Clinical Policy: Anti-Obesity Medications
Reference Number: DE.PMN.50
Effective Date: 01.23
Last Review Date: 04.26
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:

- Saxenda® (liraglutide)
- liraglutide
- Wegovy® (semaglutide)
- Zepbound® (tirzepatide)

Policy/Criteria

Provider Documentation Requirement

Providers must submit member's relevant medical records and/or pharmacy profile and appropriate baseline diagnostic and safety biopsy, laboratory, and/or noninvasive test results supporting that the member has met approval criteria. Documentation should support FDA-labeled use, BMI criteria, and the presence of a qualifying co-morbid condition.

It is the policy of Delaware First Health that anti-obesity medications are **medically necessary** for members meeting the following criteria:

Initial Criteria – Weight Loss:

Adults:

1. For non-preferred products: Trial and failure of two (2) preferred products unless clinically significant adverse effects are experienced or all are contraindicated;
2. Documentation confirms at least one co-morbid condition related to overweight/obesity is present in addition to BMI criteria as required by the Delaware Medicaid State Plan.
3. The medication must be used in conjunction with a reduced calorie diet; AND
4. A regimen of increased physical activity unless medically contraindicated by co-morbidity; AND
5. Baseline body mass index (BMI) must be:
    a. $\geq$ 30 kg/m^2 OR

b. ≥ 27 kg/m^2 and at least one qualifying co-morbid condition (e.g., Type 2 diabetes, established coronary heart disease, other atherosclerotic cardiovascular disease, hypertension, dyslipidemia, or obstructive sleep apnea), consistent with FDA-labeled indications for chronic weight management products.

6. Requested medication is being used consistent with its FDA-approved labeling, including indication, dose, route, and frequency.
7. There is no FDA-labeled contraindication to the requested medication, or if a labeled warning/precaution is present, the prescriber documents that potential benefits outweigh the potential risks (see Table 2).

Approval Duration: 6 Months in ≤ 30-day supplies

Pediatric:

1. Member meets the FDA-approved age range for the requested medication AND
2. Member BMI ≥ the 95th percentile for age and weight; AND
3. Member does not have any FDA-labeled contraindication, or prescriber documents that benefits outweigh risks where labeling allows clinical judgment (see Table 2).

Approval Duration: 6 Months in ≤ 30-day supplies

Initial Criteria – MASH

1. Requested agent must be prescribed by or in conjunction with a hepatologist or gastroenterologist
2. Member must have moderate to advanced liver fibrosis (consistent with stages F2 to F3) confirmed by one (1) of the following (a or b):
   a. Biopsy
   b. Non-invasive tests (e.g., FibroScan or MRE + MRI-PDFF)
3. While obesity is a risk factor for MASH, a BMI ≥ 27 kg/m^2 is not a requirement for approval

Approval Duration: 6 Months

Initial Criteria – Prevention of Major Adverse Cardiovascular Events (MACE)

1. Member must be overweight as defined by a BMI between ≥ 27 kg/m^2 and < 30 kg/m^2.
2. Member must have established CVD

Approval Duration: 6 Months in ≤ 30-day supplies

Continuation Criteria:

1 For Weight Loss:

a. The prescriber must provide documentation that a substantial, minimal amount of weight loss has occurred. The minimum weight loss that must occur is ≥ 5% for adults and ≥ 4% for adolescents of the baseline weight.

b. If required documentation has been provided and adequate weight loss has occurred or been maintained, the GLP-1 agonist will be re-authorized for up to 6 months, dispensed in ≤ 90-day supplies.

c. If at any time more than 50% of what has been lost is regained or if total weight loss from the baseline is ever < 5% for adults or < 4% for adolescents, then the prior authorization for a GLP-1 agonist, as determined by the DMAP, may not be renewed for at least one year.

