Reference number(s)
5098-C

Initial Prior Authorization with Quantity Limit
Anti-Obesity Agents (Specific States)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths except Zepbound vials, which are covered under the LillyDirect manufacturer program. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	**Generic Name**
Adipex-P	phentermine
benzphetamine (all brands)	benzphetamine
Contrave	naltrexone/bupropion extended-release
diethylpropion (all brands)	diethylpropion
Lomaira	phentermine
phendimetrazine (all brands)	phendimetrazine
phentermine (all brands)	phentermine
Qsymia	phentermine/topiramate extended-release
Saxenda	liraglutide
Wegovy	semaglutide
Xenical	orlistat
Zepbound	tirzepatide

Indications

FDA-approved Indications

Adipex-P (phentermine), Lomaira (phentermine), Phentermine

Phentermine is indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

Benzphetamine

Benzphetamine Hydrochloride Tablets are indicated in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m^2 or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The limited usefulness of agents of this class should be weighed against possible risks inherent in their use.

Benzphetamine Hydrochloride Tablets are indicated for use as monotherapy only.

Contrave (naltrexone/bupropion extended-release)

Contrave is indicated 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 overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

- The effect of Contrave on cardiovascular morbidity and mortality has not been established.
- Contrave contains naltrexone and bupropion. Coadministration with other naltrexone-containing products is not recommended. Coadministration with other bupropion-containing products is contraindicated.

Diethylpropion (extended and immediate release)

Diethylpropion hydrochloride is indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m^2 or higher and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The usefulness of agents of this class should be measured against possible risk factors inherent in their use. Diethylpropion hydrochloride is indicated for use as monotherapy only.

Phendimetrazine (extended release)

Phendimetrazine tartrate is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The usefulness of agents of this class

should be measured against possible risk factors inherent in their use. Phendimetrazine tartrate is indicated for use as monotherapy only.

Phendimetrazine (immediate release)

Phendimetrazine tartrate is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m^2 or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.

Phendimetrazine tartrate is indicated for use as monotherapy only.

Qsymia (phentermine/topiramate extended-release)

Qsymia is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:

- Adults and pediatric patients aged 12 years and older with obesity
- Adults with overweight in the presence of at least one weight-related comorbid condition

Limitations of Use

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Saxenda (liraglutide)

Saxenda is indicated in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:

- Adult and pediatric patients aged 12 years and older with body weight greater than 60 kg and obesity
- Adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

- Saxenda contains liraglutide. Coadministration with other liraglutide-containing products or with any other glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.

Wegovy (semaglutide)

Wegovy injection is indicated in combination with a reduced calorie diet and increased physical activity:

- 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:
    - Adults and pediatric patients aged 12 years and older with obesity.

    - Adults with 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. This indication is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

Wegovy tablets are indicated in combination with a reduced calorie diet and increased physical activity:

- 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.

Limitations 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.

Xenical (orlistat)

Xenical is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss. Xenical is indicated for obese patients with an initial body mass index (BMI) greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

Zepbound (tirzepatide)

Zepbound is indicated 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.
- to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Limitations of Use

Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

Coverage Criteria

Morbid Obesity (Adult)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient is actively enrolled in a weight loss program that involves a reduced-calorie diet AND increased physical activity adjunct to therapy. [ACTION REQUIRED: Documentation is required for approval.]
- The patient's age is appropriate according to FDA labeling of the requested drug.
- The patient is NOT receiving TWO drugs for weight loss at the same time.
- The patient does NOT have ANY contraindications to the requested drug.
- The requested drug is being used for an FDA approved indication.
- The patient is 18 years of age or older.
- The patient meets ONE of the following:
    - The patient has a documented diagnosis of morbid obesity defined by a current body mass index (BMI) of greater than or equal to 40 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a documented diagnosis of morbid obesity defined by a current BMI of greater than or equal to 35 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.] In addition, the following criteria is met:
        - The patient has one or more comorbid conditions (i.e., cardiovascular disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) OR other obesity-related medical condition (e.g., sleep apnea). [ACTION REQUIRED: Documentation is required for approval.]
- If the request is for Adipex-P (phentermine), benzphetamine, diethylpropion, Lomaira (phentermine), phendimetrazine, or phentermine, then the following criteria is met:
    - The patient has NOT received 3 months of therapy or more with the requested drug in the past 365 days.

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (Adult)

Authorization may be granted when the requested drug is being prescribed 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 an adult when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide) injection.
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist.
- The patient's moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following: non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]) OR historical liver biopsy. [ACTION REQUIRED: Documentation is required for approval.]

