 2 diabetes mellitus and established cardiovascular disease
- Canagliflozin is indicated to reduce the risk 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 albuminuria

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

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 in adults with type 2 diabetes mellitus and established cardiovascular disease
- to reduce the risk 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 albuminuria

Limitations of use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. 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 m2.

Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended- release), Januvia (sitagliptin), Kazano (alogliptin/metformin), Nesina (alogliptin), Onglyza (saxagliptin), Oseni (alogliptin/pioglitazone), Zituvimet (sitagliptin/metformin), Zituvio (sitagliptin) are indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of use: Should not be used in patients with type 1 diabetes.
Additional limitation for Onglyza (saxagliptin): Not used for treatment of diabetic ketoacidosis.
Additional limitation for Januvia (sitagliptin), Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release), Zituvimet (sitagliptin/metformin), Zituvio (sitagliptin): Has not been studied in patients with a history of pancreatitis.

Jardiance (empagliflozin) is indicated:

- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA Class II-IV).
- 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.

Limitations of Use: 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. 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 m2. 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.

Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended- release), Tradjenta (linagliptin) are indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of use (Jentadueto, Jentadueto XR): Not for treatment of type 1 diabetes. Has not been

studied in patients with a history of pancreatitis.
Limitations of use (Tradjenta): Should not be used in patients with type 1 diabetes. Has not been studied in patients with a history of pancreatitis.

Kombiglyze (saxagliptin/metformin) is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

Limitations of use: Not recommended for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

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

Limitations of use: Has not been studied in patients with a history of pancreatitis. Is not indicated for use in patients with type 1 diabetes mellitus.

Ozempic (semaglutide), Rybelsus (semaglutide) are indicated:
- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (both)
- to reduce the risk of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (Ozempic only).
- 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 (Ozempic only)

Limitations of use: Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy. Not for treatment of type 1 diabetes mellitus.

Qtern (dapagliflozin/saxagliptin) 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.

Segluromet (ertugliflozin/metformin), Steglatro (ertugliflozin), Steglujan (ertugliflozin/sitagliptin) are indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of use (Segluromet, Steglatro): Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Limitations of use (Steglujan): Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus Has not been studied in patient with a history of pancreatitis.

Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended-release) are 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
- Empagliflozin when used as a component of Synjardy and Synjardy XR is indicated in adults with type 2 diabetes mellitus to reduce the risk of cardiovascular death in adults with established cardiovascular disease and cardiovascular death and hospitalization for heart failure in adults with heart failure

Limitations of use: Not recommended for use in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Because of the metformin component, Synjardy and Synjardy XR are not recommended for use in patients with heart failure without type 2 diabetes mellitus.

Trulicity (dulaglutide) 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, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of use: Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in these patients. Not for treatment of type 1 diabetes mellitus. Not recommended in patients with severe gastrointestinal disease, including severe gastroparesis.

Victoza (liraglutide) is indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years and older with type 2 diabetes mellitus
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of use: Not for treatment of type 1 diabetes. Should not be coadministered with other liraglutide-containing products.

Xigduo XR (dapagliflozin and metformin) 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
- 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
- in adults with type 2 diabetes mellitus to reduce the risk of Cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in patients with heart failure
- in adults with type 2 diabetes mellitus to reduce the risk of Hospitalization for heart failure in patients with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors

Limitations of use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. Because of the metformin HCl component, the use of Xigduo XR is limited to patients with type 2 diabetes mellitus for all indications. 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 the treatment of kidney disease. Xigduo XR is not expected to be effective in these populations.

