



Weight Management Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-27-2026

Date of Origin
02-15-2024

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Foundayo™ (orforglipron calcium) Tablet	In combination with a reduced-calorie diet and increased 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 of Use: Concomitant use with another GLP-1 receptor agonist is not recommended		46
Saxenda® (liraglutide) Subcutaneous injection solution*	In combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in: <ul style="list-style-type: none"> Adults and pediatric patients aged 12 years and older with body weight greater than 60 kg and obesity Adults overweight in the presence of at least one weight related comorbid condition Limitations of Use: <ul style="list-style-type: none"> Coadministration with other liraglutide-containing products or with any other GLP-1 receptor agonist is not recommended The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established 	*generic available	1
Wegovy® (semaglutide) Tablet	In combination with a reduced calorie diet and increased physical activity: <ul style="list-style-type: none"> To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition Limitation(s) of Use: Concomitant use of Wegovy (semaglutide) tablets or Wegovy (semaglutide) injection with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended		2
Wegovy® HD (semaglutide)	To reduce excess body weight and maintain weight reduction long term in: <ul style="list-style-type: none"> Adults with obesity 		2

Agent(s)	FDA Indication(s)	Notes	Ref#
Subcutaneous injection solution	<ul style="list-style-type: none"> Adults with overweight in the presence of at least one weight-related comorbid condition <p>Limitation(s) of Use: Concomitant use of Wegovy (semaglutide) tablets or Wegovy (semaglutide) injection with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended</p>		
Wegovy® (semaglutide) Subcutaneous injection solution	<p>In combination with a reduced calorie diet and increased physical activity:</p> <ul style="list-style-type: none"> To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight To reduce excess body weight and maintain weight reduction long term in: <ul style="list-style-type: none"> Adults and pediatric patients aged 12 years and older with obesity Adults overweight in the presence of at least one weight-related comorbid condition For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults <p>Limitation(s) of Use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended</p>		2
Zepbound® (tirzepatide) Subcutaneous injection solution Vial	<p>In combination with a reduced-calorie diet and increased physical activity:</p> <ul style="list-style-type: none"> 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 to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity <p>Limitation(s) of Use: Coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended</p>		3
Zepbound® Kwikpen® (tirzepatide) Injection	<p>In combination with a reduced-calorie diet and increased physical activity:</p> <ul style="list-style-type: none"> 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 to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity <p>Limitation of Use: Coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended</p>		3

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Obesity	Obesity rates have increased sharply over the last 30 years, creating a global public health crisis. The National Health and Nutrition Examination Surveys show that nearly 2 of 3 US adults are overweight or obese, and 1 of 3 adults are obese. Adults with body mass index (BMI) 25-29.9 kg/m ² are considered overweight; those with BMI
---------	--

greater than or equal to 30 kg/m² are considered obese.(5) Weight loss is difficult for most people and weight loss medications help reinforce behavioral strategies to lose weight. Medications for weight loss do not work on their own. Numerous guidelines recommend the addition of weight loss medications only in conjunction with lifestyle and behavioral modifications.(4,5,6,11)

GLP-1 is an endogenous incretin hormone produced by L cells within the intestinal mucosa in response to the intake of nutrients. GLP-1 receptors are expressed in multiple organs, including pancreas, gastrointestinal (GI) tract, heart, brain, kidney, lung, and thyroid. This ubiquitous expression of GLP-1 receptors could be the reason for its pleiotropic benefits for T2DM, weight loss, and cardio protection. GLP-1 has numerous metabolic effects, including but not limited to, glucose-dependent stimulation of insulin secretion, delayed gastric emptying, inhibition of food intake, and modulation of β -cell proliferation. Semaglutide was approved for the management of obesity in 2021. Having a dose-response effect on weight loss, semaglutide was approved at doses higher than indicated for T2DM. GLP-1 RAs do not have the same neuropsychiatric adverse effects as other FDA-approved drugs on the market. Other benefits include inherent glucoregulatory properties and cardio protection in select populations.(11)

The American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity recommends the following:(5)

- The principal outcome and therapeutic target in the treatment of obesity should be to improve the health of the patient by preventing or treating weight related complications using weight loss, not the loss of body weight per se
- For overweight (BMI 25-29.9 kg/m²) or obese (BMI greater than or equal to 30 kg/m²) patients, evaluate for adiposity related complications (e.g., type 2 diabetes, dyslipidemia, hypertension, cardiovascular disease, obstructive sleep apnea).
- Pharmaceutical therapy should only be used as adjunct to lifestyle modifications and depends on the staging of obesity:
 - Overweight Stage 0 (BMI 25-29.9 kg/m² or 23-24.9 kg/m² in certain ethnicities* with no complications)
 - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
 - Obesity Stage 0 (BMI greater than or equal to 30 kg/m² or greater than or equal to 25 kg/m² in certain ethnicities* with no complications)
 - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral intervention
 - Weight loss medications – consider if lifestyle therapy fails to prevent progressive weight gain (BMI greater than or equal to 27 kg/m²)
 - Obesity Stage 1 (BMI greater than or equal to 25 kg/m² or greater than or equal to 23 kg/m² in certain ethnicities* with greater than or equal to 1 mild/moderate complications)
 - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
 - Weight loss medications – consider if lifestyle therapy fails to achieve therapeutic target or initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m²)
 - Obesity Stage 2 (BMI greater than or equal to 25 kg/m² or greater than or equal to 23 kg/m² in certain ethnicities* with greater than or equal to 1 severe complications):
 - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
 - Weight loss medication – initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m²)

- Consider bariatric surgery (BMI greater than or equal to 35 kg/m²)

*Certain ethnicities (A BMI cutoff point value of greater than or equal to 23 kg/m² should be used in the screening and confirmation of excess adiposity in South Asian, Southeast Asian, and East Asian adults)

The Endocrine Society clinical practice guidelines suggests medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone. They recommend adherence to American Heart Association Guidelines (2013) [see below] which include advice for assessment and treatment with diet and exercise, as well as bariatric surgery for appropriate candidates.(4)

- Diet, exercise, and behavioral modification should be included in all overweight and obesity management approaches for BMI greater than or equal to 25 kg/m² and other tools [e.g., pharmacotherapy (if BMI greater than or equal to 27 kg/m² with comorbidity or BMI greater than 30 kg/m²) and bariatric surgery (BMI greater than or equal to 35 kg/m² with comorbidity or BMI greater than 40 kg/m²)] should be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when possible. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications.
- Assessment of efficacy and safety of prescribed weight loss medications should be performed at least monthly for the first 3 months, then at least every 3 months thereafter.
- Clinicians are recommended to perform annual and symptom-based screening for major obesity related chronic conditions in all adult patients with a BMI greater than or equal to 30 kg/m², including diabetes, cardiovascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, non-alcoholic fatty liver disease, osteoarthritis, and major depression.
- Prescribers should identify chronic medications, for concomitant medical conditions, that contribute to weight gain, and prescribe drugs that are weight neutral or that will promote weight loss when possible.
- If a patient's response to a weight loss medication is deemed effective (weight loss greater than or equal to 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. If deemed ineffective (weight loss less than 5% at 3 months) or if there are safety or tolerability issues at any time, the medication should be discontinued and alternative medications or referral for alternative treatment approaches instead considered.

