GLP-1, GIP/GLP-1 Agonists for Diabetes

Policy # 00324
Original Effective Date: 11/16/2011
Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Wegovy™‡ (semaglutide) is addressed separately in medical policy 00886.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of the available data, the Company may consider glucagon-like-peptide-1 (GLP-1) receptor agonists and glucose-dependent insulinotropic polypeptide (GIP)/(GLP-1) receptor agonists that are FDA approved for the treatment of diabetes, including but not limited to exenatide injection, liraglutide injection (Victoza®, generics)‡, Trulicity™‡ (dulaglutide), Ozempic®‡ (semaglutide) injection, Ozempic®‡ (semaglutide) tablet, Rybelsus®‡ (semaglutide), and Mounjaro™‡ (tirzepatide) to be **eligible for coverage**** when the patient selection criteria below are met for the requested drug:

Patient Selection Criteria

Coverage eligibility will be considered when selection criteria below are met for the requested drug:

- For **Trulicity (dulaglutide), Ozempic (semaglutide) injection, Ozempic (semaglutide) tablet, Rybelsus (semaglutide), or Mounjaro (tirzepatide)** requests:
  - Patient has a diagnosis of type 2 diabetes mellitus; AND
  - Diagnosis has been confirmed by documentation of ONE of the following:
    - Hemoglobin A1c greater than or equal to 6.5%; OR
    - Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL; OR
    - 2-hour plasma glucose (2-h PG) greater than or equal to 200 mg/dL; AND
  - For Trulicity and Mounjaro requests ONLY:
    - Patient is 10 years of age or older; OR
  - For Ozempic injection and tablets and Rybelsus requests ONLY:
    - Patient is 18 years of age or older; OR

- For **exenatide injection or liraglutide injection (Victoza, generics)** requests:
  - Patient has a diagnosis of type 2 diabetes mellitus; AND
  - Diagnosis has been confirmed by documentation of ONE of the following:
    - Hemoglobin A1c greater than or equal to 6.5%; OR
    - Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL; OR
    - 2-hour plasma glucose (2-h PG) greater than or equal to 200 mg/dL; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following products: Trulicity (dulaglutide injection), Ozempic (semaglutide injection), Rybelsus (semaglutide tablet), or Mounjaro (tirzepatide injection); AND (*Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met*)
  - For exenatide injection requests ONLY:
    - Patient is 18 years of age or older; OR
  - For liraglutide injection (Victoza, generics) requests ONLY:
    - Patient is 10 years of age or older; AND
    - If the request is for brand Victoza, patient has tried and failed (e.g., intolerance or inadequate response) GENERIC liraglutide injection unless there is clinical evidence or patient history that suggests GENERIC liraglutide injection will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient selection criterion is an additional Company requirement and will be denied as not medically necessary** if not met.)*

Note: Laboratory testing must be performed by an accredited laboratory. Point-of-care testing is not acceptable for confirming diagnosis.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of exenatide injection and liraglutide injection (Victoza, generics) WITHOUT having tried and failed at least TWO of the following products: Trulicity (dulaglutide), Ozempic (semaglutide) injection, Ozempic (semaglutide) tablet, Rybelsus (semaglutide), or Mounjaro (tirzepatide) to be **not medically necessary.****

Based on review of available data, the Company considers the use of brand Victoza when the patient has not tried and failed GENERIC liraglutide injection to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of GLP-1 and GIP/GLP-1 agonists that are FDA approved for the treatment of diabetes for any non-FDA approved indication for that specific drug to be **investigational.***

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Original Effective Date: 11/16/2011
Current Effective Date: 08/01/2026

Based on review of available data, the Company considers the use of exenatide injection, Ozempic injection, Ozempic tablet, and Rybelsus in patients less than 18 years of age to be **investigational.***

Based on review of available data, the Company considers the use of liraglutide injection (Victoza, generics), Mounjaro, and Trulicity in patients less than 10 years of age to be **investigational.***

Schematic

Preferred	Non-Preferred
Trulicity Ozempic injection Ozempic tablet Rybelsus Mounjaro	exenatide injection liraglutide injection (Victoza, generics)