Weight loss is excluded from coverage per Social Security 1927(d)(2)(A)
A State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is contained in the list:

- ***Agents when used for anorexia, weight loss, or weight gain.***
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Agents when used to promote smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

COMPENDIAL APPROVED OFF-LABELED USES:

Jardiance (empagliflozin) ONLY- Diabetic kidney disease

APPENDIX

APPENDIX:

Appendix 1:

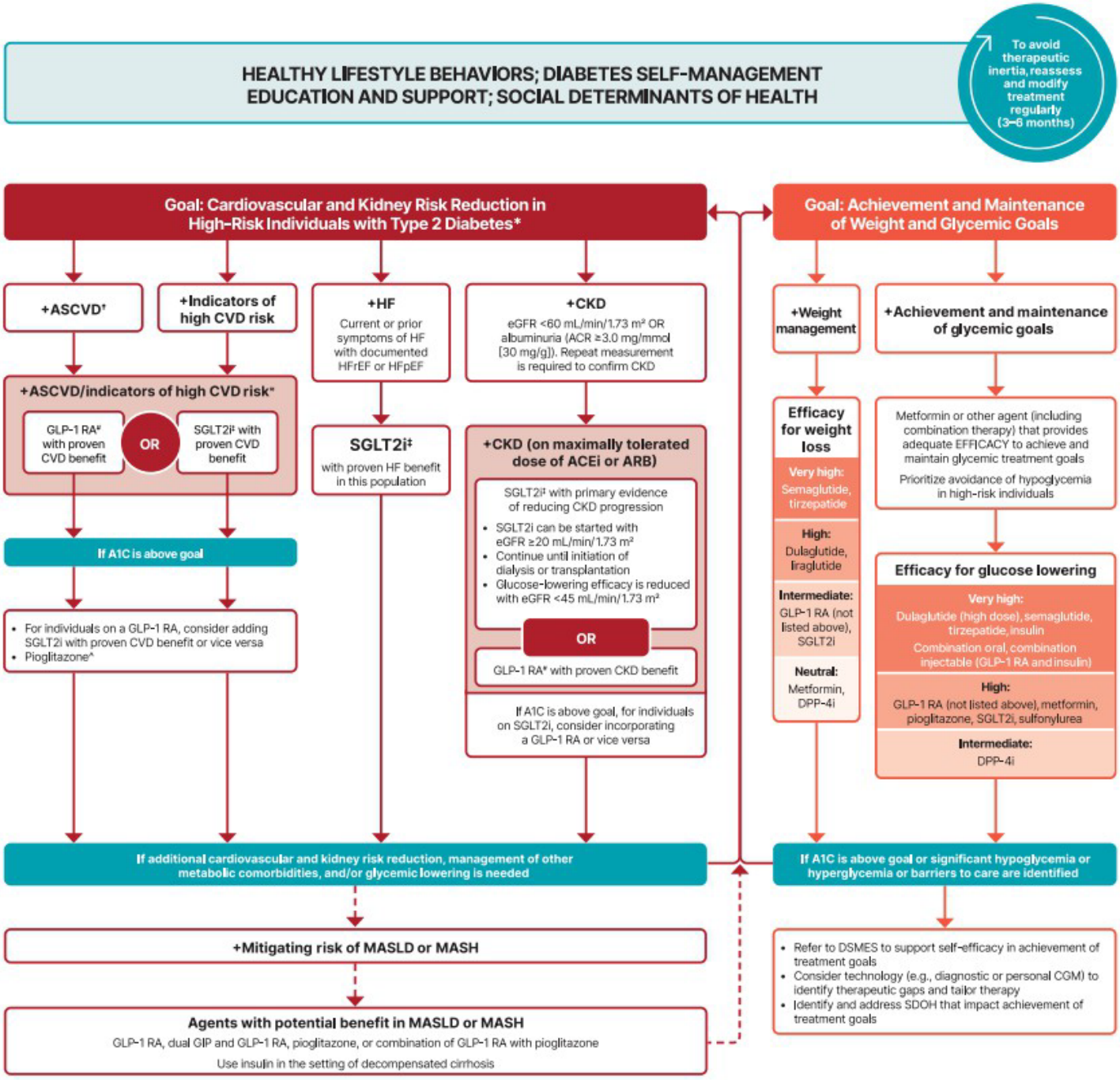
Reference: Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2025. Diabetes Care 2025;48 (Suppl. 1): S181-S206