2 For MASH or prevention of MACE:

a. If the member meets the above coverage requirements, Continued coverage may be approved when the prescriber attests that the member:

i Continues to derive clinical benefit, and

ii Requires ongoing therapy as part of their treatment plan. Then Prior Authorization will be granted for 6 months in ≤ 90-day supplies of an authorized GLP-1 agonist agent at a standard dose.

Approval Duration – As noted in criteria above

Table 1: Weight-Related Co-Morbid Conditions	
Condition	**Clinical Definition**
Cardiovascular Disease (CVD)	Established atherosclerotic cardiovascular disease, including coronary artery disease, cerebrovascular disease, or history of myocardial infarction or stroke.
Chronic Kidney Disease (CKD)	Chronic reduction in kidney function defined as CKD stage 3a or greater (eGFR <60 mL/min/1.73m² for ≥3 months).
Heart Failure	Clinical syndrome characterized by structural and/or functional cardiac abnormality resulting in reduced cardiac output and/or elevated intracardiac pressures.
Hyperlipidemia	Disorder of lipid metabolism resulting in elevated LDL-C, triglycerides, or total cholesterol.
Hypertension	Chronic elevation of blood pressure.
Obstructive Sleep Apnea (OSA)	Moderate to severe OSA defined as apnea–hypopnea index (AHI) >15 events/hour, without central or mixed sleep apnea.
Metabolic Dysfunction-Associated Steatohepatitis (MASH)	Noncirrhotic MASH with moderate to advanced liver fibrosis (F2–F3).

Peripheral Artery Disease (PAD)	Atherosclerotic disease of peripheral arteries resulting in reduced blood flow to extremities.
Type 2 Diabetes Mellitus	Chronic metabolic disorder characterized by insulin resistance and hyperglycemia requiring pharmacologic management.

Table 2 – Contraindications, Precautions, and Drug Interactions

Purpose: This table summarizes FDA-labeled contraindications, precautions, and clinically significant drug interactions for anti-obesity medications. Prescribers are expected to review the full FDA-approved prescribing information for each product prior to prescribing. Coverage determinations should align with FDA labeling and applicable DFH/DMAP policy.

Table 2 – Contraindications, Precautions, and Drug Interactions			
Medication	Contraindications	Precautions	Key Drug Interactions
Semaglutide(Wegovy®)	• Personal or family history of medullary thyroid carcinoma (MTC) • Multiple Endocrine Neoplasia syndrome type 2 (MEN2)	• Suicidal behavior or ideation • Acute pancreatitis • Acute gallbladder disease • Renal impairment	• Other GLP-1 receptor agonists • Insulins (use with caution; dose adjustment/clinical judgment may be required)
Liraglutide(Saxenda®)	• Pregnancy • Personal or family history of medullary thyroid carcinoma (MTC) or MEN2	• Suicidal behavior or ideation • Acute pancreatitis • Acute gallbladder disease • Renal impairment	• Other GLP-1 receptor agonists • Insulins

Policy Note: Other products (e.g., Zepbound®, additional formulations, and future FDA-approved anti-obesity agents) should be addressed through policy appendices or updates and evaluated based on current FDA-approved labeling.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	01.23	01.23
Updated age range for Wegovy requests	10.23	10.23
Annual Review – removed Qsymia and Imcrivee from criteria	10.24	10.24
Policy revised according to DMMA revisions effective 01/06/2025. Addition of Zepbound	11.24	11.24
Updated policy to match Posted Drug List (PDL).	5.25	05.25
1Q2026 Revised to align with Delaware Medicaid State Plan requirement for BMI + co-morbid condition(s) and FDA-consistent use for anti-obesity medications	03.26	05.26
Per updated PDL and State guidance: Updated initial approval duration to 6months, Added criteria for MASH and MACE, removing Contrave, Xenical and phentermine products from criteria	03.26	05.26
Per state guidance, updated reauthorization criteria for both MACE and MASH that reauthorization does not require resubmission of initial coverage documentation, provider attestation is sufficient.	04.26	06.26

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.