The American Heart Association/American College of Cardiology/Obesity Society Guideline (2013) suggests if weight and lifestyle history indicates the patient has never participated in a comprehensive lifestyle intervention program as defined in the guidelines (i.e., trained interventionist or nutritional professional supervision of diet, exercise, and behavior therapy), it is recommended that the patient undertake such a program before addition of adjunctive therapies (e.g., pharmacotherapy), since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle management alone. If a patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and has BMI greater than or equal to 30 kg/m² or greater than or equal to 27 kg/m² with greater than or equal to 1 obesity-associated comorbid condition(s), adjunctive therapy may be considered. The expert panel did not review comprehensive evidence on pharmacotherapy for weight loss. Medications should be FDA approved and clinicians should be knowledgeable about the product label. The provider should weigh potential risks of the medication vs. potential benefits of successful weight loss for the individual patient. If the patient is currently taking an obesity medication but has not lost at least 5% of initial body weight after 12 weeks on a maximal dose of the medication, the provider should reassess the risk-to-benefit ratio of that medication for the patient and consider discontinuation of that drug.(6)

	<p>The American Gastroenterological Association (AGA) clinical practice guidelines (2022) strongly recommended the use of pharmacotherapy in addition to lifestyle intervention in adults with overweight and obesity (body mass index 30 kg/m^2 or greater, or 27 kg/m^2 or greater with weight-related complications) who have an inadequate response to lifestyle interventions. The panel suggested the use of semaglutide 2.4 mg, liraglutide 3.0 mg, phentermine-topiramate ER, and naltrexone-bupropion ER (based on moderate certainty evidence), and phentermine and diethylpropion (based on low certainty evidence), for long-term management of overweight and obesity. The guideline panel suggested against the use of orlistat. The panel identified the use of Gelesis100 oral superabsorbent hydrogel as a knowledge gap.(11)</p>
<p>Pediatric Obesity</p>	<p>The current and long-term health of 14.4 million children and adolescents is affected by obesity, making it one of the most common pediatric chronic diseases. Genetics and environment are the underlying causes of the increase in pediatric obesity. Obese children and adolescents are at risk of developing the same comorbid conditions as obese and overweight adults.(9) The American Diabetes Guidelines recommends the management of diabetes in children and adolescents (individuals <18 years of age) cannot simply be derived from care routinely provided to adults with diabetes.(31)</p> <p>Obesity and overweight in children are defined on percentages specific for age and gender defined BMI values. The American Academy of Pediatrics (AAP) define obesity as a BMI greater than or equal to 95th percentile or a BMI greater than or equal to 30 kg/m^2, whichever is lower, and overweight as a BMI within 85th to 94th percentile for children and adolescents 2 years of age and older.(9,10) Clinicians should assess medical and behavioral risks in any child with a BMI above the 85th percentile before initiating any intervention.(9,10) The Endocrine Society Pediatric Obesity Treatment Guidelines also recommend that clinicians should evaluate for potential comorbidities in children and adolescents with a BMI greater than or equal to 85th percentile.(8) Risk-based screening for prediabetes and/or type 2 diabetes should be considered after the onset of puberty or greater than or equal to 10 years of age, whichever occurs earlier, in youth with overweight (BMI ≥ 85th percentile) or obesity (BMI ≥ 95th percentile) and who have one or more additional risk factors for diabetes.(31)</p> <p>The 2023 AAP guidelines recommend the use of weight loss agents in conjunction with lifestyle and behavioral changes. Pediatricians and other primary healthcare providers should treat children and adolescents for overweight with comorbidities (BMI greater than or equal to 85th percentile; comorbidities such as dyslipidemia, prediabetes, Type 2 diabetes, fatty liver disease, hypertension) and obesity (BMI greater than or equal to 95th percentile).(10)</p> <p>The 2017 Endocrine Society guidelines recommend the use of FDA approved pharmacotherapy in pediatric patients as adjunctive therapy to lifestyle modifications of the highest intensity available and only by clinicians that are experienced in the use of anti-obesity agents. Prescribing weight loss medications off-label to pediatric patients less than 16 years of age is discouraged.(8)</p>
<p>Cardiovascular</p>	<p>Wegovy (semaglutide) was studied to determine its effect relative to placebo on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of cardiovascular risk factors and individualized healthy lifestyle counseling (including diet and physical activity), in patients who are overweight or with obesity, and without diabetes. The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. Inclusion requirements of the trial included:(12)</p> <ul style="list-style-type: none"> • Patients who have established cardiovascular disease (CVD) as determined by having at least one of the following: <ul style="list-style-type: none"> ○ Prior myocardial infarction ○ Prior stroke (ischemic or hemorrhagic stroke) ○ Symptomatic peripheral arterial disease (intermittent claudication with ankle-brachial index <0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

	<ul style="list-style-type: none"> • Patients with a BMI greater than or equal to 27 kg/m² • Patients 45 years of age or over <p>Guidelines recommend that patients work towards a goal of tobacco cessation and avoiding tobacco exposure, managing hypertension to goal, and managing lipid levels to goal as risk reduction measures for CVD secondary prevention.(13,14,15)</p>
<p>Metabolic dysfunction-associated steatotic liver disease (MASLD)/Metabolic dysfunction-associated steatohepatitis (MASH)</p>	<p>Metabolic dysfunction-associated steatotic liver disease (MASLD), previously termed non-alcoholic fatty liver disease (NAFLD), is defined as steatotic liver disease (SLD) in the presence of one or more cardiometabolic risk factor(s) and the absence of harmful alcohol intake. SLD occurs when your body begins storing fat in your liver. While some fat in your liver is normal, when more than 5 to 10% of the liver's weight is fat, it is classified as steatosis. MASLD and ALD (alcohol intake >50 g/day for females and >60 g/day for males) comprise the most common causes of SLD. A new category, requiring further characterization, termed MetALD, describes those with MASLD who consume greater amounts of alcohol (20-50 g/day for females and 30-60 g/day for males, respectively), but do not meet the criteria for ALD. The history of alcohol consumption is an important factor as the current drinking pattern may not necessarily reflect previous drinking behavior. Importantly, despite sharing the same prevalence of cardiometabolic risk factors, MetALD is associated with a higher risk of all-cause mortality, underpinning MetALD as a distinct subclass of SLD with poorer prognosis. Therefore, diagnostic and treatment recommendations provided for MASLD cannot be extended to the MetALD population.(19,22,27,28)</p> <p>The spectrum of MASLD includes steatosis, metabolic dysfunction-associated steatohepatitis (MASH, previously NASH), fibrosis, cirrhosis and MASH-related hepatocellular carcinoma (HCC). With MASH, fat buildup progresses to inflammation, then tissue damage and scarring (fibrosis). Metabolic dysfunction-associated steatohepatitis (MASH) is inflammation of the liver caused by excess fat cell deposits in it (steatotic liver disease). MASH is characterized by histological features of hepatocellular ballooning and lobular inflammation. Chronic inflammation causes progressive liver damage. MASL refers to the presence of MASLD in the absence of steatohepatitis.(19,27,28)</p> <p>Metabolic dysfunction-associated steatotic liver disease (MASLD) has become the most common chronic liver disease, and its prevalence will likely continue to rise. Often, MASLD has no symptoms. When symptoms do occur, they may include fatigue, weakness, weight loss, loss of appetite, nausea, abdominal pain, spider-like blood vessels, yellowing of the skin and eyes (jaundice), itching, fluid buildup and swelling of the legs (edema) and abdomen (ascites), and mental confusion. MASLD is initially suspected if blood tests show high levels of liver enzymes with an absence of chronic alcohol intake. However, other liver diseases are first ruled out through additional tests (e.g., Wilson's disease, hepatitis).(19,20,21)</p> <p>The presence of MASLD is tightly linked to type 2 diabetes (T2D), obesity and other cardiometabolic risk factors. Studies suggest that one-third to two-thirds of people with type 2 diabetes have MASLD. Research suggests that MASLD is present in up to 75% of people who are overweight and in more than 90% of people who have severe obesity. MASLD is associated with an increased risk of cardiovascular events, chronic kidney disease, hepatic and extrahepatic malignancies, and liver-related outcomes, including liver failure and hepatocellular carcinoma (HCC). Therefore, the high socio-economic burden of MASLD poses a global health challenge that needs to be addressed by medical societies and policymakers.(19,27,28)</p> <p>The following are the adult cardiometabolic risk factors (at least 1 out of 5) in the definition of MASLD:(27,28)</p> <ul style="list-style-type: none"> • Weight (BMI or WC) Overweight or Obesity Body mass index(BMI): <ul style="list-style-type: none"> ○ Greater than or equal to 25 kg/m² (greater than or equal to 23 kg/m² in people of Asian ethnicity) OR ○ Waist Circumference (WC): 94 cm (male), 80 cm (female) or ethnicity adjusted equivalent

