

### Weight Loss Agents

- Adipex-P (phentermine HCl)
- Alli (orlistat)
- Benzphetamine (Didrex, Regimex)
- Contrave (naltrexone HCl/bupropion HCl)
- Diethylpropion (Tenuate)
- Lomaira (phentermine HCl)
- Phendimetrazine (Bontril PDM, Bontril Slow-Release)
- Qsymia (phentermine /topiramate)
- Saxenda (liraglutide)
- Wegovy (semaglutide) injection for subcutaneous use
- Wegovy (semaglutide) pill/tablet for oral use
- Xenical (orlistat)
- Zepbound (tirzepatide)

#### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Weight loss medications are used as part of a comprehensive treatment plan for chronic weight management, in addition to diet and exercise. These medications primarily work by reducing appetite and daily caloric intake. Weight loss and weight management have numerous health benefits, including a decreased risk of diabetes, high blood pressure, and heart conditions, as well as increased energy levels.

A multifaceted approach to weight loss is generally recommended, which includes dietary therapy and exercise. Drug therapy can be added for individuals who are obese or who are overweight and have other comorbid conditions (e.g., cardiovascular disease, dyslipidemia, hypertension, metabolic syndrome, obstructive sleep apnea, type 2 diabetes mellitus, metabolic dysfunction-associated steatotic liver disease). Weight loss medications are available in various formulations, including oral tablets (such as Contrave [naltrexone/bupropion], Qsymia [phentermine/topiramate], and Wegovy [semaglutide] tablets) and subcutaneous daily or weekly injections (such as Saxenda [liraglutide] and Wegovy [semaglutide] injection).

**NOTE:** Coverage of prescription drugs prescribed for the treatment of obesity or for use in any weight reduction, weight loss, or dietary control varies depending on a member's benefit policy.

- Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.
- This Clinical Guideline only applies to members whose Plan covers prescription drugs prescribed for the treatment of obesity or for use in any weight reduction, weight loss, or dietary control.
- Please refer to the Plan's Antidiabetic Agents - Glucagon-like Peptide-1 (GLP-1) Receptor Agonists (PG152) for specific coverage criteria related to the use of GLP-1 RAs in those with Diabetes Mellitus.

- Please refer to the Plan’s Zepbound (tirzepatide) for the Treatment of Obstructive Sleep Apnea (PG255) for the use of Zepbound (tirzepatide) for the management of obstructive sleep apnea (OSA) in those without diabetes mellitus.

## Definitions

“Body Mass Index (BMI)” is a value that is calculated based on an individual’s weight and height and helps determine whether a person is underweight, overweight, or normal weight.

“Caloric intake” is the amount of calories (energy that comes from foods such as fats, proteins, and sugars) an individual intakes per day.

“Compendia” are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“[s]” indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Initial Clinical Review

#### Initial Indication-Specific Criteria

#### Weight Loss

The Plan considers Weight Loss Agents medically necessary when ALL of the following criteria are met:

1. The requested medication is age-appropriate based on FDA approval or evidence-based guidelines for the specific medication (see [Appendix A](#), Table 1); *AND*
2. Recent documentation [within ONE (1) month] showing BOTH of the following:
  - a. ONE (1) of the following, as applicable:
    - i. IF the member is an adult and ONE (1) of the following is met:
      1. Body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>; *or*

2. BMI greater than or equal to 27 kg/m<sup>2</sup> AND has at least one (≥1) weight-related comorbid condition (e.g., cardiovascular disease, dyslipidemia, hypertension, metabolic syndrome, obstructive sleep apnea, type 2 diabetes mellitus, metabolic dysfunction-associated steatotic liver disease); *or*
  - ii. IF the member is a pediatric, usage is aligned to the specific medication's FDA approval or evidence-based guidelines based on BMI percentile standardized for age and sex (See [Appendix](#), Table 1); *and*
    - b. The member's baseline (i.e., pre-treatment) body weight is collected in a provider's office; *AND*
3. The prescribed medication will be used as an adjunct to a reduced-calorie diet and increased physical activity; *AND*
4. Requested medication will NOT be used in combination with other weight loss products (including prescription drugs, over-the-counter drugs, and herbal preparations) or co-administered with similar products (i.e., with a similar mechanism of action, in the same drug class) unless specifically recommended per the drug's official label/prescribing information; *AND*
5. The weight loss agent is being prescribed at a dose and frequency that is within FDA approved labeling.

