PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ANTIOBESITY AGENTS**
BRAND NAME (generic)	
	benzphetamine products
	diethylpropion products
	phendimetrazine products
	phentermine products

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

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, USP 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, USP are indicated for use as monotherapy only.

Diethylpropion
Diethylpropion hydrochloride tablets, 25 mg 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 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 tablets, 25 mg are indicated for use as monotherapy only.

Diethylpropion hydrochloride extended release tablets, 75 mg 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 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 extended release tablets, 75 mg are 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

The requested drug will be covered with prior authorization when the following criteria are met:

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

AND

- The requested drug will be used with a reduced calorie diet and increased physical activity in the management of exogenous obesity

AND

- 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

  AND

  - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

  OR

  - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

    AND

    - 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.]

AND

- The request is for phentermine

  AND

  - The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) [NOTE: Due to well documented potential for serious adverse effects, phentermine and fenfluramine are not recommended to be used concurrently.]

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.

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
Diethylpropion	25 mg IR	90 tablets / 25 days	270 tablets / 75 days
	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
	105 mg ER	30 capsules / 25 days	90 capsules / 75 days

Phentermine	15 mg	60 capsules / 25 days	180 capsules / 75 days
	30 mg	30 capsules / 25 days	90 capsules / 75 days
**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.*			

Duration of Approval (DOA):

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

REFERENCES

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