

Clinical Policy: Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Reference Number: OR.CP.CPA.16

Effective Date: 11.01.25

Last Review Date: 10.25

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following agents contain a synthetic glucagon-like peptide-1 (GLP-1) receptor agonist and require prior authorization: dulaglutide (Trulicity®), exenatide ER (Bydureon BCise®), exenatide IR (Byetta®), liraglutide (Victoza®), liraglutide/insulin degludec (Xultophy®), lixisenatide (Adlyxin®), lixisenatide/insulin glargine (Soliqua®), semaglutide (Ozempic®, Rybelsus®), and tirzepatide* (Mounjaro™).

**Tirzepatide is a combination GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonist.*

FDA Approved Indication(s)

GLP-1 receptor agonists are indicated as adjunct to diet and exercise to improve glycemic control with type 2 diabetes mellitus. Bydureon BCise, Trulicity, and Victoza are indicated in patients 10 years of age and older, while the other GLP-1 receptor agonists are indicated in adults.

Ozempic, Trulicity and Victoza are also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and:

- Established cardiovascular disease (*Ozempic, Trulicity, Victoza*);
- Cardiovascular risk factors (*Trulicity only*).

Ozempic is additionally indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

Limitation(s) of use:

- Bydureon BCise and Xultophy are not recommended as a first-line therapy for patients inadequately controlled on diet and exercise.
- GLP-1 receptor agonists should not be used for the treatment of type 1 diabetes. Xultophy and Soliqua are not for the treatment of diabetic ketoacidosis.
- Xultophy and Soliqua have not been studied in combination with prandial insulin. In addition, they are not recommended for use in combination with any other product containing a GLP-1 receptor agonist.
- Other than Ozempic, Victoza, and Xultophy, GLP-1 receptor agonists have not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered.
- Trulicity is not for patients with pre-existing severe gastrointestinal disease.
- Adlyxin and Soliqua are not recommended in patients with gastroparesis.

- Bydureon BCise is an extended-release formulation of exenatide. Do not coadminister with other exenatide containing products.
- Victoza and Xultophy contain liraglutide and should not be co-administered with other liraglutide-containing products.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that GLP-1 receptor agonists are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Preferred GLP-1 RA Therapy* (must meet all):

** If request is for a GLP-1 RA other than exenatide (generic Byetta), liraglutide (generic Victoza), Trulicity, Ozempic, or Rybelsus, please refer to criteria set I.B below*

1. Diagnosis of type 2 diabetes mellitus;
2. Request is for exenatide (generic Byetta), liraglutide (generic Victoza), Trulicity, Ozempic, or Rybelsus;
3. Age is one of the following (a or b):
 - a. Trulicity, liraglutide, exenatide: ≥ 10 years;
 - b. Ozempic, Rybelsus: ≥ 18 years;
4. Requested product is not prescribed concurrently with another GLP-1 receptor agonist;
5. Dose does not exceed the FDA-approved maximum recommended dose (*see Section V*).

Approval duration:

Rybelsus – 12 months

All other agents – 6 months or member's renewal period, whichever is longer

B. Type 2 Diabetes Mellitus* (must meet all):

** If request is for exenatide (generic Byetta), liraglutide (generic Victoza), Trulicity, Ozempic, or Rybelsus, please refer to criteria set I.A above for preferred GLP-1 RA therapy*

1. Diagnosis of type 2 diabetes mellitus;
2. Request is for Adlyxin, Bydureon BCise, Byetta, Mounjaro, Soliqua, Victoza, or Xultophy;
3. Age is one of the following (a or b):
 - a. Bydureon BCise, Victoza: ≥ 10 years;
 - b. Adlyxin, Byetta, Mounjaro, Soliqua, Xultophy: ≥ 18 years;
4. Member meets one of the following (a, b, c, d, or e):
 - a. Failure of ≥ 3 consecutive months of metformin as evidenced by $HbA1c \geq 7\%$, unless contraindicated or clinically significant adverse effects are experienced;
 - b. For antidiabetic medication-naïve members, requested agent is approvable if intended for concurrent use with metformin due to $HbA1c \geq 8.5\%$ (drawn within the past 3 months);

