PRIOR AUTHORIZATION CRITERIA

DRUG CLASS  ANTIOBESITY AGENTS

BRAND NAME*
(generic)
benzphetamine products
diethylpropion products
phendimetrazine products
phentermine products (including SUPRENZA)

Status:  CVS Caremark Criteria
Type:  Initial Prior Authorization

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated

FDA-APPROVED INDICATIONS

Benzphetamine
Benzphetamine is 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/m² 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 is indicated for use as monotherapy only.

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

Diethylpropion
Diethylpropion 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 of 30 kg/m² or higher and who have not responded to an 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 is indicated for use as monotherapy only.

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

Phendimetrazine
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/m² or greater than or equal to 27 kg/m² 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 limited usefulness of agents of this class should be weighed against possible risks inherent in their use. Phendimetrazine tartrate is indicated for use as monotherapy only.

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/m² 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. Phendimetrazine tartrate is indicated for use as monotherapy only.

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

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/m², or greater than or equal to 27 kg/m² 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.

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

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 within the past 365 days
AND
• The requested drug will be used with a reduced calorie diet and increased physical activity AND
  o The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter
  OR
  o The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Anorectics are indicated as a short-term (a few weeks) adjunct to a reduced-calorie diet and increased physical activity, in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m² or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, hyperlipidemia).1-8 The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

The guidelines state that the purpose of weight loss and weight maintenance is to reduce health risk.9, 10 Weight loss programs should begin with a basic weight loss regimen consisting of a reduced-calorie diet and increased physical activity. The major role of medications is to help with patient compliance to a weight loss plan. Therefore, drugs should be used as part of a comprehensive weight loss program and should never be used without concomitant lifestyle modification. Drugs may be used as an adjunct to diet and physical activity for patients with a BMI that is greater than or equal to 30 kg/m² or greater than or equal to 27 kg/m² if other risk factors are present (e.g., hypertension, diabetes, dyslipidemia, sleep apnea, cardiovascular disease).9,10

Sympathomimetic amine anorectic drugs have a narrow FDA labeling which reflects on the importance of prevention of inappropriate usage. The FDA approved indication for these agents is for short term treatment only. The safety of long-term anorexiant therapy has not been established conclusively beyond 12 weeks of administration. Therefore, coverage will be limited to a total of 3 months per year of one of the following: benzphetamine, diethylpropion, phendimetrazine or phentermine.

REFERENCES

Written by: UM Development (LS)
Date Written: 07/1997
Revised: (GP) 6/1998, 06/2000; (JG) 07/2002; (MG) 10/2003; (NB) 11/2004, 07/2005, 06/2006; (CT) 08/2007; (MS) 07/2008; (CT) 08/2009; (KD) 06/2010; (MS) 07/2011; (CY) 06/2012; (PL/TM) 06/2013, (PL) 06/2014, 12/2014 (removed “approval of” from question #1); (MS) 07/2015, 12/2015 (updated Q5 to make trade compatible); (SE) 01/2016 (Added guidelines for approval grid); (MS) 07/2016 (removed safety question); (JG) 07/2017 (no clinical changes), (ME) 07/2018 (no clinical changes)

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<th>CRITERIA FOR APPROVAL</th>
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| 1 Has the patient received 3 months of therapy within the past 365 days?
| Yes | No |
| [Tech note: Verify PA History AND the Prescription History before approving. If the request has been approved in the last 365 days or the patient received a paid claim, forward to RPH for review even if the pop up box asked you to approve it] |
| 2 Does the patient have a body mass index (BMI) greater than or equal to 30 kg per square meter?
| Yes | No |
| [If yes, then skip to question 4.] |
| 3 Does the patient have a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors?
| Yes | No |
| 4 Will the requested medication be used with a reduced calorie diet and increased physical activity?
| Yes | No |

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<th>Guidelines for Approval</th>
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<td>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</td>
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<td>1 Deny</td>
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<td>You do not meet the requirements of your plan. Your plan covers this drug when you have not received 3 months of therapy within the past year.</td>
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