When A1C is ≥ 1.5% above the individualized glycemic goal, many individuals will require dual combination therapy or a more potent glucose-lowering agent to achieve and maintain their goal A1C level. Insulin should be considered as part of any combination medication plan when hyperglycemia is severe, especially if catabolic features (weight loss, hypertriglyceridemia, ketosis) are present. It is common practice to initiate insulin therapy for people who present with blood glucose levels ≥ 300 mg/dL or A1C >10% or if the individual has symptoms of hyperglycemia (i.e., polyuria or polydipsia) or evidence of catabolism (unexpected weight loss). As glucose toxicity resolves, simplifying the medication plan and/or changing to noninsulin agents is possible. Additionally, there is evidence that people with type 2 diabetes and severe hyperglycemia can also be effectively treated with a sulfonylurea, GLP-1 RA, or dual GIP and GLP-1 RA, though evidence is scarce for individuals with baseline A1C above 10–12%. GLP-1 RAs and tirzepatide have additional benefits over insulin and sulfonylureas, specifically lower risks for hypoglycemia (both) and favorable weight (both), cardiovascular (GLP-1 RAs, and liver (both) end points.
Combination therapy: Because type 2 diabetes is a progressive disease, maintenance of glycemic goals often requires combination therapy. Traditional recommendations have called for the use of stepwise addition of medications to metformin to maintain A1C goals. The advantage of this is to provide a clear assessment of the positive and negative effects of new drugs and reduce potential side effects and expense. However, some data support initial combination therapy for more rapid attainment of glycemic goals and later combination therapy for longer durability of glycemic effect. Initial combination therapy should be considered in people presenting with A1C levels 1.5-2.0% above their individualized goal.

Appendix 2:

Reference: Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2025 Diabetes Care 2025;48 (Suppl. 1): S181-S206

Use of Glucose-Lowering Medications in the Management of Type 2 Diabetes



Appendix 3:

Reference: Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Medical Care in Diabetes 2025. Diabetes Care 2025; 48 (Suppl. 1): S59-S85.
Glycemic Goals and Hypoglycemia: Standards of Medical Care in Diabetes 2025. Diabetes Care 2025; 48 (Suppl. 1): S128-S145.

The goals of treatment for diabetes are to prevent or delay complications and optimize quality of life. Treatment goals and plans should be created by the care team and people with diabetes based on their individual preferences, values, and goals. This individualized management plan should take into account the patient's age, cognitive abilities, school/work schedule and conditions, health beliefs, support systems, eating patterns, physical activity, social situation, financial concerns, cultural factors, literacy and numeracy (mathematical literacy), diabetes history (duration, complications, and current use of medications), comorbidities, disabilities, health priorities, other medical conditions, preferences for care, access to health care services, and life expectancy.
Part of the assessment and treatment plan should include goal setting that may include A1c, blood glucose, and/or time in range goals; lipid goals; blood pressure goals if hypertension is present; weight management and physical activity goals; and diabetes self-management goals. A therapeutic treatment plan may include lifestyle management, pharmacologic therapy for glucose lowering and other risk factor mitigation, use of glucose monitoring and devices, and meeting with diabetes educators.
A goal of glycemic management is to prevent the microvascular and macrovascular complications of diabetes. The ADA proposes general goals but emphasizes the importance of individual goals based on key patient characteristics.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Per American Diabetes Association (ADA) 2024 guidelines, metformin is the preferred initial pharmacologic agent for the treatment of type 2 diabetes. Once initiated, metformin should be continued as long as it is tolerated and not contraindicated; other agents, including insulin, should be added to metformin. Early combination therapy can be considered in some patients at treatment initiation to extend the time to treatment failure. The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (≥300mg/dL [16.7mmol/L]) are very high. A patient-centered approach should be used to guide the choice of pharmacologic agents. Considerations include effect on cardiovascular and renal comorbidities, efficacy, hypoglycemia risk, impact on weight, cost, risk for side effects, and patient preferences. Among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease or indicators of high risk, established kidney disease, or heart failure, a sodium– glucose cotransporter 2 inhibitor or glucagon- like peptide 1 receptor agonist with demonstrated cardiovascular disease benefit is recommended as part of the glucose-lowering regimen independent of A1C and in consideration of patient-specific factors. In patients with type 2 diabetes, a glucagon-like peptide 1 receptor agonist (GLP-1 RA), including a dual glucose dependent insulinotropic polypeptide and GLP-1 RA, is preferred to insulin when possible. Recommendation for treatment intensification for patients not meeting treatment goals should not be delayed. The medication regimen and medication-taking behavior should be reevaluated at regular intervals (every 3–6 months) and adjusted as needed to incorporate specific factors that impact choice of treatment Clinicians should be aware of the potential for over basalization with insulin therapy. Clinical signals that may prompt evaluation of over basalization include basal dose more than 0.5 IU/ kg, high bedtime-morning or post-preprandial glucose differential, hypoglycemia (aware or unaware), and high variability. Indication of over basalization should prompt reevaluation to further individualize therapy.

