

MEDICAID BENEFIT (NON-PART D) PRIOR AUTHORIZATION CRITERIA

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ANTI-OBESITY AGENTS

Drug Class: Anti-Obesity/Weight Loss Agents

Available dosage forms:

Preferred (Non-GLP1's only) Prior Authorization Required

- benzphetamine (only available as generic); C-III, Tablet, 50 mg
- diethylpropion (only available as generic); C-IV, Tablet, 25 mg and 75 mg
- Xenical (orlistat), Capsules, 120 mg
- phendimetrazine (only available as generic); C-III, Tablet, 35 mg
- phendimetrazine ER, C-III, Capsule, 105 mg
- phentermine; C-IV, Tablet, 8mg, 37.5 mg
- phentermine, Capsule, 15 mg and 30 mg and 37.5 mg
- Adipex-P (phentermine), Tablet, 37.5 mg
- Lomaira (phentermine), Tablet, 8 mg
- phentermine/topiramate ER (only available as generic); C-IV, Capsule, 3.75-23 mg & 7.5-46 mg & 11.25-69 mg & 15-92 mg

Non-Preferred (GLP1's only) Prior Authorization Required

- liraglutide (generic for Saxenda), Pen Injector, 3mg/0.5mL
- Saxenda (liraglutide), Pen Injector, 3mg/0.5mL
- Wegovy (semaglutide), Pen Injector, 0.25mg/0.5mL & 0.5mg/0.5mL & 1mg/0.5mL & 1.7mg/0.75mL & 2.4mg/0.75mL
- Wegovy HD (semaglutide), Pen Injector, 7.2mg/0.75mL
- Zepbound KwikPen, 2.5mg/dose & 5mg/dose & 7.5mg/dose & 10mg/dose & 12.5mg/dose & 15mg/dose
- Zepbound, Pen Injector, 2.5mg/0.5mL & 5mg/0.5mL & 7.5mg/0.5mL & 10mg/0.5mL & 12.5mg/0.5mL & 15mg/0.5mL
- Zepbound, Vial, 2.5mg/0.5mL & 5mg/0.5mL & 7.5mg/0.5mL & 10mg/0.5mL & 12.5mg/0.5mL & 15mg/0.5mL

Coverage Criteria:

Preferred Agent (Non-GLP1's only) Initial Request

- Prescriber attests that the patient will **not** use more than one weight loss medication in this drug class concurrently; **AND**
- Patient \geq 18 years of age; **OR**
- Patient age \geq 12 years (Xenical/orlistat, phentermine/topiramate); **OR**
- Patient age \geq 17 years (phentermine); **AND**
- Patient age \geq 12 years to <18 years must have an initial BMI per CDC growth charts at the 95th percentile or greater for age and sex (obesity); **OR**
- Patient age \geq 12 years to <18 years with BMI in the 85th – 94th percentile (overweight) per CDC growth charts **and** has at least one of the following weight-related coexisting conditions:

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- diabetes;
- sleep apnea;
- hypertension; or
- dyslipidemia; **OR**
- Patient age ≥ 18 years (benzphetamine, diethylpropion, phendimetrazine); **AND**
- Patient age ≥ 18 years must have an initial body mass index [BMI] \geq than 30 kg/m²; **OR**
- Patient age ≥ 18 years must have an initial body mass index [BMI] \geq than 27 kg/m² but < 30 kg/m² **and** at least one of the following risk factors:
 - hypertension;
 - coronary artery disease;
 - diabetes;
 - dyslipidemia; or
 - sleep apnea; **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.

