Clinical Policy: Weight Management Drugs for Youth

Reference Number: OR.CP.PMN.1015
Effective Date: 07.01.24
Last Review Date: 05.24
Line of Business: Medicaid – Oregon Health Plan

Revision Log

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

Use of medications for the treatment of weight loss in adults (age ≥21 years of age) is a benefit exclusion under the Oregon Health Plan.

Description
The following agents are indicated for weight management and require prior authorization: Liraglutide (Saxenda®), Bupropion/naltrexone (Contrave®), Phentermine/topiramate (Qsymia®), Semaglutide (Wegovy®), Setmelanotide (Imcivree™), Tirzepatide (Zepbound®).

Goal(s):
- Allow case-by-case review for members covered under the EPSDT program Recommend semaglutide as weight reduction pharmacotherapy in patients which evidence has demonstrated efficacy, including CV benefits. (e.g. patients with a BMI ≥30 kg/m^2 or with a BMI of ≥27 kg/m^2 and comorbid conditions [e.g., diabetes mellitus, hypertension, dyslipidemia, or cardiovascular disease]).

FDA Approved Indication(s)
Bupropion/naltrexone, Liraglutide, Phentermine/topiramate, Semaglutide, and Tirzepatide are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:
- 30 kg/m2 or greater (obese), or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

Liraglutide, Phentermine/topiramate, and Semaglutide are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex.

Semaglutide is indicated in combination with a reduced-calorie diet and increased physical activity to reduce the risk of major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (CVD) and either obesity or overweight.

Setmelanotide is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndrome obesity due to:
- Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in

POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
- Bardet-Biedl syndrome (BBS)

Length of Authorization:
- Initial: Up to 6 months

Requires PA:
- Non-preferred drugs used for weight management

Covered Alternatives:
- Current Trillium Preferred Drug List listed at:
  - https://www.trilliumohp.com/providers/pharmacy.html

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 Trillium Community Health Plan that weight management drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Genetic Obesity Disorders (must meet all)**:**
1. Diagnosis of obesity due to POMC deficiency, PCSK1 deficiency, LEPR deficiency, or BBS (*see Appendix B*);
2. Age ≥6 years of age and <21 years of age;
3. One of the following (a or b):
   a. Genetic testing confirms that variants in the following genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (i, ii, or iii):
      i. POMC;
      ii. PCSK1;
      iii. LEPR;
   b. Diagnosis of BBS is confirmed clinically per Beales criteria (*see Appendix B*);
4. Member does not have a history of depression and/or suicidal ideation;
5. Request is for setmelanotide
6. Dose does not exceed any of the following (a and b):
   a. First 2 weeks (i or ii):
      i. Age ≥ 6 and < 18 years: 1 mg per day;
      ii. Age ≥ 18 years: 2 mg per day;
   b. Maintenance: 3 mg per day.

Approval duration: 6 months

B. Weight Management (must meet all)**:**
1. Member meets one of the following (a, b or c):
   a. BMI ≥30 kg/m^2;

b. BMI > 27 kg/m^2 with at least one indicator of increased cardiovascular risk (e.g., hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
c. If age is between 12 and 17 years: BMI at the 95th percentile or greater for age and sex (*see Appendix B*);

2. Age ≥12 years of age and <21 years of age;
3. One of the following (a or b):
   a. Member has at least one indicator of increased cardiovascular risk (e.g., hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
   b. Documentations supports member has previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6-month timeframe;
4. Documentation that member is actively engaged in a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet);
5. Requested weight management pharmacotherapy agent is FDA approved to be used to treat individuals that are the member's age (*see Appendix D*);
6. Dose does not exceed the FDA-approved maximum recommended dose;

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Genetic Obesity Disorders (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Age <21 years of age;
3. Member is responding positively to therapy as evidenced by one of the following (a, b, or c):

a. Initial re-authorization for POMC, PCSK1, or LEPR deficiency: After 12-16 weeks of treatment, reduction of at least 5% of baseline body weight or 5% of baseline BMI;
b. Initial re-authorization for BBS: After 1 year of treatment, reduction of at least 5% of baseline body weight or 5% of baseline BMI;
c. Subsequent re-authorizations for all indications: Maintenance of ≥ 5% reduction in weight or BMI compared with baseline;

4. Request is for setmelanotide
5. If request is for a dose increase, new dose does not exceed 3 mg per day.

Approval duration: up to 6 months

B. Weight Management (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Age <21 years of age;
3. Member has lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss;
4. Member is actively engaged in a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet);
5. Member has been adherent to therapy based on provider attestation;
6. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: up to 6 months

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

B. Use of medications for the treatment of weight loss in adults (age ≥21 years of age) is a benefit exclusion under the Oregon Health Plan.

