



Horizon Blue Cross Blue Shield of New Jersey

*Making Healthcare Work.*

## Medical Necessity Guideline

<b>Section</b>	Drugs
<b>Policy Number</b>	
<b>Effective Date</b>	6-25-04
<b>Review Date</b>	5-27-05, 10/27/06, 7/27/07

**Subject:**

**DRUG CLASS                    ANTI-OBESITY AGENTS**

- GENERIC NAME                Benzphetamine products
- Diethylpropion products
- Phendimetrazine products
- Phentermine products

**IMPORTANT NOTE:**

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

**Description:**

Benzphetamine and phendimetrazine 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. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

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  $\geq 30$  kg/m<sup>2</sup>, or  $\geq 27$  kg/m<sup>2</sup> in the presence of other risk factors (e.g., hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

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 a body mass index  $\geq 30$  kg/m<sup>2</sup> 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 is indicated for monotherapy only.

**Medical Necessity Guideline:**

1. Prescriptions for Benzphetamine products, Diethylpropion products, Phendimetrazine products and Phentermine products may be subject to medical necessity determination.
2. The following questionnaire will be used to determine the medical necessity.

**CRITERIA FOR APPROVAL**

1. Is the patient $\geq$ 16 years of age?	Yes	No
2. Does the patient have a diagnosis of obesity?	Yes	No
3. Have medical/ organic causes of obesity been excluded (e.g., hypothyroidism, genetic syndromes)? No	Yes	No
4. Does the patient have a body mass index (BMI) $\geq$ 30 kg/m <sup>2</sup> ? [Comment: If the answer to this question is yes, skip to question 7.]	Yes	No
5. Does the patient have a body mass index (BMI) $\geq$ 27 kg/m <sup>2</sup> ?	Yes	No
6. Does the patient have other additional risk factors (e.g., diabetes, dyslipidemia, hypertension, sleep apnea)? No		Yes
7. Has the patient been on a regimen of a low-calorie diet, increased physical exercise, and behavior therapy for a minimum of 6 months?	Yes	No
8. Did the patient lose at least one pound per week while on the weight-loss regimen?	Yes	No
9. Does the patient have poorly controlled or uncontrolled hypertension? No		Yes
10. Does the patient have symptomatic cardiovascular disease?	Yes	No
11. Does the patient have hyperthyroidism?	Yes	No
12. Does the patient have glaucoma?	Yes	No
13. Does the patient have a history of drug abuse?	Yes	No
14. Has the patient had monoamine oxidase inhibitor therapy within the last 14 days?	Yes	No
15. Will the patient have his/her blood pressure and heart rate monitored while on anorectic therapy?	Yes	No
16. Will the patient continue in an active weight-loss program consisting of low-calorie diet, increased physical exercise, and behavioral therapy? No		Yes
17. Will the physician provide information to the patient about the potential risks versus benefits associated with anorectic therapy?	Yes	No
18. Is the patient currently taking other drug products for weight loss? [Comment: If the answer is No to this question, no more questions are required]	Yes	No
19. Will the patient discontinue other drug products for weight loss?	Yes	No
20. Has the patient taken any anorectic therapy in the previous 30 days?	Yes	No

[If the answer to this question is no, then no further questions required.]

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|--|-----|----|
| 21. Has the patient lost greater than or equal to one pound per week (4 pounds) since the initiation of therapy? | Yes | No |
| 22. Has the patient received 3 months of anorectic therapy?  | Yes | No |

Guidelines for Approval							
Duration of Approval				1 month			
Set 1		Set 2		Set 3		Set 4	
Yes to questions	No to questions	Yes to questions	No to questions	Yes to questions	No to questions	Yes to questions	No to questions
1	8	1	8	1	4	1	4
2	9	2	9	2	8	2	8
3	10	3	10	3	9	3	9
4	11	4	11	5	10	5	10
7	12	7	12	6	11	6	11
15	13	15	13	7	12	7	12
16	14	16	14	15	13	15	13
17	20	17	18	16	14	16	14
18			20	17	20	17	18
19				18			20
				19			
Duration of Approval				2 months			
Set 5		Set 6		Set 7		Set 8	
Yes to questions	No to questions	Yes to questions	No to questions	Yes to questions	No to questions	Yes to questions	No to questions
1	8	1	8	1	4	1	4
2	9	2	9	2	8	2	8
3	10	3	10	3	9	3	9
4	11	4	11	5	10	5	10
7	12	7	12	6	11	6	11
15	13	15	13	7	12	7	12
16	14	16	14	15	13	15	13
17	18	17	22	16	14	16	14
20	22	18		17	18	17	22
21		19		20	22	18	
		20		21		19	
		21				20	
						21	

**Horizon BCBSNJ Pharmacy Guideline Development Process:** This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion

regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

**BLACK BOX WARNINGS:**

None.

**RATIONALE:**

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and the clinical guidelines for the treatment of obesity set by the National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI), and American Association of Clinical Endocrinologists (AACE).