- Prediabetes or type 2 diabetes:
 - Fasting serum glucose greater than or equal to 5.6 mmol/L (100mg/dL) OR
 - 2-hour post load glucose levels greater than or equal to 7.8 mmol/L (greater than or equal to 140 mg/dL) OR
 - HbA1c greater than or equal to 5.7% OR
 - Type 2 diabetes OR
 - Treatment for type 2 diabetes
- Plasma triglycerides:
 - Greater than or equal to 1.7 mmol/L (greater than or equal to 150 mg/dL) OR
 - Lipid-lowering treatment
- HDL cholesterol:
 - Less than or equal to 1.0 mmol/L (less than or equal to 39 mg/dL) in men and less than or equal to 1.3 mmol/L (less than or equal to 50 mg/dL) in women OR
 - Lipid-lowering treatment
- Blood pressure:
 - Greater than or equal to 130/85 mmHG OR
 - Specific antihypertensive drug treatment

The 2021 AACE and 2023 AASLD practice guidelines suggest the following: Clinicians should identify individuals with obesity, metabolic syndrome traits, pre-diabetes, or type 2 diabetes, as well as those showing hepatic steatosis on imaging or persistently high plasma aminotransferase levels (over six months) as "high risk" and recommend screening for NAFLD/MASLD and advanced fibrosis. Metabolic syndrome is characterized by any three of the following: obesity, hypertension, high blood triglycerides, low HDL cholesterol, and insulin resistance.(19,21)

An initial evaluation for individuals suspected of having hepatic steatosis based on imaging findings should include tests to rule out other causes of liver disease (e.g., hepatitis B and C serology, autoantibody panels, and metabolic syndrome evaluations). It's important to note that many laboratory normal ranges are higher than the accepted thresholds for NAFLD/MASLD, where normal alanine aminotransferase (ALT) levels typically range from 29 to 33 U/L in men and from 19 to 25 U/L in women.(19,21,22)

The American Gastroenterology Association (AGA) guidelines recommend best practices for diagnosing MASH/MASLD:(24)

- A Fibrosis 4 Index score below 1.3 is linked with a strong negative predictive value for advanced hepatic fibrosis and may be helpful in ruling out advanced fibrosis in NAFLD/MASLD patients
- A combination of two or more NITs, incorporating serum biomarkers and/or imaging biomarkers, should be used for staging and risk assessment
- In patients with a Fibrosis 4 Index score above 1.3. FIB-4 risk categories from low risk (<1.3) to intermediate risk (1.3–2.67) to high risk (>2.67) can be used to evaluate clinical progression
- NITs should be evaluated in the context of relevant clinical data (e.g., physical examination, biochemical tests, and imaging) to enhance positive predictive value in identifying patients with advanced fibrosis
- Liver biopsy should be considered for patients with indeterminate or conflicting NIT results, discrepancies with other clinical or laboratory findings, or when other liver disease causes are suspected

NITs (non-invasive tests) derived from clinical variables can estimate the presence of advanced fibrosis. Several have been developed (e.g., FIB-4, NAFLD/MASLD Fibrosis Score, AST Platelet Ratio Index); however, FIB-4 is the most validated. FIB-4 is calculated using a simple algorithm based upon age, ALT, AST, and platelet count and outperforms other calculations in its ability to identify patients with a low probability of advanced fibrosis. The FIB-4 index can be calculated from age and three parameters

obtained in routine laboratory assessments: alanine aminotransferase (ALT), aspartate aminotransferase (AST), and platelet count. A change in FIB-4 status category from low risk (<1.3) to intermediate risk (1.3–2.67) to high risk (>2.67) may be used to assess clinical progression. Although FIB-4 is statistically inferior to other serum-based fibrosis markers such as the Enhanced Liver Fibrosis (ELF) panel, FIBROSpect II, and imaging-based elastography methods to detect advanced fibrosis, FIB-4 is still recommended as a first-line assessment for general practitioners and endocrinologists based on its simplicity and minimal added cost.(19,23,24)

Those who may have a moderate or high risk of advanced disease based on FIB-4 should undergo secondary risk assessment. Vibration-controlled transient elastography (VCTE) (e.g., FibroScan) is the most commonly used method to assess liver stiffness and can be used to exclude significant hepatic fibrosis. Magnetic resonance elastography (MRE) is more sensitive than VCTE in the detection of fibrosis stage greater than 2 and is considered to be the most accurate noninvasive imaging-based biomarker of fibrosis in NAFLD/MASLD. Although MRE is not a first-line approach to risk stratification in a patient with NAFLD/MASLD, it can be an important tool if clinical uncertainty exists, if there is a need for concomitant cross-sectional imaging, or when other elastography techniques are unavailable. Among patients with cirrhosis, a baseline liver stiffness measure (LSM) by MRE predicts future risk of incident hepatic decompensation and death. Controlled Attenuation Parameter (CAP) as a point-of-care technique may also be used to identify steatosis. A liver biopsy is the optimal approach to confirm the diagnosis and stage of the severity of liver fibrosis. However, it is recognized that this may not be feasible or acceptable to several individuals.(19,23,24)

