BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

GLP-1 RECEPTOR AGONISTS AND GIP/GLP-1 RECEPTOR AGONISTS:
BYDUREON BCISE® (exenatide)
BYETTA® (exenatide)
EXENATIDE (exenatide)
Liraglutide
MOUNJARO™ (tirzepatide)
OZEMPIC® (semaglutide)
RYBELSUS® (semaglutide)
TRULICITY® (dulaglutide)
VICTOZA® (liraglutide)
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for GLP 1 RECEPTOR AGONISTS and MOUNJARO (tirzepatide)

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Criteria for Initial Therapy:

Indication
- **ONE** of the following:
  - **For ANY agent:** Type 2 diabetes as an adjunct to diet and exercise to improve glycemic control, and the medication is **NOT** solely being used for weight loss
  - **For Ozempic, Trulicity, Victoza & liraglutide generic:** Type 2 diabetes with established clinical atherosclerotic cardiovascular disease (ASCVD) or high ASCVD risk to reduce major adverse cardiovascular events
  - **For Ozempic:** Type 2 diabetes with chronic kidney disease (CKD) to reduce risk of sustained decline in estimated glomerular filtration rate (eGFR), end stage kidney disease, and cardiovascular death

Age Requirement
- Age is consistent with FDA labeling

Baseline Clinical Evaluation
- Medical regimen includes standard of care for both type 2 diabetes and other disease of concern
- Does not have type 1 diabetes
- **For type 2 diabetes: ONE** of the following:
  - A1C greater than or equal to 6.5 percent
  - Fasting plasma glucose greater than or equal to 126 mg/dL
  - Two hour plasma glucose greater than or equal to 200 mg/dl during oral glucose tolerance test
  - Random plasma glucose greater than or equal to 200 mg/dL

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety
- There is **NONE** of the following:
  - Severe gastrointestinal disease (gastroparesis)
  - Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2

- **For Bydureon BCise, Byetta, and Exenatide:** No history of drug induced immune mediated thrombocytopenia from exenatide products
- Concomitant use of more than one GLP 1 Receptor Agonist or in combination with a tirzepatide containing product

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (A1C and glucose values)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 12 months OR end of plan year
- Individual may be referred to case management for diabetes related ancillary services

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Indication

- **ONE** of the following:
  - **For ANY agent:** Type 2 diabetes as an adjunct to diet and exercise to improve glycemic control, and the medication is **NOT** solely being used for weight loss
  - **For Ozempic, Trulicity, Victoza & liraglutide generic:** Type 2 diabetes with established clinical atherosclerotic cardiovascular disease (ASCVD) or high ASCVD risk to reduce major adverse cardiovascular events
  - **For Ozempic:** Type 2 diabetes with chronic kidney disease (CKD) to reduce risk of sustained decline in estimated glomerular filtration rate (eGFR), end stage kidney disease, and cardiovascular death

Clinical Response

- **For type 2 diabetes:** Decrease in A1C from baseline

Adherence

- Adherence to prescribed therapy regimen for diabetes, including diet and exercise

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Safety

- There is **NONE** of the following:
  - Pancreatitis
  - Severe hypersensitivity reaction (anaphylaxis, angioedema)
  - Acute kidney injury
  - Severe gastrointestinal disease (gastroparesis)
  - Drug induced immune mediated thrombocytopenia
  - Acute gallbladder disease (cholelithiasis, cholecystitis)
  - Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2
  - Concomitant use of more than one GLP 1 Receptor Agonist or in combination with a tirzepatide containing product

Documentation Requirements

- Chart notes
- Lab values confirming safe use
- Evidence of improvement

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

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Glucagon-like peptide-1 (GLP-1) receptor agonists activate the GLP-1 receptor and increase intracellular cyclic AMP (cAMP) leading to insulin release in a glucose-dependent manner. They also decrease glucagon secretion and slow gastric emptying. They do not usually cause hypoglycemia in the absence of therapies that otherwise cause hypoglycemia. An additional benefit in many individuals with type 2 diabetes is weight-loss.
Bydureon BCise (exenatide) is an extended-release formulation of exenatide that 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. It is not recommended as first-line therapy for patients inadequately controlled on diet and exercise.

Byetta (exenatide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Ozempic (semaglutide) 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 (semaglutide oral tablet) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is not recommended as first-line therapy for patients inadequately controlled on diet and exercise.

Trulicity 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 or multiple cardiovascular risk factors. Trulicity is not recommended in patients with severe gastrointestinal disease, including severe gastroparesis.

Victoza (liraglutide) 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.

Limitations for use: All the above agents are not for treatment of type 1 diabetes mellitus. All of the above agents, except Victoza (liraglutide), have not been studied in patients with a history of pancreatitis and other antidiabetic therapies should be considered in these patients.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Criteria for the diagnosis of diabetes in nonpregnant individuals

Meets ONE of the following:	Additional Information
1. A1c ≥ 6.5%*	The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay
2. FPG ≥ 126mg/dl*	Fasting is defined as no caloric intake for at least 8 hours
3. 2-hour PG ≥ 200mg/dl during OGTT*	The test should be performed as described by the WHO, using glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water
4. In an individual with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg/dl	Random is any time of the day without regard to time since previous meal

DCCT, Diabetes Control and Complications Trial; FPG, fasting plasma glucose; OGTT, oral glucose tolerance test, NGSP, National Glycohemoglobin Standardization Program; WHO, World Health Organization; *In the absence of unequivocal hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate test samples.