The ADA 2025 guidelines remain largely unchanged as related to pharmacologic approach to therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of listed agents and combinations are considered experimental/investigational and

therefore, will follow Molina's Off- Label policy.
Contraindications to GLP-1 agonists or combinations include: Hypersensitivity to requested product, or any component of the formulation; history of or family history of medullary thyroid carcinoma (MTC); patients with multiple endocrine neoplasia syndrome type 2 (MEN2).
Contraindications to Alogliptin, Saxagliptin, Linagliptin, Sitagliptin include: Hypersensitivity (e.g., anaphylaxis, angioedema, exfoliative skin conditions) to the requested product or any component of the formulation.
Contraindications to SGLT2 inhibitors include severe renal impairment (see individual agent for eGFR limit), ESRD or dialysis, metabolic acidosis, history of serious hypersensitivity to drug or components of the formulations.

Exclusions/Discontinuation:
Off-label, unsupported uses include those where any positive evidence is assumed to be derived by the action of weight loss and not as a direct result of the novel GLP-1 agonist mechanism of action, as well as diagnoses related to labeled indications. Off-label, unsupported uses include, but are not limited to, the following:

- Weight loss, obesity
- Pre-diabetes
- Type 1 diabetes
- Any disorder of glucose not classified specifically as type 2 diabetes (e.g., impaired fasting glucose, hyperglycemia, impaired glucose tolerance, unspecified insulin resistance, abnormal glucose, etc.)
- Obstructive sleep apnea
- Polycystic ovary syndrome (PCOS)
- Atherosclerosis
- Heart disease
- Hypertension
- Lymphedema
- Metabolic disorder or syndrome
- Fatty liver disease
- Alcohol use disorder

Nonalcoholic steatohepatitis (NASH) or Metabolic Dysfunction-Associated Steatohepatitis (MASH) are not considered off-label supported indications at this time. Clinical trial data suggests that some agents may reduce liver fat and inflammation, but they have not achieved fibrosis resolution in a majority of patients, which is a key endpoint in this disease state. Current professional guidelines do not recommend GLP-1 agonists off-label as first line therapy. Therefore, the off-label use of GLP-1 agonists labeled for diabetes in the absence of diabetes will remain investigational until phase 3 data support a formal indication.