The purpose of weight loss and weight maintenance is to reduce health risk. Only patients who are at increased medical risk should use weight loss medications. Weight loss programs should begin with a basic regimen of low calorie diet, increased physical activity, and behavioral therapy. After at least 6 months on the basic weight loss program, if a patient has not lost the recommended one pound per week, careful consideration may be given to pharmacotherapy. Organic causes of obesity (e.g., untreated hypothyroidism) should also be excluded before prescribing pharmacotherapy. The major role of medications is to help with patient compliance to 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  $\geq 30 \text{ kg/m}^2$  or  $\geq 27 \text{ kg/m}^2$  if other risk factors are present (e.g., hypertension, diabetes, hyperlipidemia). Patient should be monitored regularly while on a weight loss regimen. People with high blood pressure, symptomatic cardiovascular disease, hyperthyroidism, glaucoma, history of drug abuse, or have taken a monoamine oxidase inhibitor in the previous 14 days should not take anorectic therapy. In addition, patients should be informed of the potential risks versus the benefits of pharmacotherapy.

For renewal after one month of therapy, in order to limit unwarranted exposure and risks, therapy should be continued only if the patient has satisfactory weight loss with in the first four weeks of treatment. The patient must lose at least one pound per week (4 pounds in 4 weeks).

Anorectic drugs have a narrow FDA labeling which reflects on the importance of prevention of inappropriate usage. The approval duration is limited to 3 months because labeling and guidelines support up to 12 weeks of therapy. The safety of long-term anorexiant therapy has not been established conclusively beyond 12 weeks of administration. To be considered for therapy, the patient must be at least 16 years of age. Even though benzphetamine and phendimetrazine are approved for use in children at least 12 years of age or greater, the treatment guidelines do not recommend the use of pharmacotherapy in children or adolescents.

**ADDITIONAL INFORMATION**

**Dosage and Administration**

**Diethylpropion**

*Immediate Release*

One 25 mg tablet three times daily, one hour before meals, and in mid-evening if desired to overcome night hunger.

*Controlled Release*

One 75 mg tablet, swallowed whole, in the morning.

**Didrex**

Dosage should be individualized according to the response of the patient. The suggested dosage ranges from 25 mg to 50 mg one to three times daily. Treatment should begin with 25 mg to 50 mg once daily with subsequent increase in individual dose or frequency according to response. A single daily dose is preferably given in mid-morning or mid-afternoon, according to the patient's eating habits. In an occasional patient it may be desirable to

avoid late afternoon administration. Use of benzphetamine is not recommended in individuals under 12 years of age.

### **Bontril**

One slow-release capsule (105 mg) in the morning, taken 30 minutes to 60 minutes before the morning meal. Phendimetrazine is not recommended for use in children under 12 years of age.

### **Ionamin**

One capsule daily, taken before breakfast or 10 hours to 14 hours before retiring. For individuals exhibiting greater drug responsiveness, Ionamin-15 will usually suffice. Ionamin-30 is recommended for less responsive patients. Ionamin is not recommended for use in pediatric patients under 16 years of age. Ionamin capsules should be swallowed whole.

## **CONTRAINDICATIONS/WARNINGS/PRECAUTIONS**

### **Contraindications:**

- Advanced arteriosclerosis
- Cardiovascular disease
- Moderate to severe hypertension
- Hyperthyroidism
- Known hypersensitivity
- Idiosyncrasy to the sympathomimetic amines
- Glaucoma
- Agitated states
- Patients with a history of drug abuse
- During or within 14 days following the administration of monoamine oxidase inhibitors

### **Warnings**

**Benzphetamine, phendimetrazine and phentermine are indicated only as short-term monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss, including selective serotonin reuptake inhibitors (e.g., fluoxetine, sertraline, fluvoxamine, paroxetine), have not been established. Therefore, co-administration of these drug products for weight loss is not recommended.**

**Primary Pulmonary Hypertension (PPH)—a rare, frequently fatal disease of the lungs—has been reported to occur in patients receiving a combination of phentermine with fenfluramine or dexfenfluramine. The possibility of an association between PPH and the use of phentermine alone cannot be ruled out; there have been rare cases of PPH in patients who reportedly have taken phentermine alone. The initial symptom of PPH is usually dyspnea. Other initial symptoms include: angina pectoris, syncope or lower extremity edema. Patients should be advised to report immediately any deterioration in exercise tolerance. Treatment should be discontinued in patients who develop new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema.**

**Valvular Heart Disease: Serious regurgitant cardiac valvular disease, primarily affecting the mitral, aortic and/or tricuspid valves, has been reported in otherwise health persons who had taken a combination of phentermine with fenfluramine or dexfenfluramine for weight loss. The etiology of these valvulopathies has not been established and their course in individuals after the drugs are stopped is not known. The possibility of an association between valvular heart disease and the use of phentermine alone cannot be ruled out; there have been rare cases of valvular heart disease in patients who reportedly have taken phentermine alone.**

If tolerance develops to an anorectic drug, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

Anorectic drugs may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle.

Anorectic agents are related chemically and pharmacologically to amphetamine and other stimulant drugs that have been extensively abused. The possibility of abuse should be considered.

Safe use in pregnancy has not been established. Benzphetamine is classified as category X.

The use of anorectic agents for greater than three months was associated with a 23-fold increase in the risk of developing pulmonary hypertension.

**Precautions:**

Caution should be exercised in prescribing anorectic drugs in patients with even mild hypertension.

Insulin requirements in diabetes mellitus may be altered in association with the use of anorectic drugs and the concomitant dietary regimen.

Psychological disturbances have been reported in patients who receive an anorectic agent together with a restrictive dietary regime.

**REFERENCES:**

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7. National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. [www.guideline.gov](http://www.guideline.gov). 2000.
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9. American Gastroenterological Association (AGA) Medical Position Statement on Obesity. *Gastroenterology* September 2002; 123(3):879-881.

*Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.*

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