VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Glucagon-Like Peptide-1 Agonists (Optional) Prior Authorization Policy
- Adlyxin® (lixisenatide subcutaneous injection – sanofi-aventis [obsolete 01/01/2023])
- Bydureon BCise® (exenatide extended-release subcutaneous injection – AstraZeneca)
- Byetta® (exenatide subcutaneous injection – AstraZeneca)
- Mounjaro® (tirzepatide subcutaneous injection – Eli Lilly)
- Ozempic® (semaglutide subcutaneous injection – Novo Nordisk)
- Rybelsus® (semaglutide tablets – Novo Nordisk)
- Trulicity® (dulaglutide subcutaneous injection – Eli Lilly)
- Victoza® (liraglutide subcutaneous injection – Novo Nordisk, generic)

REVIEW DATE: 04/10/2024; selected revision 06/05/2024, 09/18/2024 (effective 01/01/2025), and 01/29/2025

OVERVIEW

The glucagon-like peptide-1 (GLP-1) receptor agonists and the GLP-1/glucose-dependent insulinotropic polypeptide-1 (GIP) agonist addressed in this policy are indicated as adjuncts to diet and exercise to improve glycemic control in adults with **type 2 diabetes**.[1-7,13] Liraglutide, Trulicity, and Bydureon BCise are additionally indicated for type 2 diabetes in patients ≥ 10 years of age.[2,6,7] Liraglutide, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.[4,6,7] Additionally, Ozempic is indicated to reduce the risk of sustained estimated glomerular filtration decline, end-stage kidney disease, and CV death in adults with type 2 diabetes and chronic kidney disease (CKD).[4]

Guidelines

According to the American Diabetes Association Standards of Care (2025), diabetes may be diagnosed based on plasma glucose criteria, either fasting plasma glucose (FPG) ≥ 126 mg/dL or 2 hour plasma glucose (2-h PG) value ≥ 200 mg/dL during a 75-g oral glucose tolerance test (OGTT), hemoglobin A_{1c} (HbA_{1c}) ≥ 6.5%, or a random glucose ≥ 200 mg/dL accompanied by classic hyperglycemic symptoms (e.g., polyuria, polydipsia, and unexplained weight loss) or hyperglycemic crises (i.e., diabetic ketoacidosis and/or hyperglycemia hyperosmolar state).[8] Generally, FPG, 2-h PG during 75-g OGTT, and HbA_{1c} are equally appropriate for diagnostic screening.

The Standards recommend that pharmacologic therapy be guided by person-centric treatment factors including comorbid conditions, as well as treatment goals, and preferences.[8] Pharmacotherapy should be initiated at the time type 2 diabetes is diagnosed unless there are contraindications.

In adults with type 2 diabetes and established atherosclerotic CV disease (ASCVD), heart failure (HF), and/or CKD, treatment should include agents that reduce CV or kidney disease risk.[8] In individuals without ASCVD, HF, or CKD, the choice of therapy should be based on considerations of weight management, mitigation of metabolic-dysfunction associated liver disease (MASLD) or metabolic-dysfunction associated steatohepatitis (MASH) risk, and achievement and maintenance of individualized glycemic goals. In general, higher-efficacy approaches, including combination therapy, have a greater likelihood of achieving treatment goals. Weight management is a distinct treatment goal, along with glycemic management, as it has multifaceted benefits, including reduction of HbA_{1c}, reduction in hepatic steatosis, and improvement in CV risk factors.

GLP-1 agonists are broadly recognized not only for their glycemic effects but for other beneficial effects in patients with type 2 diabetes.[8] Among patients with type 2 diabetes with established ASCVD or indicators of high ASCVD risk, GLP-1 agonists with proven CV benefit (i.e., labeled indication of reducing CV disease events) or a sodium glucose co-transporter-2 (SGLT-2) inhibitor are preferred regardless of baseline metformin use.[9] In individuals with type 2 diabetes with HF with preserved ejection fraction and obesity, a GLP-1 agonist with demonstrated benefits for both glycemic management and reduction of HF-related symptoms, irrespective of HbA_{1c} is recommended (data are currently available with semaglutide [Wegovy® {semaglutide SC injection}] and tirzepatide [e.g., Mounjaro and Zepbound® {tirzepatide SC injection}]). In adults with type 2 diabetes and advanced CKD (estimated glomerular filtration rate < 30 mL/min), a GLP-1 agonist is preferred for glycemic management due to lower risk of hypoglycemia and for CV event reduction. Ozempic has a beneficial effect on ASCVD, mortality, and kidney outcomes among individuals with CKD, and therefore is a recommended first-line agent for individuals with CKD. Other GLP-1 agonists and Mounjaro may have CKD benefits, however, no dedicated kidney trials have been published.