OTHER SPECIAL CONSIDERATIONS:
Bydureon BCise (exenatide), Mounjaro (tirzepatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), Victoza (liraglutide), Xultophy (insulin degludec and liraglutide) have a black box warning for risk of thyroid c-cell tumors.
Invokamet XR (canagliflozin/metformin extended-release), Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended- release), Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release), Kazano (alogliptin/metformin), Kombiglyze XR (saxagliptin/metformin extended-release), Synjardy (empagliflozin/metformin, Synjardy XR (empagliflozin/metformin ER), Segluromet (ertugliflozin/metformin), Xigduo XR (dapagliflozin/metformin), Zituvimet (sitagliptin/metformin) have a black box warning for lactic acidosis.
Oseni (alogliptin/pioglitazone) has a black box warning for congestive heart failure.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors & SGLT2/DPP-4 Inhibitor Combinations & SGLT2-Biguanide Combinations & SGLT2/DPP-4 Inhibitor/Biguanide Combination

Bexagliflozin 20MG
Brenzavvy TABS 20MG
Dapagliflozin 5MG, 10MG
Dapagliflozin-Metformin 5-1000MG, 10-1000MG
Farxiga TABS 10MG
Farxiga TABS 5MG
Glyxambi TABS 10-5MG
Glyxambi TABS 25-5MG
Invokamet TABS 150-1000MG
Invokamet TABS 150-500MG
Invokamet TABS 50-1000MG
Invokamet TABS 50-500MG
Invokamet XR TB24 150-1000MG
Invokamet XR TB24 150-500MG
Invokamet XR TB24 50-1000MG
Invokamet XR TB24 50-500MG
Invokana TABS 100MG
Invokana TABS 300MG
Jardiance TABS 10MG
Jardiance TABS 25MG
Qtern TABS 10-5MG
Qtern TABS 5-5MG
Segluromet TABS 2.5-1000MG
Segluromet TABS 2.5-500MG
Segluromet TABS 7.5-1000MG
Segluromet TABS 7.5-500MG
Steglatro TABS 15MG
Steglatro TABS 5MG
Steglujan TABS 15-100MG
Steglujan TABS 5-100MG
Synjardy TABS 12.5-1000MG
Synjardy TABS 12.5-500MG
Synjardy TABS 5-1000MG
Synjardy TABS 5-500MG
Synjardy XR TB24 10-1000MG
Synjardy XR TB24 12.5-1000MG
Synjardy XR TB24 25-1000MG
Synjardy XR TB24 5-1000MG
Trijardy XR TB24 10-5-1000MG
Trijardy XR TB24 12.5-2.5-1000MG
Trijardy XR TB24 25-5-1000MG
Trijardy XR TB24 5-2.5-1000MG
Xigduo XR TB24 10-1000MG
Xigduo XR TB24 10-500MG
Xigduo XR TB24 2.5-1000MG
Xigduo XR TB24 5-1000MG
Xigduo XR TB24 5-500MG

Incretin Mimetic Agents, GLP-1 Receptor Agonists, and GIP and GLP-1 Receptor Agonists, and combinations

Adlyxin SOPN 20MCG/0.2ML
Adlyxin Starter Pack PNKT 10 & 20MCG/0.2ML
Bydureon Bcise AUIJ 2MG/0.85ML
Bydureon PEN 2MG
Byetta 10 MCG Pen SOPN 10MCG/0.04ML
Byetta 5 MCG Pen SOPN 5MCG/0.02ML
Mounjaro SOPN 10MG/0.5ML
Mounjaro SOPN 12.5MG/0.5ML
Mounjaro SOPN 15MG/0.5ML
Mounjaro SOPN 2.5MG/0.5ML
Mounjaro SOPN 5MG/0.5ML
Mounjaro SOPN 7.5MG/0.5ML
Ozempic (0.25 or 0.5 MG/DOSE) SOPN 2MG/1.5ML
Ozempic (0.25 or 0.5 MG/DOSE) SOPN 2MG/3ML
Ozempic (1 MG/DOSE) SOPN 2MG/1.5ML
Ozempic (1 MG/DOSE) SOPN 4MG/3ML
Ozempic (2 MG/DOSE) SOPN 8MG/3ML
Rybelsus TABS 1.5MG, 3MG, 4MG, 7MG, 9MG, 14MG
Soliqua SOPN 100-33UNT-MCG/ML
Trulicity SOPN 0.75MG/0.5ML
Trulicity SOPN 1.5MG/0.5ML
Trulicity SOPN 3MG/0.5ML
Trulicity SOPN 4.5MG/0.5ML
Victoza SOPN 18MG/3ML
Xultophy SOPN 100-3.6UNIT-MG/ML

