DRUG DETERMINATION POLICY

Title: DDP-25 Chronic Weight Management

Effective Date: 8/23/23

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 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. General Considerations

A. Limitations of use: One attempt of each medication if initial trial failed or caused significant adverse effects.

B. Concomitant drugs: Not to be used in combination with other weight loss products.

C. Etiology of weight gain: Other causes of weight gain have been addressed and corrected if possible (hypothyroid, drug-induced).

D. Exclusions: History of eating disorders (anorexia, binge eating disorder, etc.)

E. Adjunctive agent: These products will be used with reduced calorie diet and increased physical activity for chronic weight management.

F. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

II. Chronic Weight Management

A. Contrave (naltrexone 8mg/bupropion 90mg). [must meet all listed below]:

1. Age: at least 18 years old.

2. Body mass index (BMI): Recorded within the last 30 days [must meet one listed below]:

a. At least 30 kg per m^2

b. At least 27 kg per m^2 for those with weight-related risk factors besides obesity (for example, diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, or sleep apnea).

3. Non-pharmacological and non-surgical therapies including documentation of program names with start and stop dates [must meet both listed below]:

a. Participated in two separate and non-concurrent supervised weight management programs for at least three months each. Programs must encourage behavioral modification, reduced calorie diet and increased physical activity (e.g., Noom, Weight Watchers, Medical Weight Loss).

b. Participation in one supervised weight management program must have been for at least three consecutive months immediately prior to using the requested medication.

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]: at least 12 years old

2. Body mass index (BMI – See Appendix I): Recorded within the last 30 days [must meet one listed below]:

a. At least 30 kg per m^2

b. At least 27 kg per m^2 for those with weight-related risk factors besides obesity (for example, diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, or sleep apnea).

3. Non-pharmacological and non-surgical therapies including documentation of program names with start and stop dates [must meet both listed below]:

a. Participated in two separate and non-concurrent supervised weight management programs for at least three months each. Programs must encourage behavioral modification, reduced calorie diet and increased physical activity (e.g., Noom, Weight Watchers, Medical Weight Loss).

b. Participation in one supervised weight management program must have been for at least three consecutive months immediately prior to using the requested medication.

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 to each preferred agent.

D. Approval.

1. Initial approval: six months (If switching drugs during the initial trial the total approval duration is still six months)

2. Re-approval: six months to one year [must meet both below]

a. Weight loss of at least five percent after six months and ongoing maintenance of weight loss.

b. Adherence to prescribed therapy: Fill history documenting the medication has been filled and received by the patient once per month.

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 pages 5 - 6.

7.0 Revision History:

Original Effective Date: 04/22/2010

Next Review Date: 11/01/2024

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 (phentermine 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 replaced 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
1/23	Off-cycle review, added general consideration with limits of use, concomitant drugs, etiology of weight gain address and adjunctive agent; clarify weight losss programs and one being prior to use of drug, indicated BMI needs to be within one month of request time; extended reapproval to also include 1 year
5/23	Off-cycle review;, added weight-related to clarify comorbidity, added to other therapies need names of programs with start and stop dates, clarified that if drug switched during 6 month initial still 6 moths total; addition of adherence to reapproval section
8/23	Annual review: clarified that the two programs must be separate, non-concurrent, and for at least three months each. Pharmaceutical sample use not recognized by plan as trial or for continuation of therapy.

Appendix I: Adult and Pediatric BMI Charts

Table 1. BMI Conversion Chart

Weight	(lb)	125	130	135	140	145	150	155	160	165	170	175	180	185	190	195	200	205	210	215	220	225
	(kg)	56.8	59.1	61.4	63.6	65.9	68.2	70.5	72.7	75.0	77.3	79.5	81.8	84.1	86.4	88.6	90.9	93.2	95.5	97.7	100.0	102.3
Height																						
(in)	(cm)																					
58	147.3	26	27	28	29	30	31	32	34	35	36	37	38	39	40	41	42	43	44	45	46	47
59	149.9	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	43	44	45	46
60	152.4	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44
61	154.9	24	25	26	27	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
62	157.5	23	24	25	26	27	27	28	29	30	31	32	33	34	35	36	37	38	38	39	40	41
63	160.0	22	23	24	25	26	27	28	28	29	30	31	32	33	34	35	36	36	37	38	39	40
64	162.6	22	22	23	24	25	26	27	28	28	29	30	31	32	33	34	34	35	36	37	38	39
65	165.1	21	22	23	23	24	25	26	27	28	28	29	30	31	32	33	33	34	35	36	37	38
66	167.6	20	21	22	23	23	24	25	26	27	27	28	29	30	31	32	32	33	34	35	36	36
67	170.2	20	20	21	22	23	24	24	25	26	27	27	28	29	30	31	31	32	33	34	35	35
68	172.7	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	34	34
69	175.3	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	33
70	177.8	18	19	19	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	32	32
71	180.3	17	18	19	20	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	31
72	182.9	17	18	18	19	20	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31
73	185.4	17	17	18	19	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30
74	188.0	16	17	17	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	28	28	29
75	190.5	16	16	17	18	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	28	28
76	193.0	15	16	16	17	18	18	19	20	20	21	21	22	23	23	24	24	25	26	26	27	27

Table 2. BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (CDC Criteria)

Age (years)	Body mass index (kg/m²) at 95% Percentile	
	Males	Females
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30

Appendix II - 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