Clinical Policy: Anti-Obesity Medications
Reference Number: NH.PMN.50
Effective Date: 07.21
Last Review Date: 06.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following are anti-obesity medications requiring prior authorization:

- Adipex-P® (phentermine)
- Contrave® (naltrexone/bupropion)
- Imcivree® (setmelanotide)
- Phentermine
- Lomaira® (phentermine)
- Qsymia® (phentermine/topiramate)
- Saxenda® (liraglutide)
- Wegovy® (semaglutide)
- Xenical® (orlistat)

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that anti-obesity medications are **medically necessary** for members meeting the following criteria:

Initial Criteria:

Requests for Imcivree®:

1. Patient must be ≥ 6 years of age; AND
2. Baseline BMI must be ≥ 30 kg/m2 OR ≥ 95th percentile on pediatric growth chart; AND
3. Patient has proopiomelanocortin (POMC) , proprotein convertase subtilisin/kexin Type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test; AND
    a. Genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance; OR
4. Patient has Bardet-Biedl Syndrome (BBS) as evidenced by three or more of the following:
    a. Intellectual impairment
    b. Renal anomalies
    c. Polydactyly
    d. Retinal degeneration
    e. Genital anomalies
5. Prescribed by or in consultation with an endocrinologist or geneticist.

Approval Duration: 3 Months

Requests for all other agents:

Adults:

1. Patient must be ≥ 12 years of age (Wegovy®), ≥ 16 years of age (Adipex®, phentermine, Lomaira®) or ≥ 18 years of age; AND
2. Documented failure of at least a three-month trial on a low-calorie diet; AND
3. A regimen of increased physical activity unless medically contraindicated by co-morbidity; AND
4. Baseline body mass index (BMI) must be:
    a. ≥ 30 kg/m^2 with no risk factors; OR
    b. ≥ 27 kg/m^2 with at least one very high factor (see Table 1); OR
5. Waist circumference must be >102 cm for men and > 88 cm for women with atleast one very high risk factor; OR
6. At least two other risk factors (see Table 1); AND
7. No contraindication (disease state or current therapy) should exist unless the prescriber documents that benefits outweigh risks (see Table 2).

Approval Duration: 6 Months

Pediatric:

1. Patient is ≥ 12 years of age (Wegovy®) or ≥ 12 years of age and < 18 years of age (Saxenda®, Qsymia®, Xenical® only); AND
2. Body weight is > 60 kg AND initial BMI corresponds to 30 kg/m^2 for adults or > 95th percentile on pediatric growth chart; AND
3. Medical treatment will be used in combination with a reduced calorie diet and increased physical activity; AND
4. No contraindications (disease state or current therapy) should exist unless the prescriber documents that benefits outweigh risks (see Table 2).

Approval Duration: 3 Months

Continuation Criteria:

Requests for Imcivree®:

1. First approval will be for 4 months; AND
2. After four months of therapy, patient must have lost at least 5% of the baseline body weight (or ≥ 5% of baseline BMI in those with continued growth potential); AND
3. The patient has not experienced treatment-limiting adverse reactions (e.g. gastrointestinal intolerability below labeled dosing for age, sexual adverse effects, depression, or suicidal ideation).

Requests for all other agents:

1. Ongoing prescriber documentation of adherence to a low-calorie diet (1,200 kcal/day for women, 1,600 kcal/day for men); AND
2. A regimen of increased physical activity (unless medically contraindicated by co-

morbidity) during anti-obesity therapy; AND

3. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks (see Table 2); AND
4. Patients ≥ 16 years of age:
    a. After 6 months of therapy, a six-month approval may be granted if a 5% weight reduction from baseline has been achieved (see exception below);
        i. If renewal request is for Saxenda®, a six-month approval may be granted if a 4% weight reduction from baseline has been achieved.
5. Pediatric patients ≥ 12 years of age:
    a. After 3 months of therapy, patient must have had a reduction in body weight of at least 1% from baseline.
6. After lapses of therapy, additional trials may be approved if criteria requirements are met;
7. If request is for phentermine, approval may not be granted beyond nine months of treatment;
8. If request is for Xenical®, approval may not be given beyond four years.

Approval Duration – As noted in criteria above

Table 1: Risk Factors	
Very high risk	✦ Type 2 diabetes ✦ Established coronary heart disease ✦ Other atherosclerotic disease ✦ Sleep apnea
Other risk factors	✦ Hypertension ✦ Dyslipidemia ✦ Impaired fasting glucose concentration ✦ Cigarette smoking ✦ Stress incontinence ✦ Gallstones Osteoarthritis Gynecologic abnormalities Family history of premature heart disease Age (men > 45 years, women > 55 years or postmenopausal)

Table 2: Contraindications, Precautions, and Drug Interactions			
Drug	**Contraindications**	**Precautions**	**Drug Interactions**
orlistat	✦ Chronic malabsorption syndrome ✦ Cholestasis ✦ Pregnancy	✦ Hx of hyperoxaluria or Ca oxalate nephrolithiasis ✦ Patients with deficiency of any fat-soluble vitamins	

phentermine	✦ Hx of glaucoma ✦ Hx of hypertension (moderate to severe) ✦ Hx of hyperthyroidism ✦ Hx of cardiovascular disease	✦ Hx of drug abuse ✦ Hx of anxiety disorders ✦ Hx of diabetes mellitus ✦ Hx of hypertension (mild)	✦ Monoamine oxidase inhibitors (MAOI): contraindicated
phentermine/ topiramate	✦ Pregnancy ✦ Glaucoma ✦ Hyperthyroidism	✦ Increase in heart rate ✦ Suicidal behavior and ideation ✦ Acute myopia and secondary angle closure glaucoma	✦ MAOIs ✦ Oral contraceptive ✦ Non-potassium sparing diuretic CNS depressants including alcohol
naltrexone/bupropion	✦ Uncontrolled hypertension ✦ Seizure disorders ✦ Anorexia nervosa or bulimia ✦ Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs ✦ Chronic opioid use	✦ Suicidal thoughts and ideation	✦ MAOI ✦ Opioid analgesics Concurrent use of other buproprion-containing products if the total daily dose of all bupropion-containing products above the FDA maximum recommended dose
semaglutide	✦ Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia type 2	✦ Suicidal behavior or ideation ✦ Acute pancreatitis ✦ Acute gallbladder disease ✦ Renal impairment	✦ GLP-1 receptor agonist ✦ Insulins
liraglutide	✦ Pregnancy ✦ Personal or family Hx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2	✦ Suicidal behavior and ideation ✦ Acute pancreatitis ✦ Acute gallbladder disease ✦ Renal impairment	✦ GLP-1 receptor agonists ✦ Insulins

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed.	07.21	07.21
Annual review; no changes	07.22	07.22
Updated policy with new clinical evidence around drugs; updated approval durations; updated appendix charts; updated age ranges.	01.23	01.23
Updated age range for Wegovy requests	06.23	06.23

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.