Research findings have suggested that patients with NAFLD/MASLD exhibit lower levels of biologically active incretin hormones when compared to healthy individuals and this may be attributed to either an increased degradation of these hormones by dipeptidyl peptidase-4 (DPP-4) or a diminished production of these hormones. GLP-1RAs can exert control over energy intake and weight gain through mechanisms such as prolonging gastric emptying and suppressing appetite. These effects help regulate food consumption and contribute to weight management. Additionally, GLP-1RAs have shown the ability to enhance liver enzyme functions, alleviate liver steatosis, and notably reduce liver fat content. Semaglutide, a second-generation GLP-1-RA, is available in both oral (daily administration) and subcutaneous (weekly administration) formulations. Clinical studies have provided evidence of the favorable effects of semaglutide in patients with NAFLD/MASLD. Nevertheless, there is a lack of comprehensive systematic reviews or meta-analyses that have extensively summarized and quantified these effects. Hence, this systematic review and meta-analysis aimed to evaluate the influence of a 24-week administration of semaglutide in patients with NAFLD/MASLD or NASH/MASH.(18)

A systematic review and meta-analysis was conducted (six hundred studies were screened and eight were included) to evaluate the efficacy and safety of 24 weeks of semaglutide treatment in patients with NAFLD/MASLD or NASH/MASH. The following were concluded:(18)

- Semaglutide could be used in patients with non-alcoholic fatty liver disease or non-alcoholic steatohepatitis
- It significantly improves liver enzymes, reduces liver stiffness, and improves metabolic parameters in these patients
- Gastrointestinal adverse effects and gallbladder-related diseases could be a major concern

The 2024 European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD) and European Association for the Study of Obesity (EASO) guidelines suggest in adults with MASLD, lifestyle modification which includes weight loss, dietary changes, physical exercise and discouraging alcohol consumption. In addition, they recommend optimal management of comorbidities, including use of incretin-based therapies (e.g., semaglutide, tirzepatide) for type 2 diabetes or obesity, if indicated. Bariatric surgery is also an option in individuals with

	<p>MASLD and obesity. If locally approved and dependent on the label, adults with non-cirrhotic MASH and significant liver fibrosis (stage greater than or equal 2) should be considered for a MASH-targeted treatment with resmetirom, which demonstrated histological effectiveness on steatohepatitis and fibrosis with an acceptable safety and tolerability profile. No MASH-targeted pharmacotherapy can currently be recommended for the cirrhotic stage. Management of MASH-related cirrhosis includes adaptations of metabolic drugs, nutritional counselling, surveillance for portal hypertension and HCC, as well as liver transplantation in decompensated cirrhosis.(27)</p> <p>While an initial study with liraglutide indicated a histological benefit in MASH, drugs that are being developed for MASH now include semaglutide, and dual GLP1-GIP (e.g., tirzepatide), dual GLP1-glucagon (e.g., cotadutide, survodutide, efinopegdutide) or triple GLP1-GIP-glucagon (e.g., retatrutide) agonists. The largest available trial on semaglutide in MASH (vs. placebo over an 18-month treatment period) demonstrated resolution of steatohepatitis but no fibrosis improvement. A large registrational, phase III study with semaglutide is ongoing. Combining semaglutide with lipogenesis inhibitors may provide additional benefit and such approaches are being tested in larger trials. Histology data are not yet available for the newer dual and triple agonists. Tirzepatide (GLP1-GIP RA) has been shown to significantly reduce both liver and visceral fat in those with type 2 diabetes, in association with major weight loss (comparable to bariatric surgery), and promising results on steatohepatitis resolution from a phase II study in MASH have been communicated. Dual GLP1-glucagon RAs (cotadutide and efinopegdutide) have also been shown to improve liver steatosis, liver enzymes and indexes of fibrosis in individuals with MASLD.(17,27)</p>
Obstructive Sleep Apnea (OSA)	<p>Obstructive sleep apnea (OSA) is a condition where the throat collapses during sleep, leading to breathing interruptions, low oxygen levels, and frequent awakenings. This disorder affects over 900 million people globally and can cause excessive daytime sleepiness and increase the risk of cardiovascular diseases. Guidelines recommend diagnosis with polysomnography, or a home sleep apnea testing with a technically adequate device (in un-complicated adult patients). If a single home sleep apnea test is negative, inconclusive or technically inadequate, polysomnography (PSG) be performed for the diagnosis of OSA.(29,30)</p> <p>Traditional treatments focus on mechanical support, like Positive Airway Pressure (PAP) therapy (i.e., Continuous Positive Airway Pressure or CPAP), which helps reduce sleep interruptions but may not significantly lower cardiovascular risks. Other options include oral appliances, a device that helps keep the throat open by moving the jaw forward, and other airway pressure devices [e.g., bilevel positive airway pressure (BPAP)].(29,30)</p> <p>Obesity is a major modifiable risk factor for OSA and its complications. Guidelines recommend a 7-11% weight reduction, but achieving this through lifestyle changes alone can be challenging. While bariatric surgery is effective, it's not suitable for everyone. Recent trials with tirzepatide, a medication targeting obesity, showed promising results for patients with moderate-to-severe OSA and obesity. Participants who took tirzepatide experienced a significant reduction in the number of apnea events compared to those on placebo, with many reaching levels of severity that may not require PAP therapy. This medication may also aid in reducing cardiovascular risks associated with OSA and obesity, highlighting the need for diverse treatment options. Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. Polysomnography is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.(29,30)</p>
Efficacy	<p>SELECT Trial (Wegovy)</p> <p>Study 1 (NCT03574597) was a multi-national, multi-center, placebo-controlled, double-blind trial to determine the effect of Wegovy relative to placebo on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity). The primary endpoint, MACE, was the time to</p>

first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. All patients were 45 years or older, with an initial BMI of 27 kg/m² or greater and established cardiovascular disease (prior myocardial infarction, prior stroke, or peripheral arterial disease). Patients with a history of type 1 or type 2 diabetes were excluded.(2)

In this trial, 17,604 patients were randomized to Wegovy or placebo. At baseline, the mean age was 62 years and 12,732 patients (72.3%) were male. The mean BMI was 33 kg/m², and 12,580 patients (71.5%) met the BMI criterion for obesity (≥ 30). The mean glycated hemoglobin level was 5.8%, and 11,696 patients (66.4%) met the glycated hemoglobin criterion for prediabetes (defined as a mean level of 5.7 to 6.4%). At baseline, prior myocardial infarction was reported in 76% of randomized individuals, prior stroke in 23%, and peripheral arterial disease in 9%. Heart failure was reported in 24% of patients. At baseline, cardiovascular disease and risk factors were managed with lipid lowering therapy (90%), platelet aggregation inhibitors (86%), angiotensin converting enzyme inhibitors or angiotensin II receptor blockers (74%), and beta blockers (70%). A total of 10% had moderate renal impairment (eGFR 30 to <60 mL/min/1.73m²) and 0.4% had severe renal impairment eGFR <30 mL/min/1.73m².(2,16)

Patients were randomly assigned, with the use of a centralized system in a double-blind manner and in a 1:1 ratio without stratification, to receive once-weekly subcutaneous semaglutide at a dose of 2.4 mg or placebo. The starting dose of semaglutide was 0.24 mg once weekly, and the dose was increased every 4 weeks (to once weekly doses of 0.5, 1.0, 1.7, and 2.4 mg) until the target dose of 2.4 mg was reached after 16 weeks. If dose escalation led to unacceptable adverse effects, the dose-escalation intervals could be extended, treatment could be paused, or maintenance doses below the 2.4 mg per week target dose could be used.(16)

Among the 17,604 patients with a BMI of 27 or greater and preexisting cardiovascular disease but without diabetes, treatment with once-weekly subcutaneous semaglutide at a dose of 2.4 mg for a mean duration of 33 months reduced the risk of a composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke by 20% (hazard ratio, 0.80; 95% CI, 0.72 to 0.90).