Dipeptidyl Peptidase-4 Inhibitors (DPP4) and Combinations

Alogliptin Benzoate TABS 6.25MG, 12.5MG, 25MG
Alogliptin-metFORMIN HCl TABS 12.5-1000MG
Alogliptin-metFORMIN HCl TABS 12.5-500MG
Alogliptin-Pioglitazone TABS 12.5-15MG
Alogliptin-Pioglitazone TABS 12.5-30MG
Alogliptin-Pioglitazone TABS 12.5-45MG
Alogliptin-Pioglitazone TABS 25-15MG
Alogliptin-Pioglitazone TABS 25-30MG
Alogliptin-Pioglitazone TABS 25-45MG
Janumet TABS 50-1000MG
Janumet TABS 50-500MG
Janumet XR TB24 100-1000MG
Janumet XR TB24 50-1000MG
Janumet XR TB24 50-500MG
Januvia TABS 25MG, 50MG, 100MG
Jentadueto TABS 2.5-1000MG
Jentadueto TABS 2.5-500MG
Jentadueto TABS 2.5-850MG
Jentadueto XR TB24 2.5-1000MG
Jentadueto XR TB24 5-1000MG
Kazano TABS 12.5-1000MG
Kazano TABS 12.5-500MG
Kombiglyze XR TB24 2.5-1000MG
Kombiglyze XR TB24 5-1000MG
Kombiglyze XR TB24 5-500MG
Nesina TABS 6.25MG, 12.5MG, 25MG
Onglyza TABS 2.5MG, 5MG
Oseni TABS 12.5-15MG
Oseni TABS 12.5-30MG
Oseni TABS 12.5-45MG
Oseni TABS 25-15MG
Oseni TABS 25-30MG
Oseni TABS 25-45MG
sAXagliptin HCl TABS 2.5MG, 5MG
sAXagliptin-metFORMIN ER TB24 2.5-1000MG, 5-1000MG, 5-500MG
Tradjenta TABS 5MG
Zituvio TABS 25MG, 50MG, 100MG
Zituvimet XR TB25 50-500MG, 50-1000MG, 100-1000MG

REFERENCES

1. Jardiance (empagliflozin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; September 2023.
2. Farxiga (dapagliflozin) tablets, for oral use [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2024.
3. Steglatro (ertugliflozin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; December 2024.

4. Invokana (canagliflozin) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; December 2024
5. Synjardy XR (empagliflozin/metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October 2023.
6. Synjardy (empagliflozin/metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October 2023.
7. Segluromet (ertugliflozin/metformin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corporation; December 2024.
8. Xigduo XR (dapagliflozin and metformin) [prescribing information]. Wilmington, DE: AstraZeneca; December 2024.
9. Glyxambi (empagliflozin/linagliptin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; October 2023.
10. Qtern (dapagliflozin/saxagliptin) [prescribing information]. Wilmington, DE; AstraZeneca Pharmaceuticals; November 2024
11. Steglujan (ertugliflozin/sitagliptin) [prescribing information]. Whitehouse Station, NJ; Merck Sharp & Dohme Corp: December 2024.
12. Janumet (sitagliptin and metformin) tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; July 2022.
13. Janumet XR (sitagliptin and metformin) extended-release tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; July 2022.
14. Januvia (sitagliptin) [prescribing information] Whitehouse Station, NJ: Merck & Co Inc; July 2023.
15. Jentadueto (linagliptin and metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; June 2023.
16. Jentadueto XR (linagliptin and metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; June 2023.
17. Kazano (alogliptin and metformin) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; July 2023.
18. Kombiglyze XR (saxagliptin/metformin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October2024.
19. Nesina (alogliptin) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; July 2023.
20. Onglyza (saxagliptin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2024.
21. Oseni (alogliptin and pioglitazone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; June 2024.
22. Tradjenta (linagliptin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; June 2023.
23. Adlyxin (lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; June 2022.
24. Bydureon (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; May 2023.
25. Bydureon Bcise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024
26. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024.
27. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2024 .
28. Soliqua (insulin glargine/lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis USLLC; November 2024.
29. Xultophy (insulin degludec and liraglutide) [prescribing information]. Plainsboro, NJ: NovoNordisk; November 2024.
30. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2024.
31. Brenzavvy (bexagliflozin) tablets [prescribing information]. Marlborough, MA: TherascosBio,:LLC; February 2024.
32. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; December 2024.
33. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2024.
34. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2024.
35. Trijardy XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets) [prescribing