In patients without cardiorenal risk factors described above, the GLP-1 agonists are additionally recommended in patients based on glycemic needs.[8] Metformin or other agents that provide adequate efficacy to achieve and maintain glycemic treatment goals are recommended. In general, higher efficacy approaches have a greater likelihood of achieving glycemic goals. The GLP-1 agonists, Ozempic and Trulicity [high dose] and the GLP-1/GIP agonist, Mounjaro, are among the agents considered to have "very high" efficacy for glucose lowering; the other GLP-1 agonists are considered to have "high" efficacy for glucose lowering.

Many individuals with diabetes with obesity are at high risk for developing MASLD or MASH as well as MASH cirrhosis.[8] In adults with type 2 diabetes, MASLD, and overweight or obesity, a GLP-1 agonist (i.e., liraglutide, semaglutide) or GLP-1/GIP agonist (i.e., tirzepatide) with potential benefits in MASH for glycemic management, in addition to healthy interventions for weight loss, is recommended. In adults with type 2 diabetes and MASH or those at high risk for liver fibrosis (based on non-invasive tests), pioglitazone, GLP-1 agonists, or a GLP-1/GIP agonist is preferred for glycemic management due to potential beneficial effects on MASH.

Weight management is also a treatment goal in individuals with type 2 diabetes due to multiple benefits including improved glycemic control, reduction in hepatic steatosis, and improvement in CV risk factors.[9] The choice of therapy for glycemic control should support weight management goals in those with obesity; Mounjaro and Ozempic are noted to have the highest efficacy in terms of glucose lowering and weight loss, followed by Trulicity, liraglutide, and Bydureon BCise. Additional weight management approaches, alone or in combination, should be used if needed to achieve an individual's weight loss goals (i.e., intensive behavioral therapy, weight loss pharmacotherapy, or metabolic surgery).

American Association of Clinical Endocrinologists statement on the comprehensive care for type 2 diabetes (2023) provides principles for the management of type 2 diabetes.[11] In patients with type 2 diabetes and established ASCVD or at high risk for ASCVD, GLP-1 agonists and SGLT-2 inhibitors are recommended. In a patient with type 2 diabetes and established ASCVD or are at high risk, a GLP-1 agonist with proven CV benefit (liraglutide, Ozempic, Trulicity) should be initiated as a first-line therapy independent of the glycemic goal or other antihyperglycemic treatments, including metformin; SGLT-2 inhibitors are an alternative. In patients with type 2 diabetes and ASCVD or at high risk of ASCVD use of a GLP-1 agonist is also recommended to reduce the risk of stroke. To reduce the risk of progression of diabetic kidney disease and CV disease in patients with type 2 diabetes, SGLT-2 inhibitors are recommended; GLP-1 agonists are also an option to reduce progression of albuminuria, renal function decline, and ASCVD risk in individuals with type 2 diabetes and diabetic kidney disease (Ozempic and Trulicity are cited). For patients with type 2 diabetes but without established or high risk for ASCVD, heart failure, stroke, or CKD,

metformin should be the initial therapy unless contraindicated. In patients who are overweight or obese, the following therapies are recommended and listed in order of preference: Mounjaro, GLP-1 agonists, and SGLT-2 inhibitors. In patients with a history of hypoglycemia, at high risk of hypoglycemia, or at risk of severe complications from hypoglycemia, recommended therapies (in order of preference) are: GLP-1 agonists, SGLT-2 inhibitors, Mounjaro, thiazolidinediones, and dipeptidyl peptidase-4 inhibitors.

Kidney Diseases Improving Global Outcomes 2024 guidelines for the clinical evaluation and management of CKD recommend a long-acting GLP-1 agonist (prioritizing agents with documented CV benefits) in adults with type 2 diabetes and CKD who have not achieved individualized glycemic targets despite use of metformin and an SGLT-2 inhibitors, or who are unable to take those medications.[12]

A report of the American College of Cardiology and American Heart Association (2024) recommends GLP-1 agonists (liraglutide, Ozempic) and SGLT-2 inhibitors to reduce the risk of major adverse CV events in adults with type 2 diabetes and peripheral arterial disease.[14]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of the GLP-1 agonists and the GLP-1/GIP agonist targeted in this policy. Of note, Saxenda® (liraglutide subcutaneous injection), Wegovy® (semaglutide subcutaneous injection), and Zepbound® (tirzepatide subcutaneous injection) are not indicated for the treatment of diabetes are not indicated for the treatment of diabetes and are not targeted in this policy. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Type 2 Diabetes Mellitus.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** If the request is for Adlyxin, Byetta, Mounjaro, Ozempic, Rybelsus: Approve if the patient is ≥ 18 years of age; OR
   - **B)** If the request is for Bydureon BCise, Trulicity, Victoza, liraglutide: Approve if the patient is ≥ 10 years of age.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage is not recommended in the following situations:

