Reference number(s)
18-C

Initial Prior Authorization with Quantity Limit
Antiobesity Agents
Weight Loss Management

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Generic Name
benzphetamine products
diethylpropion products
phendimetrazine products
phentermine products

Indications

FDA-approved Indications

Adipex-P, Lomaira, 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.

Diethylpropion

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

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.

Phendimetrazine tartrate extended-release capsules are 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.

Coverage Criteria

Exogenous Obesity

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity in the management of exogenous obesity when ALL of the following criteria are met:

- The patient has NOT received 3 months of therapy with the requested drug within the past 365 days

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced-calorie diet, AND increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
- The patient meets ONE of the following:
    - The patient has a baseline body mass index (BMI) greater than or equal to 30 kg/m^2 [ACTION REQUIRED: Documentation is required for approval.] [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.]
    - The patient has a baseline BMI greater than or equal to 27 kg/m^2 [ACTION REQUIRED: Documentation is required for approval.] [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.] In addition, the following criteria is met:
        - The patient has at least ONE weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia) [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.]

Quantity Limits Apply

Quantity Limit

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.

Drug	Dosage	1 Month Limit	3 Months 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
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

Drug	Dosage	1 Month Limit	3 Months Limit
Phentermine	30 mg	30 capsules / 25 days	90 capsules / 75 days

Duration of Approval (DOA)

- 18-A: DOA: 3 months (90 days of therapy) per year

References

1. Adipex-P [package insert]. Parsippany, NJ: Teva Pharmaceuticals; March 2024.
2. Benzphetamine hydrochloride [package insert]. Laurelton, NY: Epic Pharma, LLC; June 2023.
3. Diethylpropion hydrochloride [package insert]. Congers, NY: Chartwell RX, LLC.; March 2023.
4. Diethylpropion hydrochloride ER [package insert]. Congers, NY: Chartwell RX, LLC.; March 2023.
5. Lomaira [package insert]. Newtown, PA: KVK-Tech, Inc.; December 2023.
6. Phendimetrazine tartrate [package insert]. Newtown, PA: KVK-TECH, INC.; September 2019.
7. Phendimetrazine tartrate extended-release [package insert]. Langhorne, PA: Virtus Pharmaceuticals, LLC; March 2021.
8. Phentermine hydrochloride [package insert]. Rahway, NJ: Sunrise Pharmaceutical, Inc.; April 2022.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
10. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
11. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/28/2024).
12. Jensen MD, Ryan DH, Apovian DM, 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(suppl 2):S102-S138.
13. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(2):342–362.
14. FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen). July 2005. Available at: https://wayback.archive-it.org/7993/20170723090512/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm. Accessed July 8, 2024.