

MEDICATION COVERAGE POLICY



PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Weight Loss	P&T DATE:	9/11/18
THERAPEUTIC CLASS:	Gastrointestinal Disorders	REVIEW HISTORY:	5/17, 5/16
LOB AFFECTED:	Medi-Cal	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Diet, exercise, and behavioral modification are all recommended as first line of obesity management prior to pharmacotherapy and bariatric surgery interventions. The Endocrine Society developed a clinical practice guideline in hopes of re-iterating this concept to streamline an approach towards achieving long-term weight maintenance. With the addition of approved weight loss medications to the treatment regimen, amplification of adherence to proposed behavior changes and possibly improved ability to engage in physical activity can occur. Candidates for weight loss medications would be those who have a history of unsuccessfully losing and maintaining their weight. Health Plan of San Joaquin will cover Bariatric Surgery if the patient meets the medical necessity requirements per the Milliman Care Guidelines. The purpose of this coverage policy will be to examine currently FDA approved agents for weight management and their coverage criteria.

Table 1: FDA-Approved Weight Loss Agents (Current as of 8/2018)

Therapeutic Class	Generic (Brand)	Strengths	Formulary Status	Avg Cost Per RX	Notes	
Lipase Inhibitor	Orlistat (Alli-OTC, Xenical)	Alli: 60 mg Capsules	PA	--	BMI of ≥ 27 with 2 or more comorbidities OR [2] BMI > 30	
		120 mg Capsules		\$398.56		
Serotonin 5-HT _{2c} Receptor Agonist	Lorcaserin Hcl (Belviq)	10 mg Tablets	NF	--		
		20 mg XR Tablets		--		
Sympathomimetics	Benzphetamine Hcl (Regimex)	25 mg Tablets	NF	--		
		50 mg Tablets		--		
		Regimex 25 mg Tablets		--		
	Diethylpropion Hcl (Tenuate)	25 mg Tablets	NF	--		
		75 mg ER Tablets		--		
	Phendimetrazine Tartrate (Bontril)	35 mg Tablets	NF	--		
		105 mg Capsules		--		
	Phentermine (Adipex-P, Lomaira)	Phentermine (Adipex-P, Lomaira)	8 mg Tablets	NF	--	BMI of ≥ 27 with 2 or more comorbidities OR [2] BMI > 30
			37.5 mg Tablets	PA	\$4.83	
			15 mg Capsules	NF	\$6.82	
30 mg Capsules			--			
37.5 mg Capsules			--			
Adipex-P 37.5 mg Tablets			--			
Adipex-P 37.5 mg Capsules	--					
GLP-1 Agonist	Liraglutide (Saxenda)	18 mg/3 mL Pen	NF	--		
Opioid Antagonist-Dopamine/Norepin-	Bupropion/Naltrexone	8/90 mg Tablets	NF	--		

ephrine Reuptake Inhibitor	(Contrace)				
Combination	Phentermine/ Topiramate (Qsymia)	Qsymia 3.75/23 mg Tablets	NF	--	
		Qsymia Tablets 7.5/46 mg		--	
		Qsymia Tablets 11.25/69 mg		--	
		Qsymia Tablets 15/92 mg		--	

ODT = Orally disintegrating tablet; F = Formulary, ST = Step therapy, PA = Prior Authorization required.

Clinical Justification:

Body mass index (BMI), waist circumference, and overall medical risk are part of routine patient weight loss assessment. BMI can be estimated using the following equation: BMI = [weight (in pounds) X 703] / height (inches) squared. ²

Waist circumference evaluations are used to assess the risk associated with obesity or overweight. Although waist circumference evaluation is of little use in individuals with BMI ≥ 35 kg/m², it is of particular value in individuals who fall into BMI classification of normal to overweight. Waist circumference > 40 inches in men, and > 35 inches in women are higher risk of diabetes, dyslipidemia, hypertension, and cardiovascular disease.

