

DRUG DETERMINATION POLICY

Title: DDP-25 Weight Loss Products

Effective Date: 03/09/2021



Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Contrave and Saxenda are agents used to facilitate weight loss in obese individuals. These criteria were developed and implemented to ensure appropriate use of conventional treatment first, as well as use for the intended severity of condition.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

- I. Treatment of obesity.
 - A. Contrave (naltrexone 8mg/bupropion 90mg):
 1. Age: at least 18 years old.
 2. Body mass index (BMI): at least 30.
 3. Non-pharmacological therapies [must meet one listed below]:
 - a. Participation in two supervised non-pharmacological weight loss treatment programs.
 4. Pharmacological therapies [must meet both listed below]:
 - a. Contraindicated, inadequate response after four months or significant adverse events with one stimulant: benzphetamine, diethylpropion, phendimetrazine or phentermine.
 - b. Must be used with diet and exercise.

5. Dosage: Contrave.

Dose	Week 1	Week 2	Week 3	Week 4
am dose	one tab	one tab	two tabs	two tabs
pm dose	none	one tab	one tab	two tabs

B. Saxenda subcutaneous (liraglutide SQ).

1. Age: at least 18 years old.
2. Body mass index (BMI): at least 30.
3. Non-pharmacological therapies [must meet one listed below]:
 - a. Participation in two supervised non-pharmacological weight loss treatment programs with one being a run in program [must meet below]:
 - Run in program: four to twelve week program just prior to Saxenda treatment.
4. Pharmacological therapies [must meet both listed below]:
 - a. Contraindicated, inadequate response after four months or significant adverse events with one stimulant and Contrave [must meet both below]:
 - Stimulants: benzphetamine, diethylpropion, phendimetrazine or phentermine.
 - Contrave (naltrexone 8mg/bupropion 90mg):
 - b. Must be used with diet and exercise.
5. Dosage: Saxenda subcutaneous - 0.6mg daily for one week, increase by 0.6mg weekly until target dose of 3mg daily.

C. Excluded products: Xenical oral (orlistat), Qsymia (phenterimine and topiramate).

1. Contraindication, inadequate response after four months or significant adverse effects.

D. Approval.

1. Initial approval: three months.
2. Re-approval:
 - a. Continued weight loss of greater than five percent.
 - b. Renewals can be continued for up to one year total coverage.

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. NIH The Practical Guideline: Identification, Evaluation and Treatment of Overweight and Obesity in Adults October 2000.
2. CDC Overweight and Obesity prevention Strategies and Guidelines 2018;
<https://www.cdc.gov/obesity/resources/strategies-guidelines.html> assessed July 2020.
3. AACE Comprehensive Clinical Practice Guidelines for the Medical of Patient with Obesity (2016);
<https://www.aace.com/disease-state-resources/nutrition-and-obesity/clinical-practice-guidelines/comprehensive-clinical>; assessed July 2020.
4. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; phentermine, Orlistat, Contrave Saxenda accessed March 2021.
5. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, Feb 2015;100(2);342-262.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 04/22/2010

Next Review Date: 09/22/2021

Revision Date	Reason for Revision
7/20	Reinstated archived policy, updated to add Saxenda, updated references, approved by P&T Committee 8/26/20.
2/21	Off cycle review; updated to exclude drugs Qsymia (phenterimine and topiramate); clarified criteria instructions

Appendix I - Monitoring and patient safety

Drug	Adverse Reactions	Monitoring	REMS
Adipex, Suprenza phentermine	<ul style="list-style-type: none"> • Cardiovascular: hypertension, ischemia, palpitation, pulmonary hypertension, increased heart rate • Central nervous system: dizzy, dysphoria, euphoria, headache, insomnia, overstimulation, psychosis, restlessness, nausea, • Dermatological: urticaria • Gastrointestinal: constipation, diarrhea, bad taste, xerostomia • Gastrointestinal: impotence, libido change • Neurological/musculoskeletal: tremor • Pregnancy category: C 	<ul style="list-style-type: none"> • Cardiovascular: blood pressure, pulse • Endocrine/metabolism: weight, waist circumference 	None needed
Qsymia topiramate + phentermine	<ul style="list-style-type: none"> • Cardiovascular: increased heart rate (14-78%), • Central nervous system: paresthesia (4-20%), headache (10-11%), insomnia (6-11%) • Endocrine/metabolism: ↓ bicarb (6-13%) • Gastrointestinal: xerostomia (7-19%), constipation (8-16%) • Respiratory: upper respiratory infection (14-16%), nasopharyngitis (9-13%) 	<ul style="list-style-type: none"> • Lab: bicarbonate, potassium, glucose, creatinine. (pretreatment and during) • Cardiovascular: heart rate • Central nervous system: signs and symptoms of depression, suicidal thought • Endocrine/metabolism: weight, waist circumference, signs and symptoms of acidosis 	None Needed
Alli/Xenical orlistat	<ul style="list-style-type: none"> • Central nervous system: headache (≤31%) • Gastrointestinal: oily spot (4-27%), abdominal pain/discomfort (≤26%), flatus with discontinuation (2-24%), fecal urgency (3-22%), fatty oily stool/evacuation (2-20%), increased defecation (3-11%) • Neurological/musculoskeletal: back pain (≤14%) • Respiratory: upper respiratory infection (26-38%) • Miscellaneous: influenza (≤40%) • Pregnancy category: X 	<ul style="list-style-type: none"> • Lab: serum glucose (with diabetes), thyroid (with thyroid disease), liver function tests (with hepatic dysfunction) • Endocrine/metabolism: body mass index 	Medication Guide
Saxenda liraglutide	<ul style="list-style-type: none"> • Cardiovascular: increased heart rate (5-34%) • Central nervous system: headache (14%) • Endocrine/metabolism: hypoglycemia (with diabetes: 16-44%) • Gastrointestinal: nausea/vomiting (16-39%), diarrhea (21%), constipation (19%) • Pregnancy category: X 	<ul style="list-style-type: none"> • Lab: serum glucose, HbA1c, renal function • Cardiovascular: heart rate • Central nervous system: signs and symptoms of depression, suicidal thought • Genitourinary: signs and symptoms of pancreatitis 	Medication Guide