Background/Overview

The GLP-1 receptor agonists and the GLP-1/GIP agonist addressed in this policy are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. These products are incretin mimetic agents that bind and activate the human GLP-1 receptor. Activation of this receptor increases glucose-dependent insulin secretion by pancreatic beta-cells and suppresses glucagon secretion and slows gastric emptying. GLP-1 receptor agonists are available in multiple formulations with varying administration regimens, including daily, weekly, and an oral option. Both branded and generic products are currently marketed as well. Exenatide injection, liraglutide injection (Victoza, generics), Trulicity (dulaglutide), and Ozempic (semaglutide) are antihyperglycemic GLP-1 receptor agonists for subcutaneous injection. Rybelsus was the first GLP-1 receptor agonist available in an oral dosage form. Ozempic tablets are a reformulated and rebranded version of oral semaglutide. Although Ozempic tablets and Rybelsus contain the same active ingredient (semaglutide), they are not directly interchangeable on a milligram-to-milligram basis due to differences in formulation and absorption characteristics. The newer formulation, now marketed as Ozempic tablets (1.5 mg, 4 mg, and 9 mg), is pharmacokinetically comparable to the previously approved oral semaglutide formulation marketed as Rybelsus (3 mg, 7 mg, and 14 mg). In June of 2024, Victoza became the first GLP-1 receptor agonist to have a generic formulation on the market, followed by Byetta (exenatide injection) later in the year. Since that time, Byetta and Bydureon BCise (exenatide extended-release) have been discontinued by the manufacturer, and generic formulations of Bydureon BCise have not emerged. Exenatide injection, Ozempic, and Rybelsus are FDA approved for use in adult patients only while liraglutide injection (Victoza, generics) and Trulicity are indicated for use in pediatric patients 10 years of age and older. Exenatide injection is administered subcutaneously twice daily, and Victoza is administered subcutaneously once daily. Trulicity and Ozempic injection are administered subcutaneously once weekly, while Rybelsus and Ozempic tablets are taken orally once daily. For more information on dosing for a specific product, please refer to the product's package insert. Ozempic, Rybelsus, Trulicity, and Victoza also have labeled indications for cardiovascular risk reduction in adults with type 2 diabetes. Ozempic injection is also indicated 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. Mounjaro is a subcutaneous injection indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age older with type 2 diabetes mellitus.

It selectively binds and activates both the GIP and GLP-1 receptors. It works in a glucose dependent manner by enhancing first- and second-phase insulin secretion and reducing glucagon levels. In addition to suppressing glucagon secretion, increasing glucose-dependent insulin secretion, and delaying gastric emptying, the drug also works to increase insulin sensitivity. Mounjaro is administered subcutaneously once weekly.

According to the American Diabetes Association (ADA) Standards of Care (2025), diabetes may be diagnosed in non-pregnant individuals based on the following: 1.) hemoglobin A1c greater than or equal to 6.5%, 2.) FPG greater than or equal to 126 mg/dL, 3.) a 2 hour plasma glucose value greater than or equal to 200 mg/dL during a 75 gram oral glucose tolerance test, or 4.) a random glucose greater than or equal to 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). In the absence of unequivocal hyperglycemia (e.g., hyperglycemic crises), the guidelines recommend obtaining two abnormal results from different tests which may be obtained at the same time (e.g., hemoglobin A1c and FPG), or the same test at two different time points and provide several examples of how to use these different laboratory tests for establishing a diagnosis. Given the variability in the quality and strength of scientific evidence supporting laboratory assays used in diagnosing and managing diabetes mellitus, the American Association for Clinical Chemistry (AACC) and the American Diabetes Association collaboratively developed evidence-based guidelines in 2002. These guidelines were updated in 2011, and most recently revised in 2023, to reflect advancements in laboratory technologies and emerging clinical data. The 2023 update includes refined protocols for measuring glucose and hemoglobin A1c, guidance on the use of additional biomarkers such as ketones, autoantibodies, and genetic markers, and recommendations regarding glucose meters and continuous glucose monitors. Current guidelines recommend that fasting glucose should be measured in venous plasma when used to establish the diagnosis of diabetes, and portable glucose meters should not be used in the diagnosis of diabetes, including gestational diabetes. AACC/ADA guidelines also recommend that hemoglobin A1c testing for the diagnosis of diabetes be performed in an accredited laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) reference (Grade A recommendation). The ADA cautions that point-of-care (POC) testing devices for hemoglobin A1c, also referred to as point-of-care testing (POCT), should not be used for diagnosis due to concerns regarding accuracy and standardization. The guidelines also recommend that POC hemoglobin A1c testing for diabetes screening and diagnosis should be restricted to devices approved for diagnosis by the U.S. Food and Drug Administration at Clinical Laboratory Improvement Amendments (CLIA) certified laboratories that perform testing of moderate complexity or higher by trained personnel (Grade B recommendation).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Liraglutide injection (Victoza, generics) 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 and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease and 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.