If the above prior authorization criteria are met, the requested weight loss medication will be approved as follow:<sup>[s]</sup>

- For up to 12 weeks:<sup>[s]</sup>
  - Adipex-P (phentermine)
  - Alli (orlistat)
  - Benzphetamine (Didrex)
  - Contrave (naltrexone HCl/bupropion HCl)
  - Diethylpropion (Tenuate)
  - Lomaira (phentermine HCL)
  - Phendimetrazine (Bontril PDM, Bontril Slow-Release)
  - Xenical (orlistat)
- For up to 6-months:<sup>[s]</sup>
  - Qsymia (phentermine /topiramate)
  - Saxenda (liraglutide)
  - Wegovy (semaglutide) tablet or injection
  - Zepbound (tirzepatide)

*Continued Care*

## Medical Necessity Criteria for Subsequent Clinical Review

### Subsequent Indication-Specific Criteria

#### Weight Loss

The plan considered Alli (orlistat), Contrave (naltrexone HCl/bupropion HCl), Qsymia (phentermine/topiramate), Saxenda (liraglutide), Wegovy (semaglutide) tablet or injection, Xenical (orlistat), or Zepbound (tirzepatide) medically necessary when ALL of the following criteria are met (if the member has recent chart documentation within three [3] months):

1. Continued lifestyle modifications (e.g., reduced calorie diet in conjunction with physical activity and behavioral therapy); *AND*
2. The member has achieved or sustained clinically meaningful weight loss (collected in a provider's office), defined as:
  - a. For adults, at least 5% of baseline body weight; *or*
  - b. For pediatrics, a reduction of at least 5% of baseline BMI; *AND*.
3. The weight loss agent is being prescribed at an age, dose, and frequency that is within FDA approved labeling.

If the above reauthorization criteria are met, the requested product will be authorized for up to 6-months. <sup>[s]</sup>

Adipex-P (phentermine), Benzphetamine (Didrex, Regimex), diethylpropion (Tenuate), Lomaira (phentermine HCL), and Phendimetrazine (Bontril PDM, Bontril Slow-Release), are **NOT** eligible for reauthorization.

#### Experimental or Investigational / Not Medically Necessary <sup>[s]</sup>

Weight loss medications for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. The use of Adipex-P (phentermine), benzphetamine (Didrex, Regimex), diethylpropion (Tenuate), Lomaira (phentermine HCL), and phendimetrazine (Bontril PDM, Bontril Slow Release), ) for long-term weight management (beyond 12 weeks) is considered not medically necessary.

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Table 1: FDA Approved Weight Loss Medications

Brand Name (Generic Name)	Route of Administration	Dosage	FDA-Approved Age Range
Adipex-P (phentermine)	Oral (capsule, tablet)	15 to 37.5 mg orally once daily 1-2 hours after breakfast, or 18.75 mg orally two (2) times daily (only the tablet can be split)	17 years and older
Alli (orlistat)	Oral (capsule)	60 mg orally three (3) times daily with each main meal containing fat; maximum of 180 mg/day	Adults, 18 years and older
Benzphetamine (Didrex, Regimex)	Oral (tablet)	25 to 50 mg orally daily, preferably at mid-morning or mid-afternoon; may increase up to 50 mg orally 2 to 3 times daily; maximum 150 mg/day orally  <u>NOTE:</u> recommended to be continued beyond 4 weeks only in those who have experienced a satisfactory weight loss of at least 4 pounds or as determined by the physician.	17 years and older
Contrave (naltrexone HCl/bupropion HCl)	Oral (ER tablet)	8 mg naltrexone/90 mg bupropion orally once daily for week 1, then 8 mg naltrexone/90 mg bupropion orally twice daily for 1 week, then 16 mg naltrexone/180 mg bupropion orally in the morning and 8 mg naltrexone/90 mg bupropion orally in the evening for 1 week, then 16 mg naltrexone/180 mg bupropion orally twice daily thereafter.	Adults, 18 years and older

		<u>NOTE:</u> recommended to discontinue therapy if after 12 weeks the individual has not experienced at least 5% of baseline weight.	
Diethylpropion (Tenuate)	Oral (tablet, ER tablet)	Immediate-release tablet: 25 mg orally 3 times daily  ER tablet: 75 mg orally once daily	16 years and older
Lomaira (phentermine HCL)	Oral (tablet)	4 to 8 mg orally three times daily	17 years and older
Phendimetrazine (Bontril PDM, Bontril Slow-Release)	Oral (extended release [ER] capsule, tablet)	Immediate release (IR) tablet: 35 mg orally 2 to 3 times daily, 1 hour before meals; can reduce dose to 17.5 mg; not to exceed 210 mg daily (2 tablets [70 mg] three times daily)  ER capsule: 105 mg orally daily, 30 to 60 minutes before breakfast; not to exceed 105 mg daily	IR tablet: adults, 18 years and older  ER capsule: 17 years and older
Qsymia (phentermine /topiramate)	Oral (ER capsule)	3.75 mg phentermine/23 mg topiramate orally daily for 14 days, then increase the dose to 7.5 mg phentermine/46 mg topiramate orally once daily; if weight loss is not at least 3% of baseline weight after 12 weeks, increase dose to 11.25 mg phentermine/69 mg topiramate orally daily for 14 days, then 15 mg phentermine/92 mg topiramate orally daily.  Children and adolescents 12 to 17	12 years and older

		<p>years: 3.75 mg phentermine/23 mg topiramate orally daily for 14 days, then increase the dose to 7.5 mg phentermine/46 mg topiramate orally once daily; if weight loss is not at least 3% of baseline BMI after 12 weeks, increase dose to 11.25 mg phentermine/69 mg topiramate orally daily for 14 days, then 15 mg phentermine/92 mg topiramate orally daily; consider dose reduction if weight loss exceeds 0.9 kg/week</p> <p><u>NOTE:</u> it is recommended to discontinue therapy if weight loss is not at least 5% of BMI after 24 weeks of therapy, and it is unlikely that meaningful weight loss will be achieved and sustained with continued treatment.</p>	
Saxenda (liraglutide)	Injection (Subcutaneous [SC])	<p>0.6 mg SC once daily for 1 week, then increase by 0.6 mg per week to goal of 3 mg SC daily</p> <p>Adults: discontinue use if 3 mg dose is not tolerated; efficacy has not been established in adults at lower doses.</p> <p>Children and adolescents 12 to 17 years: discontinue use if 2.4 mg dose is not tolerated; efficacy has not been established in children and adolescents at lower</p>	12 years and older

		doses.	
Wegovy (semaglutide)	Injection (Subcutaneous [SC])	0.25 mg SC once weekly for 4 weeks, then 0.5 mg SC once weekly for 4 weeks, then 1 mg SC once weekly for 4 weeks, then 1.7 mg SC once weekly for 4 weeks, then 1.7 to 2.4 mg SC once weekly thereafter	12 years and older
	Tablet for oral use	1.5 mg orally once daily for 30 days, then 4 mg once daily for 30 days (days 31-60), then 9 mg once daily for 30 days (days 61-90), then 25 mg once daily thereafter.  <u>NOTE:</u> if additional weight reduction is needed in those on 25 mg daily, consider switching to 1.7 mg SC once weekly dosage form and dose escalating from there.	Adults, 18 years and older
Xenical (orlistat)	Oral (capsule)	120 mg orally three (3) times daily with each main meal containing fat	12 years and older  <u>NOTE:</u> pediatric use it typically reserved for those with a BMI at the 95th percentile or more, meeting the adult BMI recommendation for use, or in those with BMI 85th to 94th percentile with significant, severe comorbidities who have not responded to lifestyle modifications
Zepbound (tirzepatide)	Injection (Subcutaneous [SC])	2.5 mg SC once weekly for 4 weeks, then 5 mg SC once weekly initially; may increase by 2.5 mg/week after at	Adults, 18 years and older

		least 4 weeks. Usual dosage of 5-15 mg/week; maximum 15 mg/week.	
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Clinical Guideline Revision / History Information

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