

Clinical Policy: Weight Loss Agents

Reference Number: CA.CP.PMN.02

Effective Date: 01/15

Last Review Date: 03/21

Line of Business: Medicaid - California

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by California Health and Wellness and Health Net clinical policy for weight loss agents.

The ultimate goal of drug therapy in the treatment of obesity is as an adjunct to a weight loss plan that constitutes reduced calorie diet, exercise, and behavioral modification.

Policy/Criteria

It is the policy of California Health and Wellness and Health Net that weight loss agents are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

All weight loss agents (must meet all):

- A. Documented current BMI ≥ 30 or BMI ≥ 27 with at least one of the other comorbidity: cardiovascular disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
- B. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
- C. Age must be appropriate per FDA labeling for the requested medication;
- D. Member is NOT receiving two medications for weight loss at the same time

II. Medication Specific Criteria

1. Orlistat (Xenical®)
 - A. Criteria A-D above AND
 - B. Negative history of cholestasis or chronic intestinal malabsorption in the past 12 months;
 - C. Treatment protocol:
 - a. Initial approval: 12 weeks - up to 360mg/day
 - b. Continued approval: 6 months – if member has lost at least 5% of initial body weight during the first 12 weeks of therapy, has a BMI ≥ 25 , maintains initial weight loss, dose does not exceed 360mg/day, and continues to meet all the above criteria.
2. Phentermine/Topiramate (Qsymia®)
 - A. Criteria A-D above, AND

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- B. Negative history of MAOI therapy in the last 14 days, glaucoma, hyperthyroidism;
- C. Treatment protocol:
- Initial approval: 12 weeks – up to 7.5mg/46mg per day
 - Continued approval: 6 months - up to 15mg/92mg per day if member has lost at least of 5% of initial weight, has a BMI ≥ 25 , maintains initial weight loss, dose does not exceed 15mg/92mg per day, and continues to meet all the above criteria.
3. Liraglutide (Saxenda®) (must meet all)
- A. Meets one of the following (1 or 2):
- For adults: Criteria A-D above
 - For pediatrics: Criteria B-D and member's age is between 12 and 18 years, with body weight > 60 kg and an initial BMI corresponding to 30 kg/m² for adults (obese) by international cut-offs (see Appendix);
- B. Is not being used to treat diabetes;
- C. Member is not on insulin or another GLP-1 receptor agonist;
- D. Negative history of personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN2);
- E. Treatment Protocol:
- Initial approval: 12 weeks – up to 3mg/day
 - Continued approval: 6 months – if patient has lost at least 4% of baseline body weight (for adults) or at least 1% of baseline BMI (for pediatrics) after initiating treatment, has a BMI ≥ 25 , maintains initial weight loss, dose does not exceed 3mg/day, and continues to meet all the above criteria.
4. Bupropion/Naltrexone (Contrave®)
- A. Criteria A-D above, AND
- B. Negative history of uncontrolled hypertension, use of other bupropion-containing products, chronic opioid use, MAOI therapy during or within the last 14 days, seizure disorder, anorexia or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs;
- C. Treatment Protocol:
- Initial approval: 12 weeks – up to 32mg/360 mg per day (4 tablets per day)
 - Continued approval: 6 months if patient has lost at least 5% of baseline body weight after initiating treatment, has a BMI ≥ 25 , maintains initial weight loss, dose does not exceed 32mg/360 mg per day (4 tablets per day), and continues to meet all the above criteria.
5. Noradrenergic Sympathomimetic Drugs (Benzphetamine, Phendimetrazine, Phentermine, Diethylpropion)
- A. Criteria A-D above AND

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- B. Negative history of MAOI therapy in the last 14 days, cardiac disease (CAD, stroke, arrhythmias, heart failure, uncontrolled hypertension), hyperthyroidism, glaucoma, or history of drug abuse;
- C. Treatment Protocol:
 - a. Initial approval: 12 weeks and request does not exceed maximum FDA approved dose.
 - b. Continued approval: total 12 weeks treatment duration – if patient has evidence of weight loss from baseline, has a BMI ≥ 25 , and request does not exceed maximum FDA approved dose.

Background

FDA Approved Indications:

Treatment of obesity as an adjunct to a reduced-calorie diet and increased physical activity.

Description/Mechanism of Action:

- Orlistat (Xenical®) exerts its anti-obesity effects by altering the digestion of fats through the inhibition of pancreatic lipases.
- Phentermine/Topiramate (Qsymia®) is a combination of a sympathomimetic and an antiepileptic. Phentermine increases the release of norepinephrine and dopamine from nerve terminals and inhibits their reuptake, resulting in reduced appetite and food consumption. Topiramate suppresses appetite and enhances satiety through its pharmacologic effects, including enhancing the activity GABA, blocking voltage-gated sodium channels, antagonizing glutamate receptors, or inhibiting carbonic anhydrase. Its exact mechanism of action on weight loss is not known.
- Liraglutide (Saxenda®), a GLP-1 agonist, reduces caloric consumption by activating GLP-1 receptors in the brain that regulate appetite and calorie intake.
- Naltrexone/Bupropion (Contrave®) contains an opioid antagonist and a dopamine/norepinephrine inhibitor. Although studies have suggested that naltrexone and bupropion have effects on the hypothalamus (appetite regulatory center) and the mesolimbic dopamine circuit (reward system), the exact mechanism of weight loss is unknown.
- Phentermine (Adipex-P®, Lomaira®), Diethylpropion (Radtue®), Benzphetamine (Didrex®), and Phendimetrazine (Bontril SR®, Bontril PDM®) are noradrenergic sympathomimetic agents that act by stimulating the release of norepinephrine or inhibiting its reuptake into nerve terminals receptor, resulting in early satiety and consequently reduced food intake.