Rybelsus and Ozempic tablets are ~~is~~ indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events. In January 2026, the FDA approved a name change for Rybelsus 1.5 mg, 4 mg and 9 mg (previously referred to as "R2" Rybelsus) to Ozempic tablet 1.5 mg, 4 mg and 9 mg. Currently, Rybelsus 3 mg, 7 mg, and 14 mg tablets remain available on the market.

Trulicity and Mounjaro are 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. Trulicity is also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

As monotherapy, Byetta 5 mcg or 10 mcg twice daily in adjunct to diet and exercise reduced glycosylated hemoglobin (HbA1c) 0.5 to 0.7% (placebo corrected); a placebo corrected weight loss of 2.7 kg to 2.9 kg was noted at the end of the 24 week trial. In general, Byetta appears to lower HbA1c by 0.5% to 1%. In addition to HbA1c reduction, Byetta reduces food intake, and on average produces a 2 kg to 3 kg weight loss over a 6-month period in diabetic patients. Byetta 10 mcg twice daily as an adjunct to metformin, a sulfonylurea, or both in patients with type 2 diabetes decreased body weight by 1.6 kg to 2.8 kg after 30 weeks. In an interim analysis involving a 52 week open-label uncontrolled extension study, which followed the 30 week double-blind period, the average weight loss in type 2 diabetics (n = 314) after a total of 82 weeks of Byetta therapy was 4.4 kg. A similar analysis of an interim report noted weight loss in type 2 diabetics (n = 92) after 82 weeks of Byetta treatment was 5.3 kg. In a multicenter, open-label, randomized, controlled trial in patients with type 2 diabetes (n = 551), at 26 weeks, treatment with Byetta led to a 2.3 kg reduction in body

weight compared with a 1.8 kg increase for patients treated with insulin glargine (Lantus®)‡. Addition of Byetta to a thiazolidinedione ([TZD] with or without metformin) resulted in a 1.51 kg mean reduction in bodyweight after 16 weeks. Reductions in bodyweight in type 2 diabetic patients treated with Byetta have been sustained for up to two years.

As monotherapy in a 52 week trial, Victoza 1.2 mg and 1.8 mg in adjunct to diet and exercise resulted in mean HbA1c reduction of 0.8% to 1.1% and a 2.1 kg to 2.5 kg weight reduction. Victoza was studied in combination with one or two other oral anti-diabetic agents in four 26 week studies. When added to metformin, Victoza 1.8 mg and 1.2 mg resulted in a mean placebo corrected HbA1c and weight reduction of 1.1% and 1.1 kg to 1.3 kg, respectively. As add-on to sulfonylurea (glimepiride), Victoza 1.2 mg and 1.8 mg treatment resulted in a placebo corrected mean HbA1c reduction of 1.3% to 1.4%. As part of a triple therapy combination with metformin and glimepiride, Victoza 1.8 mg reduced HbA1c (placebo corrected mean) by 1.1% and resulted in a mean weight reduction of 1.4 kg (placebo corrected). When added to metformin and rosiglitazone mean placebo corrected reduction in HbA1c and weight with Victoza (1.8 mg and 1.2 mg) were 0.9% (both doses) and 2.6 kg and 1.6 kg, respectively. In a head-to-head trial with Byetta, weight was significantly reduced in both Byetta (10 mcg twice daily) and Victoza (1.8 mg daily) and was non-significant between groups (-2.87 kg vs. -3.24 kg, respectively).

A randomized, open-label 24-week comparative trial was conducted with Bydureon and Byetta for safety and efficacy in 252 patients with type 2 diabetes. These patients had inadequate glycemic control with diet and exercise alone or with oral antidiabetic therapy, including metformin, a sulfonylurea, a TZD, or combination of two of those therapies. Patients were treated with diet and exercise alone (19%), a single oral antidiabetic agent (47%), or combination therapy of oral antidiabetic agents (35%). The mean baseline HbA1c was 8.4%. Patients were randomly assigned to receive Bydureon 2 mg once every seven days (weekly) or Byetta (10 mcg twice daily), in addition to existing oral antidiabetic agents. Patients assigned to Byetta initiated treatment with 5 mcg twice-daily then increased the dose to 10 mcg twice daily after 4 weeks. The primary endpoint was change in HbA1c from baseline to week 24 (or the last value at time of early discontinuation). Change in body weight was a secondary endpoint. Treatment with Bydureon was superior to Byetta for mean HbA1c reduction over 24 weeks.