Table 6. Classification of Overweight and Obesity by BMI and Waist Circumference (31 [EL 4; NE])

Classification	BMI		Waist	
	BMI (kg/m ²)	Comorbidity Risk	Waist Circumference and Comorbidity Risk	
			Men ≤40 in (102 cm) Women ≤35 in (88 cm)	Men >40 in (102 cm) Women >35 in (88 cm)
Underweight	<18.5	Low but other problems		
Normal weight	18.5–24.9	Average		
Overweight	25–29.9	Increased	Increased	High
Obese class I	30–34.9	Moderate	High	Very high
Obese class II	35–39.9	Severe	Very high	Very high
Obese class III	≥40	Very severe	Extremely high	Extremely high

Abbreviations: BMI = body mass index; in = inches.

AACE/ACE Obesity CPG, Endocr Pract. 2016;22(Suppl 3)

⊞ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Sympathomimetic

Phentermine (Adipex-P, Lomaira), Benzphetamine Hcl (Regimex), Diethylpropion Hcl (Tenuate), Phendimetrazine Tartrate (Bontril)

Phentermine

- Coverage Criteria:**
 - Weight loss agents are reserved for patients with Body Mass Index > 30 or ≥ 27 with > 2 comorbidities AND had received exercise and dietary counseling at least twice by a registered dietitian.
- Limits:** None
- Required Information for Approval:**
 - Documentation of BMI and comorbidities.
 - Documentation of exercise and dietary counseling at least twice by a registered dietitian.
 - Initial approval: 3 months
 - Continuation of therapy: 3 months at a time
 - Documentation of ≥5% weight loss via clinic notes that contain the patient's updated BMI or height and weight.
- Notes:**
 - Doses are individualized to achieve adequate responses with the lowest effective dose.
- Non-formulary:** Suprenza ODT, Phentermine Capsules, Lomaira, Benzphetamine Hcl (Regimex), Diethylpropion Hcl (Tenuate), Phendimetrazine Tartrate (Bontril)

Lipase Inhibitor

Orlistat (Xenical, Alli)

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- Limits:** None
- Required Information for Approval:**
 - Documentation of BMI and comorbidities.
 - Documentation of exercise and dietary counseling at least twice by a registered dietitian.
 - Initial approval: 3 months
 - Continuation of therapy: 3 months at a time
 - Documentation of ≥5% weight loss via clinic notes that contain the patient's updated BMI or height and weight.
- Notes:**
 - Dose modification must occur if patient is also taking cyclosporine or levothyroxine.
 - Alli and Xenical are administered 3 times daily with each main meal that contains fat. Doses must be omitted if a meal is missed or the meal does not contain fat.

Serotonin 5-HT_{2C} Receptor Agonist

Lorcaserin Hcl (Belviq)

- Non-formulary**

GLP-1 Agonist

Liraglutide (Saxenda)

- Non-formulary**

Opioid Antagonist-Dopamine/Norepinephrine Reuptake Inhibitor
<i>Bupropion/Naltrexone (Contrave)</i>

Non-formulary

Combination
<i>Phentermine/Topiramate (Qsymia)</i>

Non-formulary

☒ **REFERENCES**

1. Xenical® [prescribing information]. South San Francisco, CA: Genentech, CA; 2015.
2. The Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. National Institutes Of Health National Heart, Lung, And Blood Institute North American Association For The Study Of Obesity. https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd_c.pdf
3. Garvey t, Mechanick J. Brett E. et al, American Association Of Clinical Endocrinologists And American College Of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care Of Patients With Obesity. Endocrine Practice Vol 22 (Suppl 3) July 2016 1.

☒ **REVIEW & EDIT HISTORY**

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Gastrointestinal Disorders – Weight Loss 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update Policy	HPSJ Coverage Policy – Gastrointestinal Disorders – Weight Loss 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update Policy	HPSJ Coverage Policy – Gastrointestinal Disorders – Weight Loss 2018-09.docx	9/2018	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy