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Policy Number: C21858-A

## Antidiabetic Agents IL Medicaid Only

### PRODUCTS AFFECTED

#### SINGLE AGENTS:

ADLYXIN (lixisenatide), alogliptin, BYDUREON BCISE (exenatide), BYDUREON (exenatide) BYETTA (exenatide), Fortamet (metformin ER OSM 24HR), Glumetza (metformin ER MOD 24HR), metformin ER (MOD), metformin ER (OSM), NESINA (alogliptin), ONGLYZA (saxagliptin), OZEMPIC (semaglutide), PRANDIN (repaglinide), repaglinide, Riomet Solution (metformin), Riomet ER Suspension (metformin), RYBELSUS (semaglutide), STARLIX (nateglinide), STEGLATRO (ertugliflozin)

#### COMBINATION AGENTS:

ACTOPLUS MET (pioglitazone-metformin), ACTOPLUS MET XR (pioglitazone-metformin), alogliptin-metformin, alogliptin-pioglitazone, DUETACT (pioglitazone-glimepiride), GLYXAMBI (empagliflozin / linagliptin), INVOKAMET (canagliflozin/metformin), INVOKAMET XR (canagliflozin/metformin), 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), OSENI (alogliptin/pioglitazone), pioglitazone-glimepiride, pioglitazone-metformin, QTERN(dapagliflozin/saxagliptin), repaglinide-metformin, SEGLUROMET (ertugliflozin/metformin), SOLIQUA (Insulin Glargine-Lixisenatide), STEGLUJUAN (ertugliflozin/sitagliptin), SYNJARDY (empagliflozin / metformin HCl), SYNJARDY XR (empagliflozin / metformin HCl), TRIJARDY XR (empagliflozin/linagliptin/metformin), XIGDUO XR (dapagliflozin / metformin HCl), XULTOPHY (Insulin Degludec-Liraglutide)

### 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*

## Drug and Biologic Coverage Criteria

### **DIAGNOSIS:**

Type 2 Diabetes

### **REQUIRED MEDICAL INFORMATION:**

#### **A. ALL INDICATIONS**

1. Prescriber attests (or the clinical reviewer has found) that the requested drug has been prescribed for the management of type 2 diabetes  
AND
2. Prescriber attests to (or the clinical reviewer has found) 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, sitagliptins include: Hypersensitivity (e.g., anaphylaxis, angioedema, exfoliative skin conditions) to the request product or any component of the formulation. Contraindications to SGLT2 inhibitors include severe renal impairment, ESRD or dialysis, history of serious hypersensitivity to drug or components of the formulations. Contraindications to repaglinide include diabetic ketoacidosis, Type 1 diabetes, co-administration of gemfibrozil and known hypersensitivity to the drug or its inactive ingredients. Contraindications to nateglinide include known hypersensitivity to the drug or its inactive ingredients. Contraindications to metformin includes severe renal impairment (eGFR below 30 mL/min/1.73 m<sup>2</sup>), hypersensitivity to metformin, acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Contraindications to pioglitazone include use in patients with established NYHA Class III or IV heart failure.]  
AND
3. Documentation of member's current glycemic status (e.g., A1C or other glycemic measurement)  
AND
4. NON-PREFERRED SINGLE AGENT Metformin Products: Documentation of a trial and failure of all preferred metformin products.  
AND
5. FOR SINGLE AGENTS- NON-FORMULARY/NON-PREFERRED AGENTS: Member has had an inadequate response, intolerance, or contraindication to an ALL FORMULARY/PREFERRED agents within the same class.  
AND
6. FOR COMBINATION PRODUCTS NON-FORMULARY/NON-PREFERRED AGENTS:  
Documentation that member has had an inadequate response to formulary preferred single agents in the matching classes (SGLT2/GLP1/DPP4) within the combination product.  
[MOLINA REVIEWER NOTE: For example, for requests for Janumet, member would have had an inadequate response to Januvia and metformin used as separate agents.]  
AND
7. FOR NON-PREFERRED BRAND NAME requests: Documentation that member has tried and failed the generic equivalent, if available, on the preferred drug list.

### **CONTINUATION OF THERAPY:**

#### **A. ALL INDICATIONS:**

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history  
AND

## Drug and Biologic Coverage Criteria

2. Documentation of no intolerable adverse effects or drug toxicity  
AND
3. Documentation of positive clinical response as demonstrated by improvement in member's glycemic targets (e.g., hemoglobin A1C)

### **DURATION OF APPROVAL:**

Initial authorization: 12 months, Continuation of Therapy: 12 months

### **PRESCRIBER REQUIREMENTS:**

None

### **AGE RESTRICTIONS:**

Bydureon/Bydureon BCise, metformin: 10 years and older All Other Agents: 18 years or older

**QUANTITY:** See Illinois Medicaid Drug Formulary or use maximum quantity per FDA label

**Maximum Quantity Limits – Per FDA label**

### **PLACE OF ADMINISTRATION:**

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

## **DRUG INFORMATION**

### **ROUTE OF ADMINISTRATION:**

Oral, Subcutaneous

### **DRUG CLASS:**

- \*Biguanides\*\*
- \*Incretin Mimetic Agents (GLP-1 Receptor Agonists)\*\*\*
- \*Meglitinide Analogues\*\*\*
- \*Dipeptidyl Peptidase-4 (DPP-4) Inhibitors\*\*\*
- \*Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors\*\*\*
- \*Insulin-Incretin Mimetic Combinations\*\*\*
- \*Dipeptidyl Peptidase-4 Inhibitor-Biguanide Combinations\*\*\*
- \*DPP-4 Inhibitor-Thiazolidinedione Combinations\*\*\*
- \*Meglitinide-Biguanide Combinations\*\*\*
- \*Sodium-Glucose Co-Transporter 2 Inhibitor-Biguanide Comb\*\*\*
- \*SGLT2 Inhibitor - DPP-4 Inhibitor Combinations\*\*\*
- \*SGLT2 Inhibitor - DPP-4 Inhibitor - Biguanide Comb\*\*\*
- \*Sulfonylurea-Biguanide Combinations\*\*\*
- \*Sulfonylurea-Thiazolidinedione Combinations\*\*\*
- \*Thiazolidinedione-Biguanide Combinations\*\*\*

### **FDA-APPROVED USES:**

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

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

## Drug and Biologic Coverage Criteria

mellitus.

*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.*

*Limitations of use (Jentadueto, Jentadueto XR): Not for treatment of type 1 diabetes. Has not been studied in patients with a history of pancreatitis.*

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

- 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): Has not been studied in patient with a history of pancreatitis.*

Kombiglyze (saxagliptin/metformin):

- 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 use for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.*

Adlyxin (lixisenatide), Xultophy (insulin degludec and liraglutide), Soliqua (insulin glargine and lixisenatide)

- 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 (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.*

*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.*

Trulicity (dulaglutide)

- 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.*

Bydureon (exenatide):

- As an adjunct to diet and exercise to improve glycemic control in adults (immediate release and extended release) and pediatric patients aged 10 years and older (extended release only) with type 2 diabetes mellitus.

*Limitations of use: Not recommended as first-line therapy for patients who have inadequate glycemic*

## Drug and Biologic Coverage Criteria

*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)

- 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.*

### Victoza (liraglutide)

- As an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus; to reduce the risk of major adverse cardiovascular events (cardiovascular death, 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.*

### Ozempic (semaglutide), Rybelsus (semaglutide):

- 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).

*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.*

### Mounjaro (tirzepatide)

- 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.*

### Farxiga (dapagliflozin):

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV).
- to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression

*Limitations of use: Not for treatment of type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m<sup>2</sup>. 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.*

### Xigduo XR (dapagliflozin and metformin):

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

## Drug and Biologic Coverage Criteria

- to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors
- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction
- to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression

*Limitations of use: Not for treatment of type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes 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.*

### Qtern (dapagliflozin/saxagliptin):

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

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

### Invokana (canagliflozin):

- 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 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 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 adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m<sup>2</sup>.*

### 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.*

### Jardiance (empagliflozin):

- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
- to reduce the risk of cardiovascular death in 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.

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*Limitations of Use: Not recommended 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 adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m<sup>2</sup>.*

Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended-release):

- 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.*

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 m<sup>2</sup>.*

Steglatro (ertugliflozin), Segluromet (ertugliflozin/metformin), Steglujan (ertugliflozin/sitagliptin)

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

*Limitations of Use (Steglatro): Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.*

*Limitations of use (Segluromet): Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. It may increase the risk of diabetic ketoacidosis in these patients.*

*Limitations of Use (Steglujan): Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. It may increase the risk of diabetic ketoacidosis in these patients. Has not been studied in patient with a history of pancreatitis.*

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

## Drug and Biologic Coverage Criteria

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

### COMPENDIAL APPROVED OFF-LABELED USES:

N/A

## APPENDIX

### APPENDIX:

#### Appendix 1:

Reference: Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2023. Diabetes Care 2023;46 (Suppl. 1): S140-S157

When A1C is  $\geq 1.5\%$  above the glycemic target, many individuals will require dual combination therapy or a more potent glucose-lowering agent to achieve and maintain their target A1C level. Insulin has the advantage of being effective where other agents are not and should be considered as part of any combination regimen 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 in the individual has symptoms of hyperglycemia (i.e., polyuria or polydipsia) or evidence of catabolism (weight loss). As glucose toxicity resolves, simplifying the regimen and/or changing to noninsulin agents is often possible. However, there is evidence that people with uncontrolled hyperglycemia associated with type 2 diabetes can also be effectively treated with a sulfonylurea.

Combination therapy: Traditional recommendations have been to use stepwise addition of medications to metformin to maintain A1C at target. However, there are data to support initial combination therapy with dipeptidyl peptidase 4 (DPP-4) inhibitor and metformin. The VERIFY (Vildagliptin Efficacy in combination with metformin For early treatment of type 2 diabetes) trial demonstrated that initial combination therapy is superior to sequential addition of medications for extending primary and secondary failure. In the VERIFY trial, participants receiving the initial combination of metformin and the DPP-4 inhibitor vildagliptin had a slower decline of glycemic control compared with metformin alone and with vildagliptin added sequentially to metformin. These results have not been generalized to oral agents other than vildagliptin, but they suggest that more intensive early treatment has some benefits and should be considered through a shared decision making process, as appropriate. Initial combination therapy should be considered in people presenting with A1C levels 1.5-2.0% above target.

#### Appendix 2:

Reference: Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2023 Diabetes Care 2023;46 (Suppl. 1): S140-S157



## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

Per American Diabetes Association (ADA) 2021 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 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.

### 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, Sitagliptins 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.

### OTHER SPECIAL CONSIDERATIONS:

Victoza (liraglutide), Bydureon BCise (exenatide), Xultophy (insulin degludec and liraglutide), Trulicity (dulaglutide), Ozempic (semaglutide), Rybelsus (semaglutide), Mounjaro (tirzepatide) have a black box warning for risk of thyroid c-cell tumors.

Synjardy (empagliflozin/metformin, Synjardy XR (empagliflozin/metformin ER), Segluromet (ertugliflozin/metformin), 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), Invokamet (canagliflozin/metformin), Invokamet XR (canagliflozin/metformin extended-release) have a black box warning for lactic acidosis.

Oseni (alogliptin/pioglitazone) has a black box warning for congestive heart failure.

**CODING/BILLING INFORMATION**

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

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**

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

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

Adlyxin SOPN 20MCG/0.2ML	Mounjaro SOPN 15MG/0.5ML
Adlyxin Starter Pack PNKT 10 & 20MCG/0.2ML	Mounjaro SOPN 2.5MG/0.5ML
Bydureon BCise AUIJ 2MG/0.85ML	Mounjaro SOPN 5MG/0.5ML
Bydureon PEN 2MG	Mounjaro SOPN 7.5MG/0.5ML
Byetta 10 MCG Pen SOPN 10MCG/0.04ML	Ozempic (0.25 or 0.5 MG/DOSE) SOPN
Byetta 5 MCG Pen SOPN 5MCG/0.02ML	2MG/1.5ML Ozempic (0.25 or 0.5 MG/DOSE)
Mounjaro SOPN 10MG/0.5ML	SOPN 2MG/3ML
Mounjaro SOPN 12.5MG/0.5ML	

## Drug and Biologic Coverage Criteria

Ozempic (1 MG/DOSE) SOPN 2MG/1.5ML Ozempic  
(1 MG/DOSE) SOPN 4MG/3ML Ozempic (2  
MG/DOSE) SOPN 8MG/3ML  
Rybelsus TABS 14MG Rybelsus  
TABS 3MG Rybelsus TABS 7MG  
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 12.5MG  
Alogliptin Benzoate TABS 25MG  
Alogliptin Benzoate TABS 6.25MG  
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 100MG  
Januvia TABS 25MG  
Januvia TABS 50MG  
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 12.5MG  
Nesina TABS 25MG  
Nesina TABS 6.25MG  
Onglyza TABS 2.5MG  
Onglyza TABS 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  
Tadjenta TABS 5MG

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## Drug and Biologic Coverage Criteria

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## Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
Annual updates. Removal of drugs due to stipulated language.	7/2023

Illinois Medicaid Only