Clinical Policy: Weight Loss Agents

Reference Number: CA.PPA.02
Effective Date: 01/15
Last Review Date: 07/18 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 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 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 following comorbidities: diabetes, hypertension, dyslipidemia, cardiovascular disease;
B. Prescriber must submit treatment plan that includes a nutritionally balanced, reduced-calorie diet, exercise, and behavioral counseling;
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;
E. Females of reproductive age: negative pregnancy test prior to and upon renewal; member must not be breastfeeding.

II. Medication Specific Criteria

1. Orlistat (Xenical®)
   A. Criteria A-E 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. Lorcaserin (Belviq®, Belviq XR®)
   A. Criteria A-E above AND
   B. Treatment Protocol:
      a. Initial approval: 12 weeks – up to 20mg/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 20mg/day and continues to meet all the above criteria.

3. Phentermine/Topiramate (Qsymia®)
   A. Criteria A-E above, AND
   B. Negative history of MAOI therapy in the last 14 days, glaucoma, hyperthyroidism
   C. Treatment protocol:
      a. Initial approval: 12 weeks – up to 7.5mg/46mg per day
      b. 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.

4. Liraglutide (Saxenda®)
   A. Criteria A-E above, AND
   B. Is not being used to treat diabetes and member is not on insulin
   C. Negative history of pancreatitis, personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN2)
   D. Treatment Protocol:
      a. Initial approval: 12 weeks – up to 3mg/day
      b. 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 3mg/day, and continues to meet all the above criteria.

5. Bupropion/Naltrexone (Contrave®)
   A. Criteria A-E 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:
      a. Initial approval: 12 weeks – up to 32mg/360 mg per day
      b. 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, and continues to meet all the above criteria.

6. Noradrenergic Sympathomimetic Drugs (Benzphetamine, Phendimetrazine, Phentermine, Diethylpropion)
   A. Criteria A-E above AND
   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 substance 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
Description/Mechanism of Action:

- Orlistat (Xenical®) exerts its anti-obesity effects by altering the digestion of fats through the inhibition of pancreatic lipases.

- Lorcaserin (Belviq®, Belviq XR®) selectively activates central serotonin 2C receptors, leading to reduced appetite.

- 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 opiod 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®), Diethylpropion (Radtue®), Benzphetamine (Didrex®, Regimex®), 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.

Formulations:
- Orlistat (Xenical®): 120mg capsule
- Lorcaserin (Belviq®, Belviq XR®): 10mg, 20mg XR tablet
- 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®, Regimex®): 25mg, 50mg tablet
- Phendimetrazine (Bontril SR®, Bontril PDM®): 35mg tablet, 105mg SR capsule
- Phentermine (Adipex-P®): 37.5mg capsules or tablet
- Diethylpropion (Radtue®): 25mg IR & 75mg ER tablet

FDA Approved Indications:

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

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 pscyh 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

References

1. Orlistat monographs. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com.
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3. Phentermine/topiramate Monograph. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com
4. Benzphetamine Monograph. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com
5. Phendimetrazine Monograph. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com
6. Phentermine Monograph. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com
7. Diethylpropion. Clinical Pharmacology, Accessed June 2018. www.clinicalpharmacology.com

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9. Xenical® Prescribing Information. Accessed June 2018. https://www.xenical.com/pdf/PI_Xenical-brand_FINAL.PDF
10. Belviq® Prescribing Information. Accessed June 2018. https://www.belviq.com/-/media/Files/BelviqConsolidation/PDF/Belviq_Prescribing_information-pdf
11. Qsymia® Prescribing Information. Accessed June 2018. https://qsymia.com/patient/include/media/pdf/prescribing-information.pdf
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13. Contrave® Prescribing Information. Accessed June 2018. https://contravehcp.com/wp-content/uploads/2018/06/CONTRAVE_LBL-00073_PI_8MG-90MG_June2018.pdf
14. Adipex-P® Prescribing Information. Accessed June 2018. http://www.adipex.com/contents/pdf/Adipex_pi.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 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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.