NASH Trial

The efficacy of Wegovy was evaluated based on an efficacy analysis at Week 72 in Study 8 (NCT#04822181), a 240-week, randomized, double-blind, placebo-controlled trial. Enrolled patients had a baseline or recent liver biopsy showing clinically significant MASLD (metabolic dysfunction-associated steatotic liver disease), defined as MASH with fibrosis stage 2 or 3 and a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) greater than or equal to 4 with a score of 1 or more in steatosis, lobular inflammation, and hepatocyte ballooning. Efficacy determination was based on the effect of Wegovy on resolution of steatohepatitis without worsening of liver fibrosis and on at least one stage improvement in liver fibrosis without worsening of steatohepatitis, on post-baseline liver biopsies collected at 72 weeks.(2)

The Week 72 analysis included 800 patients with F2 and F3 (at eligibility) randomized 1:2 to receive placebo (n=266) or Wegovy once weekly (n=534), in addition to standard of care for cardiometabolic comorbidities and healthy lifestyle counseling. Wegovy or matching placebo was escalated to 2.4 mg once weekly during the initial 16 weeks of the treatment period. Dose escalation could be prolonged or patients could remain at a lower dose if 2.4 mg once weekly was not tolerable. Demographic and baseline characteristics were balanced between treatment and placebo groups. Median (Q1 to Q3) body mass index (BMI) was 34 (30 to 38) kg/m² and median (Q1 to Q3) body weight was 93 (79 to 110) kg.(2)

The primary endpoint results for resolution of steatohepatitis and no worsening of liver fibrosis for the placebo group was 34% as compared to the Wegovy treated group of 63%. The other primary endpoint, improvement in liver fibrosis and no worsening of

	<p>steatohepatitis, resulted in the placebo group reporting 22% and for the Wegovy treated group, 37%. Endpoints were evaluated according to the MASH Clinical Research Network (CRN). Resolution of steatohepatitis is defined as a score of 0 to 1 for lobular inflammation, 0 for ballooning, and any value for steatosis. No worsening of steatohepatitis is defined as no increase from baseline in score for ballooning, lobular inflammation, or steatosis.(2) Overall, Wegovy results were statistically significant and resulted in Wegovy being superior to the placebo.</p> <p>The secondary endpoint results of the estimated percentage of patients with resolution of steatohepatitis and improvement in liver fibrosis at Week 72 was 16% for the placebo group and 33% for the Wegovy treated group. Two pathologists independently read the liver biopsies for each patient; a third pathologist performed adjudication if consensus could not be reached between the two pathologists. Wegovy demonstrated improvement on these histopathology endpoints at Week 72 compared to placebo. Another secondary endpoint was the percent change in body weight from baseline to Week 72. Patients treated with Wegovy (mean baseline body weight 95.4 kg) achieved an average of 10.5% weight loss from baseline at Week 72, and patients treated with placebo (mean baseline weight 97.6 kg) achieved an average of 2% weight loss from baseline at Week 72; treatment with Wegovy resulted in an average of 8.5% greater weight loss from baseline compared to placebo. Starting at Week 12 and through Week 72, there was a trend of greater reductions from baseline in average ALT and AST in the Wegovy group as compared to the placebo group.(2)</p> <p>SURMOUNT-OSA Trial</p> <p>Two phase 3, double-blind, randomized, controlled trials were conducted involving adults with moderate-to-severe obstructive sleep apnea and obesity. Participants who were not receiving treatment with positive airway pressure (PAP) at baseline were enrolled in trial 1, and those who were receiving PAP therapy at baseline were enrolled in trial 2. The main exclusion criteria included: craniofacial abnormalities that may affect breathing, central or mixed sleep apnea with mixed or central apneas/hypopneas greater than or equal to 50%, Cheyne Stokes Respiration, obesity hypoventilation syndrome or daytime hypercapnia.(29) The participants were assigned in a 1:1 ratio to receive either the maximum tolerated dose of tirzepatide (10 mg or 15 mg) or placebo for 52 weeks. The primary end point was the change in the apnea-hypopnea index (AHI, the number of apneas and hypopneas during an hour of sleep) from baseline. Key multiplicity-controlled secondary end points included the percent change in AHI and body weight and changes in hypoxic burden, patient-reported sleep impairment and disturbance, high-sensitivity C-reactive protein (hsCRP) concentration, and systolic blood pressure.(3,29)</p> <p>At baseline, the mean AHI was 51.5 events per hour in trial 1 and 49.5 events per hour in trial 2, and the mean body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) was 39.1 and 38.7, respectively. In trial 1, the mean change in AHI at week 52 was -25.3 events per hour (95% confidence interval [CI], -29.3 to -21.2) with tirzepatide and -5.3 events per hour (95% CI, -9.4 to -1.1) with placebo, for an estimated treatment difference of -20.0 events per hour (95% CI, -25.8 to -14.2) (P<0.001). In trial 2, the mean change in AHI at week 52 was -29.3 events per hour (95% CI, -33.2 to -25.4) with tirzepatide and -5.5 events per hour (95% CI, -9.9 to -1.2) with placebo, for an estimated treatment difference of -23.8 events per hour (95% CI, -29.6 to -17.9) (P<0.001). Significant improvements in the measurements for all prespecified key secondary end points were observed with tirzepatide as compared with placebo. The most frequently reported adverse events with tirzepatide were gastrointestinal in nature and mostly mild to moderate in severity.(3,29)</p> <p>Among persons with moderate-to-severe obstructive sleep apnea and obesity, tirzepatide reduced the AHI, body weight, hypoxic burden, hsCRP concentration, and systolic blood pressure and improved sleep-related patient-reported outcomes.(29)</p>
Safety	Liraglutide has the following:(1)

- Contraindications:
 - Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
 - Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components.
- Boxed warnings:
 - Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether liraglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.
 - Liraglutide is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk of MTC and the symptoms of thyroid tumors.

Orforglipron has the following:(46)

- Contraindications:
 - Personal or family history of MTC or in patients with MEN 2.
 - Known serious hypersensitivity to orforglipron or any of the excipients in Foundayo
- Boxed warnings:
 - In products with glucagon-like peptide-1 (GLP-1) receptor agonist activity that are pharmacologically active in rats and mice, rodent thyroid C-cell tumors (adenomas and carcinomas) have been observed at clinically relevant exposures and are considered GLP-1 receptor-dependent effects in rodents. Orforglipron is not pharmacologically active in rats or mice and did not produce tumors in rodents. While orforglipron is pharmacologically active at the human GLP-1 receptor, the human relevance of GLP-1 receptor-dependent thyroid C-cell tumors observed in rodents has not been determined.
 - Foundayo is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Foundayo and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Foundayo.

Semaglutide has the following:(2)

- Contraindications:
 - Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
 - Known hypersensitivity to semaglutide or any of the excipients in Wegovy.
- Boxed warnings:
 - In rodents, semaglutide causes thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined
 - Wegovy is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.

