Drug Coverage Policy

Effective Date……09/01/2026
Coverage Policy Number……BEO006
Policy Title……Foundayo Benefit Exclusion Overrides Policy BMI ≥ 35

Weight Loss – Glucagon-Like Peptide-1 Agonists – Foundayo Benefit Exclusion Overrides Policy BMI ≥ 35

- Foundayo™ (orforglipron tablets – Eli Lilly)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
Foundayo is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity to **reduce excess body weight and maintain weight reduction long term** in[1]:

- Adults with overweight in the presence of at least one weight-related comorbid condition.
- Adults with obesity.

Concomitant use with another GLP-1 receptor agonist is not recommended.[1]

Dosing
In the prescribing information for Foundayo, the recommended starting dose is 0.8 mg orally once daily (QD).[1] After ≥ 30 days on the 0.8 mg dose, increase the dose to 2.5 mg QD. After ≥ 30 days on the 2.5 mg dose, increase the dose to 5.5 mg QD. The dose may be increased to the next dose level (9 mg, 14.5 mg, or 17.2 mg QD) after ≥ 30 days on the current dose based on treatment response and tolerability. The maximum dose is 17.2 mg QD (reached on Day 151).

Body mass index (BMI) is appropriate to screen for adiposity-based chronic disease/obesity and is used to classify individuals into categories of overweight (BMI ≥ 25.0 to ≤ 29.9 kg/m^2), Class I obesity (BMI ≥ 30.0 to ≤ 34.9 kg/m^2), Class II obesity (BMI ≥ 35.0 to ≤ 39.9 kg/m^2), or Class III obesity (BMI ≥ 40 kg/m^2).[2]

Coverage Policy

POLICY STATEMENT
This Benefit Exclusion Overrides policy has been developed to authorize coverage of Foundayo for the treatment of weight loss in adults with a body mass index (BMI) of ≥ 27 kg/m^2 with at least two weight-related comorbidities, or with a body mass index of ≥ 35 kg/m^2. The BMI thresholds for the weight loss indications in adults are not based on clinical data but are provided in this product offering to allow a subset of patients to obtain these medications. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Foundayo is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Weight Loss in an Adult with Overweight or Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):
      i. Patient is ≥ 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 35 kg/m^2; OR

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least TWO of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving Foundayo. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):

Note: For a patient who has not completed 8 months of initial therapy, refer to Initial Therapy criteria above.

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 35 kg/m^2; OR

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least TWO of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

Conditions Not Covered

Foundayo for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** Concomitant use Foundayo with another GLP-1 receptor agonist is not recommended.[1]

References

1. Foundayo™ tablets [prescribing information]. Indianapolis, IN: Eli Lilly; April 2026.
2. Nadolsky K, Garvey WT, Agarwal M, et al. American Association of Clinical Endocrinology consensus statement: algorithm for the evaluation and treatment of adults with obesity/adiposity-based chronic disease — 2025 Update. *Endocrine Practice*. 2025;31:1351–1394.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy	04/24/2025	07/01/2025
Wegovy: **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.** Initial Therapy. For the requirement that a patient has had a prior stroke, a note was added that a to clarify that this does not include a transient ischemic attack (TIA). Zepbound: **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The requirement that a patient had a sleep study was modified to remove the timeframe that the sleep study was within the past 1 year. A patient is still required to have a sleep study. Conditions Not Covered: **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** This condition not recommended for approval was clarified to state that concomitant use with other medications FDA-approved for weight loss is not recommended. Previously, the requirement did not specify medications were "FDA-approved" for weight loss. The note with examples of weight loss medications was updated to reflect product availability for medications FDA-approved for weight loss.	06/12/2025	08/01/2025

Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists. The note was updated to reflect availability for other GLP-1 or GLP-1/GIP agonists.		
Saxenda: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with obesity or is overweight". **Weight Loss in a Pediatric Patient with Obesity.** This condition of approval was modified to add "with obesity". Wegovy: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with obesity or is overweight". **Weight Loss in a Pediatric Patient with Obesity.** This condition of approval was modified to add "with obesity". **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease in a Patient with Obesity or Overweight.** This condition of approval was re-worded from "in an overweight or obese patient" to "in a patient with obesity or is overweight". Zepbound: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with obesity or is overweight".	07/17/2025	09/15/2025
Liraglutide, generic to Saxenda was added to the policy. **Policy Statement**: The following was added: In clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression; females are defined as individuals with the biological traits of a female, regardless of the individual's gender identity or gender expression. Because of the specialized skills required for evaluation and diagnosis of patients treated with Wegovy as well as the monitoring required for adverse events and long-term efficacy, approval requires Wegovy to be prescribed by or in consultation with a physician who specializes in the condition being treated. The Policy Statement was updated as follows to address the availability of liraglutide, generic to Saxenda: Prior Authorization is recommended for prescription benefit coverage of liraglutide (Saxenda, generic), Wegovy, and Zepbound. Of note, this policy targets liraglutide (Saxenda, generic), Wegovy, and Zepbound; other glucagon-like	11/06/2025	12/15/2025

peptide-1 agonists that do not carry an FDA-approved indication for weight loss are not targeted in this policy. **Documentation:** A requirement for documentation was added for the use of Wegovy for MASH. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information. Wegovy: **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** A new condition of coverage was added to FDA-Approved Indications. Conditions Not Covered: **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** This condition not recommended for approval was removed. Liraglutide (Saxenda, generic), Wegovy, and Zepbound: **Weight Loss in an Adult with Overweight or Obesity:** Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda. Liraglutide (Saxenda, generic) and Wegovy: **Weight Loss in a Pediatric Patient with Obesity:** Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda. Saxenda **Weight Loss in an Adult with Obesity or is Overweight.** Initial therapy **Added** preferred product requirements. **Weight Loss in a Pediatric Patient with Obesity.** Initial therapy **Added** preferred product requirements.		
Updated the policy statement. **Changed** each "Patient is Continuing Therapy" to "Patient is Currently Receiving" Wegovy **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** Initial Therapy**.** The requirement that the patient does not have cirrhosis was clarified that the patient does not have	12/18/2025	02/15/2026

cirrhosis "(F4)". Criteria for the diagnosis of MASH/NASH were updated such that the patient must have documentation of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra or Wegovy confirmed by ONE of the following: Liver biopsy performed within 3 years preceding treatment with Rezdiffra or Wegovy **[documentation required]**, vibration-controlled elastography (VCTE) performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]**, magnetic resonance imaging (MRE) performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]**, or Enhanced Liver Fibrosis (ELF) test performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]** with a score of ≥ 9.2 to ≤ 10.5 **[documentation required].** Previously, the diagnosis of MASH/NASH was confirmed by a either a liver biopsy within 3 years preceding treatment with Wegovy **[documentation required]** that showed a non-alcoholic fatty liver disease activity score of ≥ 4 with a score of ≥ 1 in steatosis, ballooning, and lobular inflammation **[documentation required]** OR an imaging exam (i.e., elastography, computed tomography, or magnetic resonance imaging) performed within 6 months preceding treatment with Wegovy **[documentation required].** The separate criterion that the patient have stage F2 or F3 fibrosis **[documentation required]** was removed (this is part of the updated criterion outlined above; patients must still have documentation of F2 or F3 fibrosis). Reference to prior to initiating therapy throughout criteria were updated to include Rezdiffra(i.e., prior to initiating treatment with Rezdiffra or Wegovy); previously only Wegovy. Patient is Currently Receiving Wegovy. The criterion requiring that according to the prescriber the patient has not progressed to stage F4 (cirrhosis) was modified to state, according to the prescriber, patient does not have cirrhosis (F4). Zepbound **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The criterion excluding coverage of a patient with central sleep apneas was modified to remove the additional requirement that the percent of central apneas/hypopneas is ≥ 50%.		
Wegovy tablet was added to the policy; new criteria were created. Wegovy injection	02/12/2026	03/01/2026

Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight. Patient is Currently Receiving Wegovy injection. The note that baseline body mass index refers to baseline prior to Wegovy injection was updated to also include Wegovy tablet.		
Foundayo was added to the Policy; new criteria were created. **Policy Statement:** Foundayo was added the list of products to which the Policy applies. The statement was also updated to reflect the availability of Wegovy tablet and Wegovy injection. Throughout the policy, Foundayo was added as an example of a glucagon-like peptide-1 (GLP-1) receptor agonist. Wegovy injection **Weight Loss in an Adult with Obesity or is Overweight.** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy tablet was added to the following: Patient is Currently Receiving Wegovy injection or Wegovy tablet. The following note was updated to include Wegovy injection and Wegovy tablet: For a patient who has not completed 7 months of initial therapy with Wegovy injection and/or Wegovy tablet, refer to Initial Therapy criteria above. **Weight Loss in a Pediatric Patient with Obesity.** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy tablet was added to the following: Patient is Currently Receiving Wegovy injection or Wegovy tablet. The following note was updated to include Wegovy injection and Wegovy tablet: For a patient who has not completed 7 months of initial therapy with Wegovy injection and/or Wegovy tablet, refer to Initial Therapy criteria above. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity.** Initial Therapy and Patient is Currently Receiving Wegovy injection criteria were combined (previously each a 1 year approval); the approval duration is 1 year The requirement that the patient has a current body mass index (BMI) of ≥ 27 kg/m^2 (previously for Initial Therapy, only) was revised that at baseline, the patient had a BMI ≥ 27 kg/m^2. The note for baseline BMI was revised to state that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound) [previously Wegovy injection or Wegovy tablet, Patient is	04/16/2026	04/30/2026

Currently Receiving Wegovy injection or Wegovy tablet]. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** Initial Therapy. Reference to Wegovy throughout criteria was updated to specify Wegovy injection. Wegovy tablet for the requirements related to identification of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra, Wegovy injection, or Wegovy tablet **[documentation required]**. Wegovy tablet was added to the following: Patient is Currently Receiving Wegovy injection or Wegovy tablet. The following note was updated to include Wegovy injection and Wegovy tablet: For a patient who has received < 1 year of therapy with Wegovy injection and/or Wegovy tablet, or who is restating therapy, refer to Initial Therapy. For the following requirement (and associated Note), reference to Wegovy was updated to specify Wegovy injection and to add Wegovy tablet: Patient has completed ≥ 1 year of therapy with Wegovy injection and/or Wegovy tablet AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH. Wegovy tablet **Weight Loss in an Adult with Obesity or is Overweight.** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Initial Therapy. The approval duration was changed to 7 months (previously 6 months). Wegovy injection was added to Patient is Currently Receiving Wegovy tablet or Wegovy injection. The following note was updated to include Wegovy injection and Wegovy tablet, and to reflect the 7-month initial approval duration: For a patient who has not completed 7 months of initial therapy with Wegovy injection and/or Wegovy tablet, refer to Initial Therapy criteria above. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity.** The same changes were made as Wegovy injection; refer to Wegovy injection *Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity,* above. Zepbound **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The requirement that the patient has a current BMI ≥ 30 kg/m^2 was revised that at baseline, patient had a BMI ≥ 30 kg/m^2. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Patient is Currently Receiving Zepbound. The notes that define		

baseline were updated that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound); previously, prior to Zepbound.		
Updated policy title and policy number. Wegovy HD injection was added to the policy; approval criteria are the same as for Wegovy injection. **Policy statement:** Wegovy HD injection was added to the Policy Statement. The statement was also updated to reflect the availability of Wegovy tablet and Wegovy injection. **Documentation:** Wegovy HD injection was added to the documentation statement. <u>Wegovy injection</u> Wegovy HD injection was added to the criteria as previously applied to Wegovy injection. In addition, the following changes were made to the Wegovy injection criteria previously in place. **Weight Loss in an Adult with Overweight or Obesity:** The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. **Weight Loss in a Pediatric Patient with Obesity:** The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH):** For initial therapy, Wegovy HD injection was added to the requirements related to identification of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra, Wegovy injection, or Wegovy tablet **[documentation required]**. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. <u>Wegovy tablet</u> **Weight Loss in an Adult with Overweight or Obesity:** The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet.	05/14/2026	06/01/2026

Removed Saxenda, liraglutide, Wegovy Tablet, Wegovy Injection and Zepbound. The products were moved to new individual policies.	07/09/2026	09/01/2026

The policy effective date is in force until updated or retired.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2026 The Cigna Group.