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Formulations:

- Orlistat (Xenical®): 120mg capsule
- Phentermine/topiramate (Qsymia®): 3.75mg/23mg, 7.5mg/46mg, 11.25mg/69mg, 15mg/92mg ER capsules
- Liraglutide (Saxenda®): 18mg/3ml pen injection
- Naltrexone/bupropion (Contrave®): 8mg naltrexone/90mg bupropion ER tablets
- Benzphetamine (Didrex®): 25mg, 50mg tablet
- Phendimetrazine (Bontril SR®, Bontril PDM®, Melfiat 105 Unicelles): 35mg tablet, 105mg ER capsule
- Phentermine (Adipex P®, Lomaira®): 8mg tablet, 37.5mg tablet, 15mg capsule, 30mg capsule, 37.5mg capsule
- Diethylpropion (Tenuate®, Radtue®): 25mg tablet, 75mg ER tablet

Appendix: Saxenda General Information

- Adults: Saxenda's prescribing information recommends that change in body weight is evaluated 16 weeks after initiation of therapy. Saxenda should be discontinued if the patient has not lost at least 4% of baseline body weight, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
- Pediatrics: Evaluate the change in BMI after 12 weeks on the maintenance dose and discontinue Saxenda if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
- International cut-offs for pediatric patients:

Pediatric Patients Aged 12 Years and Older

BMI cut-offs for obesity in pediatric patients aged 12 years and older are presented in Table 2.

Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age (years)	Body mass index 30 kg/m ²	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

Source: Saxenda Prescribing Information
<https://www.novo-pi.com/saxenda.pdf>

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Reviews, Revisions, and Approvals	Date	Approval Date
New policy	01/15	01/15
Annual review. No changes	12/15	12/15
Converted to new template. Removed weight loss agents are covered by respective health plan as they are covered by Medi-Cal. Updated references	09/16	09/16
Removed safety criteria that are not true contraindications. For Xenical, removed concurrent use with MVI as this cannot be verified in claims and is a counseling recommendation. Modified approval durations to reflect package insert guidelines. For Contrave, removed MDD or other psych disorders as this policy addresses weight loss indication. For sympathomimetic drugs, treatment duration is limited to 12 weeks.	06/17	07/17
Added Belviq XR to policy Modified initial approval to 12 weeks and reauth to 6 months for all drugs except sympathomimetics to maintain consistent criteria For sympathomimetics, modified initial approval to 12 weeks and continued approval is limited to total 12 weeks treatment duration as they are indicated for short-term use Added max dose on continued approval References updated	06/18	07/18
Added Lomaira® to available formulations. Updated References.	12/18	12/18
Renamed Policy from CA.PPA.02 to CA.CP.PMN.02	02/19	02/19
Annual review. No changes	04/19	04/19
Removed Belviq and Belviq XR from policy due to FDA withdrawal from market. For Saxenda: Added must not be on another GLP-1 agonist. Removed history of pancreatitis as this is not an absolute contraindication. Sympathomimetics: Modified contraindication to history of drug abuse (previously history of substance abuse). References updated.	04/20	04/20
Added elevated waist circumference and other obesity-related medical condition (e.g., sleep apnea) to initial criteria. Removed negative pregnancy test. Modified initial criteria to require weight loss program that includes diet and exercise (removed behavioral counseling). For Saxenda: Added pediatric indication and criteria. References updated.	03/21	4/21

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References

1. Benzphetamine Monograph. Clinical Pharmacology, Accessed March 2021. www.clinicalpharmacology.com
2. Phendimetrazine Monograph. Clinical Pharmacology, Accessed March 2021. www.clinicalpharmacology.com
3. Phentermine Monograph. Clinical Pharmacology, Accessed March 2021. www.clinicalpharmacology.com
4. Diethylpropion. Clinical Pharmacology, Accessed March 2021. www.clinicalpharmacology.com
5. Bray GA, Pi-Sunyer FX, Mulder JE. Obesity in adults: Drug Therapy Accessed March 2021. https://www.uptodate.com/contents/obesity-in-adults-drug-therapy?source=see_link#H1268482
6. Xenical Prescribing Information. Accessed March 2021. https://www.xenical.com/pdf/PI_Xenical-brand_FINAL.PDF
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11. Lomaira Prescribing Information. Accessed March 2021. https://www.lomaira.com/Prescribing_Information.pdf

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a

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contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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