information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc.; October 2023.
36. Invokamet (canagliflozin/metformin) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
37. Invokamet XR (canagliflozin/metformin extended-release) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2024.
38. Zituvio (sitagliptin) tablets, for oral use [prescribing information]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; January 2025.
39. Zituvimet (sitagliptin and metformin hydrochloride) tablets, for oral use [prescribing information]. Pharmez, Matoda, Ahmedabad, India: Zydus Lifesciences Ltd.; July 2024.
40. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 37. (Diabetes Care 2018; 41: S73-S85).
41. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2022. Diabetes Care, 45(Supplement 1). https://diabetesjournals.org/care/issue/45/Supplement_1
42. Berg DD, Wiviott SD, Scirica BM, Gurmu Y, Mosenzon O, Murphy SA, Bhatt DL, Leiter LA, McGuire DK, Wilding JPH, Johanson P, Johansson PA, Langkilde AM, Raz I, Braunwald E, Sabatine MS. Heart Failure Risk Stratification and Efficacy of Sodium-Glucose Cotransporter-2 Inhibitors in Patients With Type 2 Diabetes Mellitus. Circulation. 2019 Nov 5;140(19):1569- 1577. Doi: 10.1161/CIRCULATIONAHA.119.042685. Epub 2019 Aug 31.
43. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2023. Diabetes Care 2023; 46 (Suppl. 1): S140-S157. https://doi.org/10.2337/dc23-S009
44. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S158-S178. https://doi.org/10.2337/dc24-S009
45. Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S52-S76. https://doi.org/10.2337/dc24-S004
46. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S111-S125. https://doi.org/10.2337/dc24-S006
47. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2025. Diabetes Care 2025; 48 (Suppl. 1): S181-S206. https://doi.org/10.2337/dc25-S009
48. Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Care in Diabetes – 2025. Diabetes Care 2025; 48 (Suppl. 1): S59-S85. https://doi.org/10.2337/dc25-S004
49. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes – 2025. Diabetes Care 2025; 48 (Suppl. 1): S128-S145. doi:https://doi.org/10.2337/dc25-S006

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable Revisions: Contraindications/Exclusions/Discontinuation	Q4 2025
REVISION- Notable Revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions FDA-Approved Uses Appendix Contraindications/Exclusions/ Discontinuation Available Dosage Forms References	Q2 2025

REVISION- Notable Revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Drug Class Appendix Background Available Dosage Forms References	Q2 2024
REVISION- Notable Revisions: Products Affected FDA-Approved Uses Available Dosage Forms References	Q4 2023
REVISION- Notable Revisions: Age Restrictions FDA-Approved Uses References	Q3 2023
REVISION- Notable Revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Age Restrictions FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q2 2023
REVISION- Notable Revisions: Products Affected Quantity DrugClass FDA-Approved Uses Available Dosage Forms References	Q3 2022
REVISION- Compendial Approved Off-Labeled Uses References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file