- c. Request is for an agent with proven cardiovascular or renal benefit (Ozempic, Trulicity, Victoza), and member has established atherosclerotic cardiovascular disease (ASCVD), indicators of high ASCVD risk (*see Appendix D*), heart failure with preserved ejection fraction, or chronic kidney disease;
- d. Member has metabolic dysfunction-associated steatotic liver disease (MASLD), and (i):
 - i. Member is overweight (body mass index [BMI] 25-29.9 kg/m²) or obese (BMI ≥ 30 kg/m²);
- e. Member has metabolic dysfunction-associated steatohepatitis (MASH), and (i):
 - i. Failure of ≥ 3 consecutive month trial of pioglitazone, unless contraindicated or clinically significant adverse effects are experienced;
- 5. If request is for Adlyxin, Bydureon BCise, Byetta, Soliqua, Mounjaro, or Xultophy: Failure of ≥ 3 consecutive months of all of the following (a, b, and c), unless clinically significant adverse effects are experienced or all are contraindicated:
 - a. Liraglutide (generic Victoza);
 - b. Trulicity;
 - c. Ozempic or Rybelsus;
- 6. If request is for Victoza, member must use liraglutide (generic Victoza) unless contraindicated or clinically significant adverse effects are experienced;
- 7. Requested product is not prescribed concurrently with another GLP-1 receptor agonist;
- 8. Dose does not exceed the FDA approved maximum recommended dose (*see Section V*).

Approval duration: 6 months or member's renewal period, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. All Indications in Section I (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

- b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Requested product is not prescribed concurrently with another GLP-1 receptor agonist;
4. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose (*see Section V*).

Approval duration:**Rybelsus** – 12 months**All other agents** – 6 months or member's renewal period, whichever is longer**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information*Appendix A: Abbreviation/Acronym Key*

AACE: American Association of Clinical Endocrinologists

ACE: American College of Endocrinology

ADA: American Diabetes Association

ASCVD: atherosclerotic cardiovascular disease

BMI: body mass index

eGFR: estimated glomerular filtration rate

ER: extended-release

FDA: Food and Drug Administration

GIP: glucose-dependent insulintropic polypeptide

GLP-1: glucagon-like peptide-1

HbA1c: glycated hemoglobin

IR: immediate-release

MASH: metabolic dysfunction-associated steatohepatitis

MASLD: metabolic dysfunction-associated steatotic liver disease

SGLT2: sodium-glucose co-transporter 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metformin (Glucophage [®] , Glucophage [®] XR, Fortamet [®] *, Glumetza [®] *)	Regular-release (Glucophage): 500 mg PO BID or 850 mg PO QD; increase as needed in increments of 500 mg/week or 850 mg every 2 weeks Extended-release: - Fortamet, Glumetza: 1,000 mg PO QD; increase as needed in increments of 500 mg/week - Glucophage XR: 500 mg PO QD; increase as needed in increments of 500 mg/week	Regular-release: 2,550 mg/day Extended-release: 2,000 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Fortamet and Glumetza are non-formulary products.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Hypersensitivity to any product components
 - Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2 (*all GLP-1 receptor agonists other than Byetta, Adlyxin, and Soliqua*)
 - Use during episodes of hypoglycemia (*Soliqua and Xultophy only*)
 - History of drug-induced immune-mediated thrombocytopenia from exenatide products (*Bydureon BCise and Byetta only*)
- Boxed warning(s): thyroid C-cell tumors (*all GLP-1 receptor agonists other than Byetta, Adlyxin, and Soliqua*)

Appendix D: General Information

- Per the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines:
 - Metformin is recommended for all patients with type 2 diabetes. It is effective and safe, is inexpensive, and may reduce risk of cardiovascular events and death. Monotherapy is recommended for most patients; however:
 - Starting with dual therapy (i.e., metformin plus another agent, such as a sulfonylurea, thiazolidinedione, dipeptidyl peptidase-4 inhibitor, sodium-glucose co-transporter 2 (SGLT2) inhibitor, GLP-1 receptor agonist, or basal insulin) may be considered for patients with baseline HbA1c $\geq 1.5\%$ above their target. According to the ADA, a reasonable HbA1c target for many non-pregnant adults is $< 7\%$ ($\leq 6.5\%$ per the AACE/ACE).
 - Starting with combination therapy with insulin may be considered for patients with baseline HbA1c $> 10\%$ or if symptoms of hyperglycemia are present.