Tirzepatide has the following:(3)

- Contraindications:

	<ul style="list-style-type: none"> ○ Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. ○ Known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. <ul style="list-style-type: none"> ● Boxed warnings: <ul style="list-style-type: none"> ○ In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined. ○ Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. <p>Co-Administration</p> <p>None of the FDA approved weight loss agents have approval for co-administration with another weight loss agent. New guidelines do not support the use of co-administration of weight loss pharmacological agents.(4,5,10) Use of non-approved drug combinations for obesity treatment should be limited to clinical trials, and patients should be informed when drugs are being used off label alone or in combination.(6)</p>
--	--

REFERENCES

Number	Reference
1	Saxenda prescribing information. Novo Nordisk Inc. May 2025.
2	Wegovy prescribing information. Novo Nordisk Inc. March 2026.
3	Zepbound prescribing information. Lilly USA, LLC. January 2026.
4	Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342–362.
5	American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract. 2016 Jul;22(Suppl 3):1-203.
6	Jensen MD, Ryan DH, Apovian CM, et al. 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(25 Suppl 2):S102–S138.
7	Reference no longer used.
8	Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity - Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Jan;102(3):709–757.
9	Barlow SE, et al. Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report. Pediatrics. 2007 Dec;120(Suppl 4):S164-S192.
10	American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. Pediatrics. 2023 Jan;151(2):1-100.
11	American Gastroenterological Association (AGA) Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity. Gastroenterology. 2022 Nov;163(5):1198-1225.
12	Ryan DH, Lingvay I, Colhoun HM, et al. Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity (SELECT) rationale and design. American Heart Journal. 2020;229:61-69. doi:10.1016/j.ahj.2020.07.008.

Number	Reference
13	Smith SC, Benjamin EJ, Bonow RO, et al. AHA/ACCF Secondary Prevention and Risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update. <i>Circulation</i> . 2011;124(22):2458-2473. doi:10.1161/cir.0b013e318235eb4d.
14	Kleindorfer D, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients with stroke and Transient Ischemic Attack: A Guideline from the American Heart Association/American Stroke Association. <i>Stroke</i> . 2021;52(7). doi:10.1161/str.0000000000000375.
15	Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients with Chronic Coronary Disease: A report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. <i>Circulation</i> . 2023;148(9). doi:10.1161/cir.0000000000001168.
16	Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. <i>N Engl J Med</i> . 2023;389(24):2221-2232. doi:10.1056/NEJMoa2307563.
17	Harrison SA, Loomba R, Dubourg J, Ratziu V, Noureddin M. Clinical trial landscape in NASH. <i>Clinical Gastroenterology and Hepatology</i> . 2023;21(8):2001-2014. doi:10.1016/j.cgh.2023.03.041.
18	Bandyopadhyay S, Das S, Samajdar SS, Joshi SR. Role of semaglutide in the treatment of nonalcoholic fatty liver disease or non-alcoholic steatohepatitis: A systematic review and meta-analysis. <i>Diabetes Metab Syndr</i> . 2023;17(10):102849. doi:10.1016/j.dsx.2023.102849.
19	Rinella, Mary E, Neuschwander-Tetri, Brent A, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. <i>Hepatology</i> 77(5):p 1797-1835, May 2023. DOI: 10.1097/HEP.0000000000000323.
20	Nash causes & risk factors. American Liver Foundation. (2023, November 1). https://liverfoundation.org/liver-diseases/fatty-liver-disease/nonalcoholic-steatohepatitis-nash/nash-causes-risk-factors/ .
21	Cusi K, Isaacs S, Barb D, et al., American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). <i>Endocr Pract</i> . 2022 May;28(5):528-562. doi: 10.1016/j.eprac.2022.03.010.
22	U.S. Department of Health and Human Services. (2023). Drinking levels defined. National Institute on Alcohol Abuse and Alcoholism. https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking .
23	Blanco-Grau A, et al., Assessing Liver Fibrosis Using the FIB4 Index in the Community Setting. <i>Diagnostics (Basel)</i> . 2021 Nov 29;11(12):2236. doi: 10.3390/diagnostics11122236.
24	Wattacheril J, Abdelmalek MF, Lim JK, Sanyal AJ. AGA Clinical Practice Update on the Role of noninvasive biomarkers in the evaluation and management of nonalcoholic fatty liver Disease: Expert review. <i>Gastroenterology</i> . 2023;165(4):1080-1088. doi:10.1053/j.gastro.2023.06.013.
25	Newsome PN, Buchholtz K, Cusi K, et al. A Placebo-Controlled Trial of Subcutaneous Semaglutide in Nonalcoholic Steatohepatitis. <i>N Engl J Med</i> . 2021;384(12):1113-1124. doi:10.1056/NEJMoa2028395
26	Investigation of Efficacy and Safety of Three Dose Levels of Subcutaneous Semaglutide Once Daily Versus Placebo in Subjects With Non-alcoholic Steatohepatitis. <i>ClinicalTrials.gov</i> . https://clinicaltrials.gov/study/NCT02970942 .
27	Tacke F, Horn P, Wong VWS, et al. EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD). <i>Journal of Hepatology</i> . Published online June 1, 2024. doi:10.1016/j.jhep.2024.04.031.
28	Kanwal F, Neuschwander-Tetri BA, Loomba R, Rinella ME. Metabolic dysfunction-associated steatotic liver disease: Update and impact of new nomenclature on the American Association for the Study of Liver Diseases practice guidance on nonalcoholic fatty liver disease. <i>Hepatology</i> . 2023;79(5):1212-1219. doi:10.1097/hep.0000000000000670.
29	Malhotra A, Grunstein RR, Fietze I, et al. Tirzepatide for the treatment of obstructive sleep apnea and obesity. <i>New England Journal of Medicine</i> . Published online June 21, 2024. doi:10.1056/nejmoa2404881
30	Kapur, V. K., Auckley, D. H., Chowdhuri, S., Kuhlmann, D. C., Mehra, R., Ramar, K., & Harrod, C. G. (2017). Clinical Practice guideline for diagnostic testing for adult Obstructive sleep apnea: An