IV. Appendices/General Information:

Appendix A: Abbreviation/Acronym Key

BBS: Bardet-Biedl syndrome
BMI: body mass index
CVD: cardiovascular disease
FDA: Food and Drug Administration
GIP: glucose-dependent insulinotropic polypeptide
GLP-1: glucagon-like peptide-1
LEPR: leptin receptor
PAD: peripheral arterial disease
PCSK1: proprotein convertase subtilisin/kexin type 1
POMC: pro-opiomelanocortin
VUS: variant of uncertain significance

Appendix B: General Information:

- Body mass index calculator: https://globalrph.com/medcalcs/body-mass-index-bmi/
- BMI Cutoffs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (CDC Criteria):

	95th Percentile BMI Value	
Age (in years)	**Male**	**Female**
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

- Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.
- A clinical diagnosis of BBS is confirmed using Beales criteria. There must be presence of at least 4 primary features, OR 3 primary and 2 secondary features:
  - Primary features: rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadism in males, renal anomalies
  - Secondary features: speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, polyuria/polydipsia (nephrogenic diabetes insipidus), ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis

Appendix C: Contraindications/Boxed Warnings

Drug Name	Contraindication(s)	Boxed warning(s)
Liraglutide (Saxenda)	Personal or family history of medullary thyroid carcinoma (MTC) or with multiple endocrine neoplasia syndrome type 2 (MEN 2), pregnancy, patients with a prior hypersensitivity reaction to liraglutide or to any of the excipients in Saxenda.	Risk of thyroid C-cell tumors
Naltrexone/bupropion (Contrave)	Uncontrolled hypertension, seizure disorder, concomitant use or use within 14 days of a monoamine oxidase inhibitor, chronic opioid use, use of other bupropion-containing products, bulimia or anorexia nervosa, abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs, and hypersensitivity to any of the ingredients in Contrave	Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder and other psychiatric disorders. Monitor for worsening and emergence of suicidal thoughts and behaviors. Contrave has not been studied in pediatric patients
Phentermine/topiramate (Qsymia)	Pregnancy; glaucoma; hyperthyroidism; use during or within 14 days of taking monoamine oxidase inhibitors; known hypersensitivity to phentermine, topiramate, or other components of Qsymia or idiosyncrasy to the sympathomimetic amines	None reported
Semaglutide (Wegovy)	Personal or family history of medullary thyroid carcinoma (MTC) or with multiple endocrine neoplasia syndrome type 2 (MEN 2), known hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy	Risk of thyroid C-cell tumors
Setmelanotide (Imcivree)	None reported	None reported
Tirzepatide (Zepbound)	Personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2), known serious hypersensitivity to tirzepatide or to any of the excipients in Zepbound	Risk of thyroid C-cell tumors

Appendix D: Drugs FDA Approved for Weight Management

Drug Name	Adults	Pediatrics
Liraglutide (Saxenda)	Yes	Yes – 12 years and older
Naltrexone/bupropion (Contrave)	Yes	No
Phentermine/topiramate (Qsymia)	Yes	Yes – 12 years and older

Drug Name	Adults	Pediatrics
Semaglutide (Wegovy)	Yes	Yes – 12 years and older
Setmelanotide (Imcivree)	Yes	Yes – 6 years and older
Tirzepatide (Zepbound)	Yes	No