- For patients with established ASCVD or indicators of high ASCVD risk, heart failure, or chronic kidney disease, use of an SGLT2 inhibitor or GLP-1 receptor agonist with demonstrated cardiovascular benefit is recommended as part of the glucose-lowering regimen independent of HbA1c and metformin use. For heart failure, GLP-1 receptor agonists are specifically recommended for obese patients with preserved ejection fraction, while SGLT2 inhibitors are recommended regardless of ejection fraction or presence of obesity.
- For patients with MASLD, GLP-1 receptor agonists are recommended for glycemic management due to potential beneficial effects on MASLD.
- For patients with MASH, GLP-1 receptor agonists, pioglitazone, or a combination of the two are recommended for glycemic management due to potential beneficial effects on MASH.
- If the target HbA1c is not achieved after approximately 3 months of monotherapy, dual therapy should be initiated. If dual therapy is inadequate after 3 months, triple therapy should be initiated. Finally, if triple therapy fails to bring a patient to goal, combination therapy with insulin should be initiated. Each non-insulin agent added to initial therapy can lower HbA1c by 0.7-1%.
- According to the ADA, ASCVD includes coronary heart disease, cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin. Per American College of Cardiology, indicators of high ASCVD risk are age ≥ 55 years with coronary, carotid, or lower-extremity artery stenosis $> 50\%$; left ventricular hypertrophy; retinopathy; and other end organ damage.
- Not approvable for appetite suppression or treatment of obesity since currently there are no studies to support the use of Byetta, Trulicity, or Victoza for these conditions.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Adlyxin (lixisenatide)	Initial dose: 10 mcg SC QD for 14 days Maintenance dose: 20 mcg SC QD	20 mcg/day
Bydureon BCise (exenatide ER)	2 mg SC once weekly	2 mg/week
Byetta (exenatide IR)	5 mcg to 10 mcg SC BID	20 mcg/day
Mounjaro (tirzepatide)	Initial dose: 2.5 mg SC once weekly. May increase by 2.5 mg every 4 weeks up to 15 mg once weekly	15 mg/week
Ozempic (semaglutide)	0.25 mg to 2 mg SC once weekly, increased no more frequently than every 4 weeks For patients with type 2 diabetes and chronic kidney disease, the dosage should be increased to the maintenance dose of 1 mg once weekly after at least 4 weeks on the 0.5 mg dosage	2 mg/week

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Drug Name	Dosing Regimen	Maximum Dose
Rybelsus (semaglutide)	Formulation R1:* Initial dose: 3 mg PO QD. After 30 days on the 3 mg dose, increase to 7 mg PO QD. May increase to 14 mg PO QD if needed after at least 30 days on the 7 mg dose Formulation R2:* Initial dose: 1.5 mg PO QD. After 30 days on the 1.5 mg dose, increase to 4 mg PO QD. May increase to 9 mg PO QD if needed after at least 30 days on the 4 mg dose <i>*Formulations R1 and R2 are not substitutable on a mg per mg basis. Use either formulation, but do not use both formulations at the same time. Patients may switch between formulations after 30 days of treatment (i.e., after the initiation phase). When switching between the formulations, initiate the other formulation the day after discontinuing the previous formulation.</i>	Formulation R1: 14 mg/day Formulation R2: 9 mg/day
Soliqua (lixisenatide/insulin glargine)	Treatment naïve to basal insulin or GLP-1 receptor agonist, currently on a GLP-1 receptor agonist, or currently on less than 30 units of basal insulin daily: 15 units (15 units insulin/5 mcg lixisenatide) SC QD Currently on 30 to 60 units of basal insulin daily, with or without GLP-1 receptor agonist: 30 units (30 units insulin/10 mcg lixisenatide) SC QD	60 units insulin/20 mcg lixisenatide/day
Trulicity (dulaglutide)	0.75 mg to 1.5 mg SC once weekly For adults only: May increase to 3 mg once weekly if needed after at least 4 weeks on 1.5 mg dose. May further increase to 4.5 mg once weekly if needed after at least 4 weeks on 3 mg dose.	Pediatrics: 1.5 mg/week Adults: 4.5 mg/week
liraglutide (Victoza)	Initial: 0.6 mg SC QD for 7 days Maintenance: 1.2 mg to 1.8 mg SC QD	1.8 mg/day
Xultophy (liraglutide/insulin degludec)	Treatment naïve to basal insulin or GLP-1 receptor agonist: 10 units (10 units of insulin/0.36 mg liraglutide) SC QD	50 units insulin/1.8 mg liraglutide/day

Drug Name	Dosing Regimen	Maximum Dose
	Treatment experienced to basal insulin or GLP-1 receptor agonist: 16 units (16 units insulin/0.58 mg liraglutide) SC QD	