Number	Reference
	American Academy of Sleep Medicine Clinical Practice Guideline. Journal of Clinical Sleep Medicine, 13(03), 479–504. https://doi.org/10.5664/jcsm.6506
31	American Diabetes Association Professional Practice Committee. 14. Children and Adolescents: Standards of Care in Diabetes-2024. Diabetes Care. 2024;47(Suppl 1):S258-S281. doi:10.2337/dc24-S014
46	Foundayo prescribing information. Eli Lilly and Company. April 2026.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Saxenda	liraglutide (weight mngmt) soln pen-inj	18 MG/3ML	M ; N ; O ; Y	O ; Y		
Foundayo	orforglipron calcium (weight management) tab	0.8 MG ; 14.5 MG ; 17.2 MG ; 2.5 MG ; 5.5 MG ; 9 MG	M ; N ; O ; Y	N		
Wegovy	semaglutide (weight management) tab	1.5 MG ; 25 MG ; 4 MG ; 9 MG	M ; N ; O ; Y	N		
Wegovy ; Wegovy hd	semaglutide (weight mngmt) soln auto-injector	0.25 MG/0.5ML ; 0.5 MG/0.5ML ; 1 MG/0.5ML ; 1.7 MG/0.75ML ; 2.4 MG/0.75ML ; 7.2 MG/0.75ML	M ; N ; O ; Y	N		
Zepbound	tirzepatide (weight mngmt) soln	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	M ; N ; O ; Y	N		
Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	M ; N ; O ; Y	N		
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	10 MG/0.6ML ; 12.5 MG/0.6ML ; 15 MG/0.6ML ; 2.5 MG/0.6ML ; 5 MG/0.6ML ; 7.5 MG/0.6ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Foundayo	orforglipron calcium (weight management) tab	0.8 MG	60	Tablets	180	Days			
Foundayo	orforglipron calcium (weight management) tab	2.5 MG	60	Tablets	180	Days			
Foundayo	orforglipron calcium (weight management) tab	5.5 MG	30	Tablets	30	Days			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Foundayo	orforglipron calcium (weight management) tab	9 MG	30	Tablets	30	Days			
Foundayo	orforglipron calcium (weight management) tab	14.5 MG	30	Tablets	30	Days			
Foundayo	orforglipron calcium (weight management) tab	17.2 MG	30	Tablets	30	Days			
Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	Days			
Wegovy	semaglutide (weight management) tab	1.5 MG	60	Tablets	180	Days			
Wegovy	semaglutide (weight management) tab	4 MG	60	Tablets	180	Days			
Wegovy	semaglutide (weight management) tab	9 MG	60	Tablets	180	Days			
Wegovy	semaglutide (weight management) tab	25 MG	30	Tablets	30	Days			
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5 ML	8	Pens	180	Days			
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5 ML	8	Pens	180	Days			
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5 ML	8	Pens	180	Days			
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75 ML	4	Pens	28	Days			
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75 ML	4	Pens	28	Days			
Wegovy hd	semaglutide (weight mngmt) soln auto-injector	7.2 MG/0.75 ML	4	Pens	28	Days			
Zepbound	tirzepatide (weight mngmt) soln	2.5 MG/0.5 ML	4	Vials	180	Days			
Zepbound	tirzepatide (weight mngmt) soln	5 MG/0.5 ML	4	Vials	28	Day			
Zepbound	tirzepatide (weight mngmt) soln	7.5 MG/0.5 ML	4	Vials	28	Days			
Zepbound	tirzepatide (weight mngmt) soln	10 MG/0.5 ML	4	Vials	28	Days			
Zepbound	tirzepatide (weight mngmt) soln	12.5 MG/0.5 ML	4	Vials	28	Days			
Zepbound	tirzepatide (weight mngmt) soln	15 MG/0.5 ML	4	Vials	28	Days			
Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5 ML	4	Pens	180	Days			
Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5 ML	4	Pens	28	Days			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5 ML	4	Pens	28	Days			
Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5 ML	4	Pens	28	Days			
Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5 ML	4	Pens	28	Days			
Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5 ML	4	Pens	28	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	2.5 MG/0.6 ML	1	Pen	180	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	5 MG/0.6 ML	1	Pen	28	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	7.5 MG/0.6 ML	1	Pen	28	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	10 MG/0.6 ML	1	Pen	28	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	12.5 MG/0.6 ML	1	Pen	28	Days			
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	15 MG/0.6 ML	1	Pen	28	Days			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Foundayo	orforglipron calcium (weight management) tab	0.8 MG ; 14.5 MG ; 17.2 MG ; 2.5 MG ; 5.5 MG ; 9 MG	CHIP ; Commercial ; HIM
Saxenda	liraglutide (weight mngmt) soln pen-inj	18 MG/3ML	CHIP ; Commercial ; HIM
Wegovy	semaglutide (weight management) tab	1.5 MG ; 25 MG ; 4 MG ; 9 MG	CHIP ; Commercial ; HIM
Wegovy ; Wegovy hd	semaglutide (weight mngmt) soln auto-injector	0.25 MG/0.5ML ; 0.5 MG/0.5ML ; 1 MG/0.5ML ; 1.7 MG/0.75ML ; 2.4 MG/0.75ML ; 7.2 MG/0.75ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	10 MG/0.6ML ; 12.5 MG/0.6ML ; 15 MG/0.6ML ; 2.5 MG/0.6ML ; 5 MG/0.6ML ; 7.5 MG/0.6ML	CHIP ; Commercial ; HIM

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Foundayo	orforglipron calcium (weight management) tab	9 MG	CHIP ; Commercial ; HIM
Foundayo	orforglipron calcium (weight management) tab	2.5 MG	CHIP ; Commercial ; HIM
Foundayo	orforglipron calcium (weight management) tab	17.2 MG	CHIP ; Commercial ; HIM
Foundayo	orforglipron calcium (weight management) tab	5.5 MG	CHIP ; Commercial ; HIM
Foundayo	orforglipron calcium (weight management) tab	0.8 MG	CHIP ; Commercial ; HIM
Foundayo	orforglipron calcium (weight management) tab	14.5 MG	CHIP ; Commercial ; HIM
Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	CHIP ; Commercial ; HIM
Wegovy	semaglutide (weight management) tab	4 MG	CHIP ; Commercial ; HIM
Wegovy	semaglutide (weight management) tab	1.5 MG	CHIP ; Commercial ; HIM
Wegovy	semaglutide (weight management) tab	9 MG	CHIP ; Commercial ; HIM
Wegovy	semaglutide (weight management) tab	25 MG	CHIP ; Commercial ; HIM
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	CHIP ; Commercial ; HIM
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	CHIP ; Commercial ; HIM
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	CHIP ; Commercial ; HIM
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75ML	CHIP ; Commercial ; HIM
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75ML	CHIP ; Commercial ; HIM
Wegovy hd	semaglutide (weight mngmt) soln auto-injector	7.2 MG/0.75ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	7.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	2.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	15 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	10 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	12.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln	5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	7.5 MG/0.6ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	10 MG/0.6ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	12.5 MG/0.6ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	15 MG/0.6ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	5 MG/0.6ML	CHIP ; Commercial ; HIM
Zepbound kwikpen	tirzepatide (weight mngmt) soln pen-injector	2.5 MG/0.6ML	CHIP ; Commercial ; HIM

