DRUG DETERMINATION POLICY

Title: DDP-25 Chronic Weight Management

Effective Date: 10/26/22

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 certain Glucagon-Like Peptide 1 (GLP-1) Receptor Antagonists, are agents used for chronic weight management as an adjunct to diet and exercise 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. Chronic weight management.

   A. Contrave (naltrexone 8mg/bupropion 90mg):

      1. Age: at least 18 years old.

      2. Body mass index (BMI): at least 30Kg per m^2 or at least 27kg per m^2 for those with risk factors besides obesity (for example, diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, or sleep apnea).

      3. Non-pharmacological therapies [must meet one listed below]:

         a. Participation in two supervised non-surgical or non-pharmacological weight loss treatment programs (e.g.Noom, Weight Watchers etc.)

      4. Pharmacological therapy [must meet one listed below]:

a. Short term pharmacological weight management therapy trial: Phentermine with topiramate or Qsymia 15mg/92mg if tolerated for 12 to 24 weeks unless contraindicated or significant adverse effects

5. Dosage Regimen: 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. Glucagon-Like Peptide 1 (GLP-1) Receptor Antagonists: Saxenda subcutaneous (liraglutide SQ) and Wegovy subcutaneous (semaglutide SQ).[must meet all listed below]:

1. Age [must meet one listed below]:

a. Saxenda; at least 12 years old.

b. Wegovy: at least 18 years old.

2. Body mass index (BMI): at least 30Kg per m2 or at least 27kg per m2 for those with risk factors besides obesity (for example, diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea).

3. Non-pharmacological therapies [must meet one listed below]:

a. Participation in two supervised non-surgical non-pharmacological weight loss treatment programs (eg. Noom, Weight Watchers, etc.)

4. Dosage:

a. Saxenda subcutaneous: 0.6mg daily for one week, increase by 0.6mg weekly until target dose of 3mg daily.

b. Wegovy subcutaneous (semaglutide SQ): 0.25mg once weekly for four weeks then in four week intervals increase the dose (0.5mg, 1mg, 1.7mg)until a dose of 2.4mg is reached.

C. Excluded products: Xenical oral (orlistat),

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

D. Approval.

1. Initial approval:

a. Saxenda: four months.(includes 1 month of titration)

b. Wegovy: six months (includes 3 months of titration)

2. Re-approval:

a. Duration: six months.

b. Weight loss of at least five percent.after three months post titration and ongoing maintenance of weight loss

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 Care of Patients 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, Wegovy, Qsymia accessed August 2022.
5. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, Feb 2015;100(2);342-262.
6. The science of obesity management: an Endocrine Society scientific statement. *Endocr Rev*. 2018;39(2):79-132. doi:10.1210/er.2017-00253[PubMed 29518206]
7. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity. Gastroenterology. 2022;163(5):1198-1225. doi:10.1053/j.gastro.2022.08.045

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 04/22/2010

Next Review Date: 09/22/2023

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
6/21	Off cycle review; added drug Wegovy to purpose, dosage and safety and monitoring, changed policy name and verbiage to chronic weight management; removed stimulant and replace with Qsymia for other therapies; removed run in non-pharm weight management program stipulation; added Saxenda pediatric use, changed approval duration, outcome; removed other therapies for GLP-1 antagonists; approved by P&T 10/27/21
10/22	Annual Review, examples of weight loss treatment programs, adjusted initial approval duration to account for titration, added references, clarify Wegovy dose

Appendix I - Monitoring and patient safety

Drug	Adverse Reactions	Monitoring	REMS
Contrave Naltrexone/ bupropion	• Central Nervous System: headache (18%), sleep disorder (14%) • Gastrointestinal: nausea (33%), constipation (19%), vomiting (11%)	• Cardiovascular: blood pressure, heart rate • Central Nervous System: depression, suicidal ideation, anxiety, social functioning, mania, panic attacks • Gastrointestinal: liver function • Labs: blood glucose • Metabolic: weight, BMI • Renal: renal function	Medication guide
Qsymia phentermine/ topiramate	• Cardiovascular: increased heart rate (>5 bpm: 70% to 78%; >10 bpm: 50% to 56%; >15 bpm: 33% to 37%; >20 bpm: 14% to 20%) • Central nervous system: paresthesia (4% to 20%), headache (10% to 11%), insomnia (6% to 11%) • Endocrine & metabolic: decreased serum bicarbonate (6% to 13%; marked reductions [to <17 mEq/L] ≤1%) • Gastrointestinal: xerostomia (7% to 19%), constipation (8% to 16%) • Respiratory: upper respiratory tract infection (14% to 16%), nasopharyngitis (9% to 13%)	• Cardiovascular: resting heart rate; blood pressure • Endocrine/Metabolism: weight; acute acidosis and complications of long-term acidosis (eg, nephrolithiasis) • Labs: serum bicarbonate, potassium, glucose, and serum creatinine (pre and periodically during treatment) • Psychiatry: suicidality or mood disorders • Ophthmology: symptoms of secondary angle closure glaucoma Evaluate pregnancy status prior to use in patients who can become pregnant; a negative pregnancy test is required prior to and monthly during therapy	
Wegovy Semaglutide SQ	• Gasstrointestinal: abdominal pain (6-11%), nausea (11-20%)	• Labs: plasma glucose, hemoglobin A1c, triglycerides • Gastrointestinal: signs and symptoms of pancreatitis abd gallbladder disease • Renal: renal function	Medication guide
Saxenda Liraglutide SQ	• 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	• Labs: 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