Trulicity was studied in various trials as monotherapy as well as in addition to oral therapies and in addition to insulin. As monotherapy, Trulicity lowered the HbA1c from 0.7-0.8% vs. metformin's lowering of 0.6%. Trulicity as monotherapy also lowered the fasting plasma glucose by 26 to 29 mg/dL vs. a lowering of 24 mg/dL with metformin. In the combo therapy trials, the HbA1c lowering ranged from 0.8 to 1.6% depending on the treatment that Trulicity was combined with. Trulicity 0.75 mg and 1.5 mg was studied in pediatric patients 10 years of age and older with type 2 diabetes in combination with or without metformin and/or basal insulin treatment. In this trial, once weekly Trulicity (0.75 mg and 1.5 mg, pooled) (with or without metformin and/or basal insulin) was superior to placebo ($p < 0.001$) in the change from baseline at Week 26 in HbA1c in pediatric patients 10 years of age and older with type 2 diabetes mellitus.

Ozempic has been studied as monotherapy and in combination with metformin, metformin and sulfonylureas, metformin and/or thiazolidinedione, and basal insulin in patients with type 2 diabetes mellitus. The efficacy of Ozempic was compared with placebo, sitagliptin, Bydureon, and insulin glargine. Most trials evaluated the use of Ozempic 0.5 mg, and 1 mg, with the exception of the trial comparing Ozempic and Bydureon where only the 1 mg dose was studied. In patients with type 2 diabetes mellitus, Ozempic produced clinically relevant reduction from baseline in HbA1c compared with placebo. The various HbA1c lowering ranged from 1.1-1.6% depending on the clinical comparison. Ozempic has also been studied in adults with inadequately controlled type 2 diabetes and established cardiovascular disease (FLOW trial). Patients were randomized to receive Ozempic (0.5 mg or 1 mg) or placebo once weekly, in addition to standard care, for a minimum of two years. The primary composite endpoint, CV death, nonfatal myocardial infarction (MI), or nonfatal stroke, occurred in 6.6% of patients in the Ozempic treated group versus 8.9% in the placebo group, demonstrating a 26% relative risk reduction. Additionally, the safety and efficacy of Ozempic 1 mg once weekly was evaluated in adults with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD). Participants were required to have an estimated glomerular filtration rate (eGFR) between 25 and 75 mL/min/1.73 m^2 and elevated urinary albumin-to-creatinine ratios, in addition to receiving standard care with angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). Ozempic demonstrated a 24% relative risk reduction in the primary composite outcome of sustained ≥ 50% decline in eGFR, progression to kidney failure, or death from kidney or cardiovascular causes. Secondary outcomes included a 20% reduction in all-cause mortality and an 18% reduction in major adverse cardiovascular events (MACE).

The effectiveness Rybelsus (3 mg, 7, mg and 14 mg strengths) and Ozempic tablets (1.5 mg, 4 mg and 9 mg strengths) has been established as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus based on Rybelsus' study program which included 10 randomized, placebo-controlled or active-comparator trials. Studies included comparisons between Rybelsus and placebo, other oral anti-diabetic agents (Jardiance®, Januvia®), other GLP-1 agonist products (Victoza, Ozempic), along with additions to metformin and sulfonylurea. The various HbA1c lowering ranged from 0.6-1.9% depending on the clinical comparison. Cardiovascular outcomes for Rybelsus have been evaluated in two major randomized, double-blind, placebo-controlled trials. In the SOUL trial, 9,650 patients with type 2 diabetes mellitus and established cardiovascular disease and/or chronic kidney disease (eGFR < 60 mL/min/1.73 m^2) were randomized to receive Rybelsus 14 mg once daily or placebo, in addition to standard of care. Over a median follow-up of approximately 49.6 months, Rybelsus significantly reduced the risk of major adverse cardiovascular events (MACE), a composite of cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke, with a hazard ratio of 0.86 (95% CI: 0.77, 0.96). In the PIONEER 6 trial, 3,183 adults with inadequately controlled type 2 diabetes and atherosclerotic cardiovascular disease were randomized to Rybelsus 14 mg once daily or placebo for a median observation time of 16 months. Non-inferiority to placebo for time to first MACE was established (hazard ratio 0.79, 95% CI: 0.57, 1.11), with 3.8% of Rybelsus-treated patients and 4.8% of placebo-treated patients experiencing at least one MACE. Rybelsus significantly reduced the occurrence of MACE. The estimated hazard ratio for time to first MACE was 0.86 (95% CI: 0.77, 0.96) over the median follow-up duration of 49.6 months and 49.4 months for patients randomized to Rybelsus and placebo, respectively.