1. **Weight Loss Treatment**. Saxenda (liraglutide subcutaneous injection) contains the same chemical entity as liraglutide (Victoza, generic) and is indicated at a higher dose for chronic weight management. Wegovy (semaglutide subcutaneous injection) contains the same chemical entity as Ozempic and is indicated at a higher dose for chronic weight management. Zepbound (tirzepatide subcutaneous injection) contains the same chemical entity as Mounjaro and is indicated at the same doses for chronic weight management. Endocrine Society guidelines for pharmacological management of obesity (2015) advise against off-label prescribing of medications such as glucagon-like peptide-1 (GLP-1) receptor agonists for the sole purpose of producing weight loss.[9] The American Gastroenterology Association guidelines for pharmacological interventions for adults with obesity only provide recommendations for the GLP-1 agonists approved for weight loss (i.e., Saxenda and Wegovy).[11] The GLP-1 agonists and GLP-1/glucose-dependent insulinotropic polypeptide agonist in this policy are not FDA-approved for weight loss in a patient who is overweight (body mass index [BMI] $\geq$ 27 kg/m^2) or obese (BMI $\geq$ 30 kg/m^2) without type 2 diabetes. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.

2. **Type 1 Diabetes Mellitus.** None of the glucagon-like peptide-1 (GLP-1) agonists or the GLP-1/ glucose-dependent insulinotropic polypeptide agonist are indicated in a patient with type 1 diabetes.[1-7] Addition of GLP-1 receptor agonists to insulin therapy resulted in small (0.2%) reductions in hemoglobin A_{1c} among patients with type 1 diabetes compared with insulin alone.[8]

3. **Prediabetes/Diabetes Prevention.** GLP-1 agonists and the GLP-1/ glucose-dependent insulinotropic polypeptide agonist are not indicated in a patient with elevated blood glucose who does not have type 2 diabetes. The American Diabetes Association Standards of Care (2025) recommend consideration of metformin for the prevention of type 2 diabetes in adults at high risk of type 2 diabetes, and in individuals with prior gestational diabetes mellitus. First-line recommendations to prevent or delay type 2 diabetes are lifestyle and behavioral modification (e.g., nutrition, physical activity, sleep).[8] Further, metformin has the longest history of safety data as a pharmacologic therapy for diabetes prevention. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.

4. **Metabolic Syndrome.** The glucagon-like peptide-1 (GLP-1) agonists and the GLP-1/glucose-dependent insulinotropic polypeptide agonist are not indicated in a patient with metabolic syndrome who does not have type 2 diabetes. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.

5. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonist.** The GLP-1 agonists and the GLP-1/GIP agonist should not be combined with each other or with any other GLP-1 agonists or GLP-1/GIP agonist. There are other GLP-1 and GLP-1/GIP products not included in this policy that are FDA-approved for weight loss and are not indicated for type 2 diabetes. Note: Examples of other GLP-1 agonists not included in this policy include but are not limited to Saxenda (liraglutide subcutaneous injection) and Wegovy (semaglutide subcutaneous injection). An example of a GLP-1/GIP agonist not included in this policy is Zepbound (tirzepatide subcutaneous injection).

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Adlyxin® subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; September 2023.
2. Bydureon BCise® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
3. Byetta® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
4. Ozempic® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2025.
5. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2024.
6. Trulicity® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
7. Victoza® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2023.
8. American Diabetes Association. Standards of care in diabetes – 2025. *Diabetes Care*. 2025;48(Suppl 1):S1-S352.
9. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-362.
10. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterol.* 2022;163:1198-1225.
11. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology consensus statement: comprehensive type 2 diabetes management algorithm – 2023 update. *Endocr Pract.* 2023;29:305-340.
12. Kidney Diseases Improving Global Outcomes (KDIGO). KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int.* 2024;105(4S):S117-S314.
13. Mounjaro® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.
14. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral arterial disease: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation.* 2024;149(24):e1313-e1410.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/10/2024
Selected Revision	**Mounjaro:** This product was added to the policy (previously a stand-alone policy). **Policy Statement:** The policy statement was updated to include that Zepbound (tirzepatide subcutaneous injection) is not indicated for the treatment of diabetes and is not targeted in the policy. **Type 2 Diabetes Mellitus:** Existing criteria for Mounjaro was added to this approvable indication. Mounjaro is approved if the patient is ≥ 18 years of age. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonist:** This criterion was added to Conditions Not Recommended for Approval.	06/05/2024
Selected Revision	The following changes are effective 01/01/2025: Liraglutide (authorized generic to Victoza) was added to the policy. **Type 2 Diabetes Mellitus:** Liraglutide (authorized generic to Victoza) was added to the list of agents that may be approved if the patient is ≥ 10 years of age.	09/18/2025 (effective 01/01/2025)
Selected Revision	Reference to the "authorized generic for Victoza" was removed. The authorized generic to Victoza is now a true generic, additionally another true generic to Victoza is available. **Type 2 Diabetes Mellitus**: "Authorized generic to Victoza" was removed from criteria for liraglutide.	01/29/2025