Appendix E: Dosage and Administration

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bupropion/naltrexone (Contrave)	**Weight management** • Week 1: One tablet PO QAM • Week 2: One tablet PO BID • Week 3: Two tablets PO QAM and 1 tablet PO QPM • Week 4 and onward: 2 tablets PO BID	32/360 mg/day
Liraglutide (Saxenda)	**Weight management** • Week 1: 0.6 mg SC QD • Week 2: 1.2 mg SC QD • Week 3: 1.8 mg SC QD • Week 4: 2.4 mg SC QD • Week 5 and onward: 3 mg SC QD **Adult patients**: If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Discontinue Saxenda if the patient cannot tolerate the 3 mg dose. **Pediatric patients**: Dose escalation for pediatric patients may take up to 8 weeks. Pediatric patients who do not tolerate 3 mg daily may have their dose reduced to 2.4 mg daily. Discontinue Saxenda if the patient cannot tolerate the 2.4 mg dose.	3 mg/day
Phentermine/topiramate (Qsymia)	**Weight management** 3.75 mg/23 mg PO QD for 14 days; then increase to 7.5 mg/46 mg PO QD for up to 12 weeks total; do not exceed 7.5 mg/46 mg dose for patients with moderate or severe renal impairment or patients with moderate hepatic impairment. • After 12 weeks of treatment with Qsymia 7.5 mg/46 mg, evaluate weight loss for adults or BMI reduction for pediatric patients aged 12 years and older. If an adult patient has not lost at least 3% of baseline body weight or a pediatric patient has not experienced a reduction of at least 3% of baseline BMI, increase to 11.25 mg/69 mg PO QD for 14 days, followed by 15 mg/92 mg PO QD. If patient has not lost at least 5% of baseline	15 mg/92 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	body weight on Qsymia 15 mg/92 mg, discontinue Qsymia, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment. • Monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 lbs (0.9 kg)/week, consider dosage reduction.	
Semaglutide (Wegovy)	**Weight management** • Week 1-4: 0.25 mg SC QW • Week 5-8: 0.5 mg SC QW • Week 9-12: 1 mg SC QW • Week 13-16: 1.7 mg SC QW • Week 17 and onward: 2.4 mg SC QW	2.4 mg/week
Setmelanotide (Imcivree)	**Obesity due to POMC, PCSK1, or LEPR deficiency or due to BBS** • ≥ 12 years and older: 2 mg SC once daily for 2 weeks; if tolerated, titrate up to 3 mg SC once daily Age 6 to 12 years: 1 mg SC once daily for 2 weeks; if tolerated, titrate up to 3 mg SC once daily	3 mg/day
Tirzepatide (Zepbound)	**Weight management** The recommended starting dosage is 2.5 mg SC once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for chronic weight management. • After 4 weeks, increase the dosage to 5 mg SC once weekly. • The dosage may be increased in 2.5 mg increments, after at least 4 weeks on the current dose. The recommended maintenance dosages are 5 mg, 10 mg, or 15 mg SC once weekly. Consider treatment response and tolerability when selecting the maintenance dosage. If patients do not tolerate a maintenance dosage, consider a lower maintenance dosage.	15 mg/week

Appendix F: Product Availability:

Medication	Formulation and Strength
Bupropion/naltrexone (Contrave)	Extended-release tablet: 8 mg naltrexone/90 mg bupropion
Liraglutide (Saxenda)	Pre-filled, multi-dose pen: 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg (6 mg/mL, 3 mL)
Phentermine/topiramate (Qsymia)	Capsules: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg

Semaglutide (Wegovy)	Pre-filled, single-dose pens: 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, 2.4 mg
Setmelanotide (Imcivree)	Vial: 10 mg/mL (1 mL multi-dose)
Tirzepatide (Zepbound)	Pre-filled, single-dose pens: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg
	Pre-filled, single-dose vials: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg

V. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Available at www.clinicalpharmacology.com. Updated periodically. Accessed February 20, 2024.
2. Contrave Prescribing Information. San Diego, CA: Nalpropion Pharmaceuticals, Inc.; November 2021. Available at: https://contrave.com/. Accessed April 24, 2024.
3. Data Table of BMI-for-Age Charts. CDC National Center for Health Statistics. Available at: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm. Accessed April 24, 2024.
4. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023 Feb 1;151(2):e2022060640. doi: 10.1542/peds.2022-060640. PMID: 36622115.
5. Imcivree Prescribing Information. Boston, MA: Rhythm Pharmaceuticals, Inc.; June 2022. Available at: https://www.imcivree.com/?gclid=b54abc7805df1af23660d93bd98e430c&gclsrc=3p.ds&msclkid=b54abc7805df1af23660d93bd98e430c&utm_source=bing&utm_medium=cpc&utm_campaign=Rhythm_Imcivree_BBS_HCP_2022_Google_Branded_SplashPage_Exact&utm_term=imcivree%20prescribing%20information&utm_content=Branded_Imcivree_SplashPage. Accessed April 24, 2024.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 29, 2024.
7. Qsymia Prescribing Information. Campbell, CA: Vivus Inc; June 2022. Available at: https://qsymia.com/. Accessed April 24, 2024.
8. Saxenda Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; June 2022. Available at: www.saxenda.com. Accessed April 24, 2024.
9. Wegovy Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2024. Available at: www.wegovy.com. Accessed April 24, 2024.
10. Weight Management Drugs for Youth. Oregon Health Plan Current Drug Use Criteria. Available at: http://orpdl.org/drugs/index.php. Accessed April 24, 2024.
11. Zepbound Prescribing Information. Indianapolis, IN: Lilly USA, LLC; March 2024. Available at: https://uspl.lilly.com/zepbound/zepbound.html#pi. Accessed April 24, 2024.

Reviews, Revisions, and Approvals	Date	Plan Approval Date
Policy created; adapted from FFS policy Weight Management Drugs for Youth approved at the April 2024 State P&T meeting.	04.24.24	05.9.24

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.