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
<p>Rebate Eligible</p>	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a body mass index (BMI) greater than or equal to 35 kg/m² AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of obstructive sleep apnea (OSA) AND ALL of the following: (medical records required) <ol style="list-style-type: none"> 1. The patient has had a polysomnography (PSG) or home sleep apnea test AND 2. The patient has an apnea hypopnea index (AHI) greater than or equal to 15 events/hour from baseline (prior to initiation of pharmacotherapy) AND 3. The requested agent is Zepbound OR B. The patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) AND ALL of the following: (medical records required) <ol style="list-style-type: none"> 1. The patient has stage F2 or F3 fibrosis as confirmed by ONE of the following (prior to therapy with the requested agent): <ol style="list-style-type: none"> A. A liver biopsy OR B. Vibration-controlled transient elastography (VCTE) OR C. Enhanced liver fibrosis (ELF) score OR D. Magnetic resonance elastography (MRE) AND 2. The requested agent is Wegovy injection AND 3. The patient is an adult (18 years of age or over) AND 4. ONE of the following: <ol style="list-style-type: none"> A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) OR B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) AND 5. The patient is being monitored and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) AND 6. The patient does NOT have ANY of the following: <ol style="list-style-type: none"> A. Decompensated cirrhosis B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) AND 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis OR C. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and obesity (established cardiovascular disease is defined as coronary artery disease [CAD], acute coronary syndrome [ACS], those with history of myocardial infarction [MI], stable or unstable angina or coronary or other arterial revascularization, prior percutaneous coronary intervention/coronary bypass surgery, stroke, transient ischemic attack [TIA], carotid or other arterial stenosis, or peripheral artery disease [PAD] including aortic aneurysm, all of atherosclerotic origin) AND ALL of the following:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The requested agent is FDA labeled for the requested indication and route of administration AND 2. The patient has a history of ONE of the following: <ol style="list-style-type: none"> A. Myocardial infarction OR B. Stroke OR C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease AND 3. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent OR D. The patient is using the requested agent for weight management and ALL of the following: <ol style="list-style-type: none"> 1. Obesity is NOT restricted from coverage under the patient's benefit AND 2. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient is an adult (18 years of age or over) OR B. The patient is pediatric (12 to 17 years of age) AND has ONE of the following: <ol style="list-style-type: none"> 1. A BMI greater than or equal to 95th percentile for age and sex OR 2. A BMI greater than or equal to 85th percentile for age and sex AND at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea) AND 4. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months AND 5. ONE of the following: <ol style="list-style-type: none"> A. The patient has NOT tried a targeted weight loss agent (e.g., Saxenda, Wegovy, Zepbound) in the past 12 months OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND 2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent AND 6. If the requested agent is Saxenda, then ONE of the following: <ol style="list-style-type: none"> A. The patient is an adult (18 years of age or over) AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is starting therapy OR 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy OR 3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) OR B. The patient is pediatric (12 to 17 years of age) AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is starting therapy OR 2. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy OR 3. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) AND 7. If the requested agent is Wegovy, then ONE of the following: <ol style="list-style-type: none"> A. The patient is starting therapy OR B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy OR C. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) OR

Module	Clinical Criteria for Approval
	<p>D. If the request is for Wegovy injection for a pediatric patient (12 to 17 years of age), then the patient has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) AND</p> <p>8. If the requested agent is Zepbound, then ONE of the following:</p> <p>A. The patient is starting therapy OR</p> <p>B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy OR</p> <p>C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) OR</p> <p>E. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>3. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication AND</p> <p>4. BOTH of the following:</p> <p>A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications AND</p> <p>B. The patient will continue the weight loss regimen in combination with the requested agent AND</p> <p>5. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>6. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist (e.g., Saxenda, Wegovy, Zepbound, Bydureon, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza) AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>8. The prescriber is not a dentist, oral surgeon, podiatrist, anesthesiologist, dermatologist, plastic surgeon or psychiatrist</p> <p>Length of Approval:</p> <ul style="list-style-type: none"> • For Wegovy, Zepbound: 8 months • For Saxenda: Pediatric patients (12 to 17 years of age): 5 months; Adults: 4 months <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of obstructive sleep apnea (OSA) AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent is Zepbound AND 2. The patient has had clinical benefit with the requested agent (e.g., reduction in AHI, decrease in Epworth Sleepiness Scale) OR B. The patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) AND ALL of the following: (medical records required)

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The requested agent is Wegovy injection AND 2. ONE of the following: <ol style="list-style-type: none"> A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) OR B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) AND 3. The patient does NOT have ANY of the following: <ol style="list-style-type: none"> A. Decompensated cirrhosis B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) AND 4. The patient has had clinical benefit with the requested agent AND 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis OR <p>C. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and obesity (established cardiovascular disease is defined as coronary artery disease [CAD], acute coronary syndrome [ACS], those with history of myocardial infarction [MI], stable or unstable angina or coronary or other arterial revascularization, prior percutaneous coronary intervention/coronary bypass surgery, stroke, transient ischemic attack [TIA], carotid or other arterial stenosis, or peripheral artery disease [PAD] including aortic aneurysm, all of atherosclerotic origin) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The requested agent is FDA labeled for the requested indication and route of administration AND 2. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent AND 3. The patient has had clinical benefit with the requested agent OR <p>D. The patient is obese and is using the requested agent for weight management and ALL of the following:</p> <ol style="list-style-type: none"> 1. Obesity is NOT restricted from coverage under the patient's benefit AND 2. The patient is continuing a current weight loss course of therapy AND 3. If the patient is pediatric (12 to 17 years of age), then the current BMI is greater than or equal to 85th percentile for age and sex AND 4. The patient meets ONE of the following: <ol style="list-style-type: none"> A. If the requested agent is Saxenda, then ONE of the following: <ol style="list-style-type: none"> 1. The patient is pediatric (12 to 17 years of age) AND has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) OR 2. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) OR B. If the requested agent is Wegovy, then ONE of the following: <ol style="list-style-type: none"> 1. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose OR 2. If the requested agent is Wegovy injection for a pediatric patient (12 to 17 years of age), then the patient has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) OR C. If the requested agent is Zepbound, the patient has received less than 52 weeks of therapy on the maximum-tolerated dose OR

Module	Clinical Criteria for Approval
	<p>D. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to the initiation of requested agent) OR</p> <p>E. The patient has another FDA labeled indication for the requested agent and route of administration AND has had clinical benefit with the requested agent AND</p> <p>3. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication AND</p> <p>4. BOTH of the following:</p> <p>A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications AND</p> <p>B. The patient will continue the weight loss regimen in combination with the requested agent AND</p> <p>5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist (e.g., Saxenda, Wegovy, Zepbound, Bydureon, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza) AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>7. The prescriber is not a dentist, oral surgeon, podiatrist, anesthesiologist, dermatologist, plastic surgeon or psychiatrist</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND BOTH of the following: <ol style="list-style-type: none"> A. If the requested agent is Wegovy tablets, then the requested dose does not exceed 1 tablet per day AND B. ONE of the following: <ol style="list-style-type: none"> 1. If the requested agent is Wegovy 0.5mg or 1mg injection AND the intended use is for maintenance therapy, then BOTH of the following: <ol style="list-style-type: none"> A. The patient has an inability to use an FDA labeled strength indicated for maintenance therapy AND B. The patient has achieved weight loss on the lower requested strength from baseline (prior to initiation of pharmacotherapy) OR 2. If the requested agent is Wegovy 4mg or 9mg tablets AND the intended use is for maintenance therapy, then BOTH of the following: <ol style="list-style-type: none"> A. The patient has an inability to use an FDA labeled strength indicated for maintenance therapy AND B. The patient has achieved weight loss on the lower requested strength from baseline (prior to initiation of pharmacotherapy) OR 3. BOTH of the following: <ol style="list-style-type: none"> A. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND B. There is support for therapy with a higher dose for the requested indication OR 4. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND B. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR 5. BOTH of the following:

Module	Clinical Criteria for Approval
	<p data-bbox="565 184 1421 296"> A. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND B. There is support for therapy with a higher dose for the requested indication </p> <p data-bbox="232 331 708 363">Length of Approval: up to 12 months</p>