Clinical Policy: Orforglipron (Foundayo)

Reference Number: CP.CPA.365
Effective Date: 04.01.26
Last Review Date: 05.26
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Orforglipron (Foundayo™) is glucagon-like peptide-1 (GLP-1) receptor agonist.

FDA Approved Indication(s)

Foundayo is indicated in combination with a reduced-calorie diet and increase physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one-weight-related comorbid condition.

Limitation(s) of use: Concomitant use with another GLP-1 receptor agonist is not recommended.

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 Foundayo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Weight Management (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Body mass index (BMI) ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age ≥ 18 years;
3. For members with concurrent type 2 diabetes mellitus (T2DM), both of the following (a and b)
   a. Member has received optimal diabetic standard of care therapy as evidenced by a trial of ≥ 3 consecutive months each of all of the following (i, ii, iii, and iv), unless clinically significant adverse effects are experienced or all are contraindicated;*
      i. Ozempic® or Rybelsus®;
      ii. Trulicity®;
      iii. Liraglutide (generic Victoza®);
      iv. Mounjaro®;

      **Prior authorization may be required*

b. If member is currently receiving a GLP-1 receptor agonist and is requesting to switch to Foundayo therapy, medical justification* supports necessity for Foundayo;
**Intolerance due to common adverse effects of the GLP-1 receptor agonists class such as gastrointestinal symptoms is not considered acceptable medical justification*

4. Foundayo is not prescribed concurrently with other orforglipron-containing products or any other GLP-1 receptor agonist(s);
5. Documentation supports member's participation in a Health plan-approved weight loss program (*see Appendix E*) or other weight loss programs recommended by the prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a Health plan-approved weight loss program (*see Appendix E*) or other weight loss programs recommended by the prescriber for at least 6 months;
   b. Will continue to be actively enrolled in a weight loss program while concomitantly prescribed Foundayo;
6. Documentation of member's baseline body weight in kg;
7. Dose does not exceed 1 tablet per day and the following (a-f):
   a. Days 1 through 30: 0.8 mg per day;
   b. Days 31 through 60: 2.5 mg per day;
   c. Days 61 through 90: 5.5 mg per day;
   d. Days 91 through 120: 9 mg per day;
   e. Days 121 through 150: 14.5 mg per day;
   f. Days 151 through 180: 17.2 mg per day.

Approval duration: 6 months

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.

II. Continued Therapy

A. Weight Management (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 as evidenced by one of the following (a or b):
   a. If this is the first renewal request, member has lost ≥ 5% of baseline body weight;
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
3. Documentation of member's current body weight in kg;
4. Foundayo is not prescribed concurrently with other orforglipron-containing products or any other GLP-1 receptor agonist(s);
5. Documentation that member is actively enrolled in a Health plan approved weight loss program (*see Appendix E)* or other weight loss program recommended by the prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy;
6. Request meets all of the following (a, b, and c):
   a. After the initial dose escalation period (see *Section V*), member is able to tolerate a maintenance dose of ≥ 5.5 mg per day;
   b. Dose does not exceed 17.2 mg per day;
   c. Dose does not exceed 1 tablet per day.

Approval duration: 12 months

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMI: body mass index

FDA: Food and Drug Administration

GLP-1: glucagon-like peptide-1 T2DM: type 2 diabetes mellitus

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ozempic® (semaglutide)*	Injection: • 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 Tablet: 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	Injection: 2 mg/week Tablet: 9 mg/day
Rybelsus® (semaglutide)*	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	14 mg/day
Trulicity® (dulaglutide)	0.75 mg to 1.5 mg SC once weekly 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	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
Mounjaro® (tirzepatide)	Initial: 2.5 mg SC once weekly May increase by 2.5 mg every 4 weeks up to 15 mg once weekly	15 mg/week

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.
**Ozempic and Rybelsus tablets 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.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2); known serious hypersensitivity to orforglipron or any of the excipients in Foundayo

- Boxed warning(s): risk of thyroid c-cell tumors

Appendix D: General Information

- BMI = 703 x [weight (lbs)/height (inches)^2].
- Examples of coronary artery/heart disease include coronary artery bypass graft, angina, and history of myocardial infarction or stroke.
- The Endocrine Society practice guideline on pharmacological management of obesity states that a weight loss < 5% after 3 months of therapy indicates the weight loss medication is ineffective. In such cases, the Endocrine Society recommends that the medication be discontinued and alternative medications be considered.

Appendix E: Health Plan-Approved Weight Loss Program

Health Plan	Approved Weight Loss Program
CA	Weight watchers, Active&Fit

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	Starting dosage is 0.8 mg PO once daily. After at least 30 days, increase dosage to 2.5 mg, then 5.5 mg PO once daily. Dosage may be increased to the next dosage level (9 mg, 14.5 mg, or 17.2 mg once daily) after at least 30 days on the current dosage, based on treatment response and tolerability.	17.2 mg/day

VI. Product Availability

Tablets: 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, 17.2 mg

VII. References

1. Foundayo Prescribing Information. Indianapolis, IN: Eli Lilly; April 2026. Available at: https://uspl.lilly.com/foundayo/foundayo.html#pi. Accessed April 8, 2026.
2. ClinicalTrials.gov. A study of orforglipron (LY3502970) in adult participants with obesity or overweight with weight-related comorbidities (ATTAIN-1). Available at: https://clinicaltrials.gov/study/NCT05869903. Accessed April 8, 2026.
3. ClinicalTrials.gov. A study of orforglipron in adult participants with obesity or overweight and type 2 diabetes (ATTAIN-2). Available at: https://clinicaltrials.gov/study/NCT05872620. Accessed December April 8, 2026.
4. Wharton S, Aronne LJ, Stefanski A, et al. Orforglipron, an oral small-molecule GLP-1 receptor agonist for obesity treatment. N Engl J Med 2025;393:1796-1806.
5. Horn DB, Ryan DH, Giljanovic S, et al. Orforglipron, an oral small-molecule GLP-1 receptor agonist, for the treatment of obesity in people with type 2 diabetes (ATTAIN-2): A phase 3, double-blind, randomised, multicentre, placebo-controlled trial. The Lancet 2025;406(10522):P2927-2944.

6. Jensen MD, Ryan DH, Apovian CM, et. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014; 129 (suppl 2): S102–S138.
7. 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): 42-362.
8. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocrine Practice 2016;22(suppl 3): 1-203.
9. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198-1225.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	12.16.25	02.26
Drug is now FDA approved – criteria updated per FDA labeling: added criterion for documentation of member's current body weight in kg to initial and continued criteria; clarified weight loss program as "Health plan-approved weight loss program or other weight loss program recommended by the prescriber" in continued therapy; references reviewed and updated.	04.08.26	05.26

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.