The effectiveness of Mounjaro as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus was established in five trials. In these trials, Mounjaro was studied as monotherapy; as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors); and in combination with basal insulin with or without metformin. In these trials, Mounjaro was compared with placebo, semaglutide 1 mg, insulin degludec, and/or insulin glargine. Monotherapy with Mounjaro once weekly for 40 weeks resulted in a statistically significant reduction in HbA1c compared with placebo that ranged from a 1.7-1.8% decrease. Depending on the clinical comparisons of Mounjaro in combination with other agents, the HbA1c lowering ranged from 1.9-2.4%. Mounjaro 5 mg and 10 mg was studied in pediatric patients 10 years of age and older with type 2 diabetes in combination with metformin and/or basal insulin. Treatment with Mounjaro 5 mg once weekly and 10 mg once weekly for 30 weeks, both pooled and individually, resulted in a statistically significant reduction in HbA1c compared with placebo.

Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using the non-preferred agents mentioned in this policy over the preferred agents mentioned in this policy. The active ingredient in the non-preferred products have not demonstrated superiority in head to head studies comparing preferred products with the non-preferred products.

This policy is also intended to ensure that the GLP-1 and GIP/GLP-1 agonist products approved for the treatment of type 2 diabetes are used for the indication of type 2 diabetes only.

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Policy History

Original Effective Date: 11/16/2011
Current Effective Date: 08/01/2026

11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. New policy.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Added Bydureon (exenatide ER) to the title and coverage statement.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Revision to coverage language without changing the intent of the policy. Coverage eligibility unchanged.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Changed title. Added Tanzeum to the policy. Updated background information and rationale to reflect new product and title change.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Changed title. Added Trulicity to policy. Updated background and rationale.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Chose preferred products in this class (Byetta, Bydureon, Victoza, and Trulicity).
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Clarified to use two preferred products.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. No change to coverage.

07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Added Ozempic and Bydureon BCise to the policy.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Moved Byetta and Bydureon/Bydureon BCise to non-preferred
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added a new drug, Rybelsus, as a preferred option. Removed Tanzeum from the policy as it has been discontinued.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. No change to coverage.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Moved Byetta and Bydureon/Bydureon BCise from non-preferred to preferred. Updated the patient selection criteria and background information. Removed the original Bydureon formulation from the policy due to discontinuation as the Bydureon BCise auto-injector is the only formulation now available.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Changed title of policy from GLP-1 Agonists for Diabetes to GLP-1, GIP/GLP-1 Agonists for Diabetes. Added new drug, Mounjaro, to policy as a preferred product.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Removed Adlyxin from the policy due to discontinuation. Moved Byetta, Bydureon BCise, and Victoza from preferred to non-preferred. Added authorized Liraglutide generic to the policy as non-preferred with associated criteria. Updated criteria to require documentation of laboratory tests to support diagnosis and age requirement per product label. Updated background information.
05/01/2025	Medical Policy Committee review
05/13/2025	Medical Policy Implementation Committee approval. Removed Liraglutide (authorized [branded] generic) from the policy. Updated background section. Coverage eligibility unchanged.
11/06/2025	Medical Policy Committee review
11/12/2025	Medical Policy Implementation Committee approval. Removed branded Byetta and Bydureon BCise from the policy as non-preferred products due to manufacturer discontinuation. Added new criterion requiring trial of generic liraglutide injection before brand. Updated background section.

Policy # 00324
Original Effective Date: 11/16/2011
Current Effective Date: 08/01/2026

04/02/2026	Medical Policy Committee review
04/10/2026	Medical Policy Implementation Committee approval. Updated criteria and background information to reflect FDA approval of Mounjaro for patients 10 years of age older.
07/21/2026	Pre-Pharmacy and Therapeutics Committee review
07/22/2026	Pharmacy and Therapeutics Committee approval. Added Ozempic tablets, a rebranded and reformulated semaglutide product, as a preferred product with applicable criteria. Updated the background section.

Next Scheduled Review Date: 07/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.