Diabetes Medications

CLASS	Generic Name	Brand Name
Biguanide	Metformin	Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet
Sulfonylurea	Glimepiride	Amaryl
	Glipizide, Glipizide XL	Glucotrol XL
	Glyburide	
DPP-4 Inhibitor	Sitagliptin	Januvia
	Saxagliptin	Onglyza
	Linagliptin	Tradjenta
	Alogliptin	Nesina
SGLT2 Inhibitor	Canagliflozin	Invokana
	Dapagliflozin	Farxiga
	Empagliflozin	Jardiance
	Ertugliflozin	Steglatro
GLP-1 Receptor Agonist (Incretin Mimetic)	Exenatide	Byetta, Bydureon BCise
	Liraglutide	Victoza

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	Dulaglutide	Trulicity
	Lixisenatide	Adlyxin
	Semaglutide	Ozempic, Rybelsus
GIP/GLP-1 Receptor Agonist	Tirzepatide	Mounjaro
Thiazolidinedione (Insulin Sensitizing Agent)	Pioglitazone	Actos
Amylin Analog	Pramlintide	Symlin
Alpha-glucosidase inhibitor	Acarbose	
	Miglitol	
Meglitinide Analog	Nateglinide	
	Repaglinide	
Insulin	Glargine	Lantus, Basaglar, Toujeo, Semglee
	Detemir	Levemir
	Degludec	Tresiba
	NPH	Novolin N, Humulin N
	Lispro	Humalog, Admelog, Lyumjev
	Aspart	Novolog, Fiasp
	Glulisine	Apidra
	Regular	Humulin, Novolin
	Insulin inhalation powder	Afrezza
Combination Products		
DPP-4 Inhibitor/biguanide	Sitagliptin/metformin	Janumet, Janumet XR
	Linagliptin/metformin	Jentadueto, Jentadueto XR
	Alogliptin/metformin	Kazano
	Saxagliptin/metformin	Kombiglyze XR
DPP-4 Inhibitor/thiazolidinedione	Alogliptin/pioglitazone	Oseni
Insulin/GLP-1 Receptor Agonist	Glargine/lixisenatide	Soliqua
	Degludec/liraglutide	Xultophy
SGLT2 inhibitor/DPP-4 inhibitor	Empagliflozin/linagliptin	Glyxambi
	Dapagliflozin/saxagliptin	Qtern
	Ertugliflozin/sitagliptin	Steglujan
SGLT2 inhibitor/biguanide	Canagliflozin/metformin	Invokamet, Invokamet ER
	Ertugliflozin/metformin	Segluromet
	Empagliflozin/metformin	Synjardy, Synjardy XR
	Dapagliflozin/metformin	Xigduo XR
Sulfonylurea/biguanide	Glipizide/metformin	

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	Glyburide/metformin	
Sulfonylurea/thiazolidinedione	Pioglitazone/glimepiride	Duetact
SGLT2 inhibitor/DPP-4 inhibitor/biguanide	Empagliflozin/linagliptin/metformin	Trijardy XR

Resources:

Bydureon BCise (exenatide) extended-release subcutaneous injection prescribing information, revised by AstraZeneca Pharmaceuticals LP 05-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Byetta (exenatide) subcutaneous injection prescribing information, revised by AstraZeneca Pharmaceuticals LP 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Exenatide subcutaneous injection prescribing information, revised by Amneal Pharmaceuticals LLC. 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Trulicity (dulaglutide) subcutaneous injection prescribing information, revised by Eli Lilly and Company 06-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Liraglutide subcutaneous injection prescribing information, revised by Teva Pharmaceuticals USA, Inc 01-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 27, 2026.

Mounjaro (tirzepatide) product information, revised by Eli Lilly and Company 01-2026. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 31, 2026.

Victoza (liraglutide) subcutaneous injection prescribing information, revised by Novo Nordisk 10-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Ozempic (semaglutide) subcutaneous injection prescribing information, revised by Novo Nordisk 10-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Rybelsus (semaglutide) tablet prescribing information, revised by Novo Nordisk 12-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Dungan K, DeSantis A. Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus. In: UpToDate, Nathan DM, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through December 2025. Last updated January 08, 2026. Accessed January 27, 2026.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT01720446: A Long-term, Randomized, Double-blind, Placebo-controlled, Multinational, Multi-center Trial to Evaluate Cardiovascular and Other Long-term Outcomes With Semaglutide in Subjects With Type 2 Diabetes (SUSTAIN™ 6 - Long-term Outcomes). Available from: http://clinicaltrials.gov. Last update posted June 27, 2019. Last verified June 2019. Accessed January 27, 2026.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03819153: Effect of Semaglutide Versus Placebo on the Progression of Renal Impairment in Subjects With Type 2 Diabetes and Chronic Kidney Disease. Available from: http://clinicaltrials.gov. Last update posted March 20, 2025. Last verified March 2025. Accessed January 27, 2026.

American Diabetes Association Professional Practice Committee. American Diabetes Association Standards of care in diabetes – 2024. Diabetes Care. 2024 January;47(Suppl 1): S1-328. Accessed January 22, 2024. Re-evaluated January 27, 2026.

Davies MJ, Aroda VR, Collins BS, et al.: Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2022;45(11):2753–2786. Accessed January 13, 2024. Re-evaluated January 27, 2026.

ElSayed NA, Aleppo G, Aroda VR, et al.: American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1): S140–S157. Accessed January 13, 2024. Re-evaluated January 27, 2026.