VI. Product Availability

Drug Name	Availability
Adlyxin (lixisenatide)	Multi-dose prefilled pen: 50 mcg/mL in 3 mL (14 doses; 10 mcg/dose), 100 mcg/mL in 3 mL (14 doses; 20 mcg/dose)
Bydureon BCise (exenatide ER)	Single-dose autoinjector: 2 mg
Byetta (exenatide IR)	Prefilled pen: 5 mcg/dose (0.02 mL) in 1.2 mL (60 doses), 10 mcg/dose (0.04 mL) in 2.4 mL (60 doses)
Mounjaro (tirzepatide)	- Single-dose prefilled pen: 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL - Single-dose vial: 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL
Ozempic (semaglutide)	Prefilled pen: 2 mg/3 mL (0.68 mg/mL); delivers 0.25 mg or 0.5 mg per injection 4 mg/3 mL (1.34 mg/mL); delivers 1 mg per injection 8 mg/3 mL (2.68 mg/mL); delivers 2 mg per injection
Rybelsus (semaglutide)	- Tablets (formulation R1): 3 mg, 7 mg, 14 mg - Tablets (formulation R2): 1.5 mg, 4 mg, 9 mg
Soliqua (lixisenatide/insulin glargine)	Single-patient use pen: 33 mcg/100 units per mL in 3 mL
Trulicity (dulaglutide)	Single-dose prefilled pen: 0.75 mg/0.5 mL, 1.5 mg/0.5 mL, 3 mg/0.5 mL, 4.5 mg/0.5 mL
liraglutide (Victoza)	Multi-dose prefilled pen: 18 mg/3 mL (6 mg/mL; delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg)
Xultophy (liraglutide/insulin degludec)	Single-patient use pen: 3.6 mg/100 units per mL in 3 mL

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; added new dosage strength (4 mg/3 mL) form for Ozempic; references reviewed and updated.	10.26.20	02.21
Removed Trulicity step-wise dose escalation criteria based on cost/PA analysis and low anticipation for inappropriate usage.	03.11.21	
Added Steglatro and Segluromet to Appendix B.	04.09.21	
RT4: updated indication and age limits down to 10 years of age for Bydureon and Bydureon BCise per updated prescribing information.	08.03.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.16.21	02.22
RT4: added new dosage strength (2 mg) form for Ozempic.	04.13.22	
RT4: added newly FDA approved drug, Mounjaro.	05.31.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per August SDC and prior clinical guidance, for Rybelsus removed redirection to SGLT2. Template changes applied to other diagnoses/indications and continued therapy section.	08.23.22	11.22
1Q 2023 annual review: added bypass of metformin for members with ASCVD, indicators of high ASCVD risk, or chronic kidney disease per ADA guidelines; RT4: added new dosage strength (2 mg/3 mL pen) for Ozempic; RT4: added pediatric expansion for age ≥ 10 years for Trulicity; RT4: removed limitation of use regarding first line use for Rybelsus per updated PI; references reviewed and updated.	01.17.23	02.23
Added the following requirement to both initial and continued therapy: requested product is not prescribed concurrently with another GLP-1 receptor agonist.	07.31.23	
RT4: Added newly approved Mounjaro vial formulations.	09.12.23	
Per SDC, added separate initial approval criteria for preferred agents [Trulicity, Victoza, Ozempic, Rybelsus] with diagnosis, age, "not prescribed concurrently with another GLP-1 receptor agonist" criteria, and maximum dose limit requirements; for initial approval criteria, applied existing Type 2 Diabetes Mellitus criteria set to non-preferred agents [Adlyxin, Bydureon, Bydureon BCise, Byetta, Mounjaro, Soliqua, Xultophy] and modified redirection to require "Ozempic or Rybelsus"; for continued therapy, updated "Type 2 Diabetes Mellitus" header to "All Indications in Section I."	12.11.23	
1Q 2024 annual review: no significant changes; for Ozempic, removed 2 mg/1.5 mL (1.34 mg/mL) from section VI as strength is not currently marketed; updated Appendix D; references reviewed and updated.	10.16.23	02.24
Per SDC request, removed brand Victoza from section I.A and added to Section I.B with redirection to liraglutide (Victoza authorized generic); replaced brand Victoza with liraglutide (Victoza authorized generic) as a preferred product.	11.12.24	12.24
1Q 2025 annual review: no significant changes; removed Bydureon from policy as product has been discontinued; references reviewed and updated. RT4: added new Rybelsus formulation (R2 tablets: 1.5 mg, 4 mg, and 9 mg); per 2025 ADA guidelines, added bypass of metformin trial for members with MASLD, MASH, and heart failure with preserved ejection fraction. Per SDC request, modified preferred liraglutide product to state 'liraglutide (generic Victoza).'	12.17.24	02.25
RT4: updated policy to reflect Ozempic's new FDA indication for use in diabetic patients with chronic kidney disease; added "renal" benefit to criterion I.B.4.c.	02.12.25	

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated policy to add exenatide (generic Byetta) as a preferred GLP-1 receptor agonist	09.25.25	10.14.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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