Obesity (Pediatric)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient is actively enrolled in a weight loss program that involves a reduced-calorie diet AND increased physical activity adjunct to therapy. [ACTION REQUIRED: Documentation is required for approval.]
- The patient's age is appropriate according to FDA labeling of the requested drug.
- The patient is NOT receiving TWO drugs for weight loss at the same time.
- The patient does NOT have ANY contraindications to the requested drug.
- The requested drug is being used for an FDA approved indication.
- The patient is 12 to 17 years of age.
- If the request is for Qsymia (phentermine/topiramate extended-release), then the following criteria is met:
    - The patient has an initial body mass index (BMI) in the 95th percentile or greater standardized for age and sex. [ACTION REQUIRED: Documentation is required for approval.]
- If the request is for Saxenda (liraglutide), then ALL of the following criteria are met:
    - The patient has a body weight above 60 kg. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria). [ACTION REQUIRED: Documentation is required for approval.]
- If the request is for Wegovy (semaglutide) injection, then the following criteria is met:
    - The patient has an initial BMI in the 95th percentile or greater standardized for age and sex. [ACTION REQUIRED: Documentation is required for approval.]

Obstructive Sleep Apnea (Adult)

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a current body mass index (BMI) greater than or equal to 30 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

Risk Reduction of Major Adverse Cardiovascular Events (Adult)

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following: [ACTION REQUIRED: Documentation is required for approval.]
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient has a baseline body mass index (BMI) greater than or equal to 27 kg/m^2. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]
- The patient does NOT have type 2 diabetes. [NOTE: Ozempic is indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Patients with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]
- The patient is currently receiving guideline-directed management and therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) OR the patient has clinical reason not to be treated with GDMT for cardiovascular disease. [ACTION REQUIRED: Documentation is required for approval.]

Continuation of Therapy

Morbid Obesity (Adult)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient is actively enrolled in a weight loss program that involves a reduced-calorie diet AND increased physical activity adjunct to therapy. [ACTION REQUIRED: Documentation is required for approval.]
- The patient's age is appropriate according to FDA labeling of the requested drug.
- The patient is NOT receiving TWO drugs for weight loss at the same time.
- The patient does NOT have ANY contraindications to the requested drug.
- The requested drug is being used for an FDA approved indication.
- The patient is 18 years of age or older.
- If the request is for Adipex-P (phentermine), benzphetamine, diethylpropion, Lomaira (phentermine), phendimetrazine, or phentermine, then ALL of the following criteria are met:

    - The patient has NOT received 3 months of therapy or more with the requested drug in the past 365 days.
    - The patient has evidence of weight loss from baseline.
- If the request is for Contrave (naltrexone/bupropion extended-release), then the following criteria is met:
    - The patient has lost at least 5 percent of baseline body weight after 12 weeks of therapy at a stable maintenance dose OR the patient continues to maintain their initial 5 percent weight loss.
- If the request is for Qsymia (phentermine/topiramate extended-release), then ONE of the following criteria are met:
    - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 15 mg/92 mg therapy and the following criteria is met:
        - The patient has lost at least 5 percent of baseline body weight OR the patient continues to maintain their initial 5 percent weight loss.
    - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 7.5 mg/46 mg therapy and the following criteria is met:
        - The patient meets ONE of the following: the patient has lost at least 3 percent of baseline body weight, the patient continues to maintain their initial 3 percent weight loss, the patient's dose has been increased to Qsymia (phentermine/topiramate extended-release) 11.25 mg/69 mg AND will follow the recommended dose escalation schedule.
- If the request is for Saxenda (liraglutide), then the following criteria is met:
    - The patient has lost at least 4 percent of baseline body weight after 16 weeks of therapy at a stable maintenance dose OR the patient continues to maintain their initial 4 percent weight loss.
- If the request is for Wegovy (semaglutide), then the following criteria is met:
    - The patient has lost at least 5 percent of baseline body weight after 12 weeks of therapy at a stable maintenance dose OR the patient continues to maintain their initial 5 percent weight loss.
- If the request is for Xenical (orlistat), then the following criteria is met:
    - The patient has lost at least 5 percent of initial body weight after 6 months of therapy OR the patient continues to maintain their initial 5 percent weight loss.
- If the request is for Zepbound (tirzepatide), then the following criteria is met:
    - The patient has lost at least 5 percent of baseline body weight after 12 weeks of therapy at a stable maintenance dose OR the patient continues to maintain their initial 5 percent weight loss.

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (Adult)

Authorization may be granted when the requested drug is being prescribed 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 an adult when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide) injection.
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in Enhanced Liver Fibrosis [ELF] score, improvement in liver stiffness measurement [LSM] by ultrasound-based elastography, magnetic resonance elastography [MRE]). [ACTION REQUIRED: Documentation is required for approval.]
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

Obesity (Pediatric)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient is actively enrolled in a weight loss program that involves a reduced-calorie diet AND increased physical activity adjunct to therapy. [ACTION REQUIRED: Documentation is required for approval.]
- The patient's age is appropriate according to FDA labeling of the requested drug.
- The patient is NOT receiving TWO drugs for weight loss at the same time.
- The patient does NOT have ANY contraindications to the requested drug.
- The requested drug is being used for an FDA approved indication.
- The patient is 12 to 17 years of age.
- If the request is for Qsymia (phentermine/topiramate extended-release), then ONE of the following criteria are met:
    - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 15 mg/92 mg therapy and the following criteria is met:
        - The patient has lost at least 5 percent of baseline body mass index (BMI) OR the patient continues to maintain their initial 5 percent BMI reduction.
    - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 7.5 mg/46 mg therapy and the following criteria is met:
        - The patient meets ONE of the following: the patient has lost at least 3 percent of baseline BMI, the patient continues to maintain their initial 3 percent BMI reduction, the patient's dose has been increased to Qsymia (phentermine/topiramate extended-release) 11.25 mg/69 mg AND will follow the recommended dose escalation schedule.
- If the request is for Saxenda (liraglutide), then the following criteria is met:
    - The patient has lost at least 1 percent of baseline BMI after 12 weeks of therapy at a stable maintenance dose OR the patient continues to maintain their initial 1 percent BMI reduction.
- If the request is for Wegovy (semaglutide) injection, then the following criteria is met:
    - The patient has a reduction in their baseline BMI after successfully titrating to a stable maintenance dose OR the patient continues to maintain their initial BMI reduction.

Obstructive Sleep Apnea (Adult)

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has achieved or maintained a positive response to treatment from baseline, evidenced by a decrease in OSA symptoms.
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

Risk Reduction of Major Adverse Cardiovascular Events (Adult)

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following: [ACTION REQUIRED: Documentation is required for approval.]
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

Quantity Limits Apply

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

Drug	Dosage	1 Month Limit	3 Month Limit
Adipex-P (phentermine)	37.5 mg	30 units / 25 days	90 units / 75 days
Benzphetamine	50 mg	90 tablets / 25 days	270 tablets / 75 days
Contrave (naltrexone/bupropion extended-release)	8 mg / 90 mg	120 tablets / 25 days	360 tablets / 75 days
Diethylpropion	25 mg IR	90 tablets / 25 days	270 tablets / 75 days
Diethylpropion	75 mg ER	30 tablets / 25 days	90 tablets / 75 days
Lomaira (phentermine)	8 mg	90 tablets / 25 days	270 tablets / 75 days
Phendimetrazine	35 mg IR	180 tablets / 25 days	540 tablets / 75 days
Phendimetrazine	105 mg ER	30 capsules / 25 days	90 capsules / 75 days
Phentermine	15 mg	60 capsules / 25 days	180 capsules / 75 days
Phentermine	30 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	3.75 mg / 23 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	7.5 mg / 46 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	11.25 mg / 69 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	15 mg / 92 mg	30 capsules / 25 days	90 capsules / 75 days

Drug	Dosage	1 Month Limit	3 Month Limit
Saxenda (liraglutide)	18 mg / 3 mL (provides variable dosing)	15 mL (1 package of 5 3 mL pens) / 25 days	45 mL (3 packages of 5 3 mL pens each) / 75 days
Wegovy (semaglutide) injection	0.25 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide) injection	0.5 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide) injection	1 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide) injection	1.7 mg / 0.75 mL	3 mL (1 package of 4 pens each) / 21 days	9 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide) injection	2.4 mg / 0.75 mL	3 mL (1 package of 4 pens each) / 21 days	9 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide) tablet	1.5 mg, 4 mg, 9 mg, 25 mg	30 tablets / 25 days	90 tablets / 75 days
Xenical (orlistat)	120 mg	90 capsules / 25 days	270 capsules / 75 days
Zepbound (tirzepatide)	2.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	7.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	10 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days

Drug	Dosage	1 Month Limit	3 Month Limit
Zepbound (tirzepatide)	12.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	15 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days

Duration of Approval (DOA)

- 5098-C:
  - Adipex-P, benzphetamine, diethylpropion, Lomaira, phendimetrazine, phentermine: DOA: 3 months
  - Contrave, Qsymia, Saxenda, Xenical: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
  - Wegovy (semaglutide) Injection:
    - Reduction in excess body weight, maintenance of weight reduction long term: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
    - Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (MASH): DOA: 12 months
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months
  - Wegovy (semaglutide) Tablet:
    - Reduction in excess body weight, maintenance of weight reduction long term: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months
  - Zepbound:
    - Obstructive Sleep Apnea (OSA): Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months
    - Reduction in excess body weight, maintenance of weight reduction long term: Initial therapy DOA: 8 months; Continuation of therapy DOA: 12 months

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