Non-Preferred (GLP1's only) Agent Criteria

- Allergy to all five types of preferred medications (e.g., at least 1 of each benzphetamine, diethylpropion, orlistat products, phendimetrazine, and phentermine products); **OR**
- Contraindication or drug to drug interaction with all five types of preferred medications; **OR**
- History of unacceptable side effects of all five types of preferred medications; **OR**
- Trial and failure with all five types of preferred agents (e.g., at least one orlistat agent and one phentermine product in addition to benzphetamine, diethylpropion and phendimetrazine); **AND**
- *See additional clinical PA criteria below:*
- Prescriber attests that the patient will **not** use more than one weight loss medication in this drug class concurrently; **AND**
- Prescriber attests there has been documented failure of all other clinically appropriate weight loss interventions; **AND**
- Prescriber attests that use of this GLP1 agent for weight loss is considered only as a measure to avert the need for higher-cost bariatric surgery; **AND**
- Prescriber attests that the patient will not use an anti-obesity GLP-1 agonist (Wegovy, Wegovy HD, Saxenda/liraglutide or Zepbound) concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin); **AND**
- Patient ≥ 18 years of age (Wegovy HD, Zepbound); **OR**
- Patient age ≥ 12 years (Wegovy, Saxenda/liraglutide); **AND**
- Prescriber attests patient age ≥ 12 years to < 18 years and has an initial BMI per CDC growth charts for age and sex and is classified as morbidly obese; **OR**

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- Prescriber attests patient age ≥ 18 years and has an initial body mass index (BMI) classified as morbidly obese (e.g., baseline BMI ≥ 40 kg/m² or greater); **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.

Renewal Request (Preferred and Non-Preferred Agents)

- For patients age ≥ 12 years to < 18 years, prescriber provides clinical documentation demonstrating BMI associated with the renewal request and showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy.
- For patients age ≥ 18 years, prescriber provides clinical documentation demonstrating weight associated with the renewal request and showing that the patient has maintained a weight loss of $\geq 5\%$ from baseline weight at initiation of therapy.

1st GLP-1 Renewal Request – For Weight Loss ONLY – in Established Members with Initial Approval Prior to 1/1/2026 Criteria Changes

- Prescriber attests that the patient was classified as morbidly obese when they were initially started on the GLP1 agent for weight loss; **AND**
- Prescriber attests there was documented failure of all other clinically appropriate weight loss interventions prior to starting the GLP1 agent for weight loss; **AND**
- Prescriber attests that use of the GLP1 agent for weight loss was considered only as a measure to avert the need for higher-cost bariatric surgery; **AND**
- For patients age ≥ 12 years and < 18 years, prescriber provides clinical documentation demonstrating BMI associated with the renewal request and showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy; **OR**
- For patients age ≥ 18 years, prescriber provides clinical documentation demonstrating the weight associated with the renewal request and showing that the patient has maintained a weight loss of $\geq 5\%$ from baseline weight at initiation of therapy.

Length of Authorization:

- Initial = 6 months, Renewal = 6 months

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Quantity Limits:

liraglutide (generic for Saxenda) 18 mg/3 mL pens	15 mL (5 pens) per 30 days
Saxenda (liraglutide) 18 mg/3 mL pens	15 mL (5 pens) per 30 days
Xenical (orlistat) 120 mg capsules	90 caps per 30 days
Wegovy (semaglutide) 0.25 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 0.50 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 1 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 1.7 mg/0.75 mL pens	3 mL (4 pens) per 28 days
Wegovy (semaglutide) 2.4 mg/0.75 mL pens	3 mL (4 pens) per 28 days
Wegovy HD (semaglutide) 7.2 mg/0.75 mL pens	3 mL (4 pens) per 28 days
Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 12.5 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Zepbound (tirzepatide) 15 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Zepbound KwikPen (tirzepatide) 2.5 mg/dose (10 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days
Zepbound KwikPen (tirzepatide) 5 mg/dose (20 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days
Zepbound KwikPen (tirzepatide) 7.5 mg/dose (30 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days
Zepbound KwikPen (tirzepatide) 10 mg/dose (40 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days
Zepbound KwikPen (tirzepatide) 12.5 mg/dose (50 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days
Zepbound KwikPen (tirzepatide) 15 mg/dose (60 mg/2.4 mL)	2.4 mL (1 KwikPen) per 28 days

RAYALDEE (CALCIFEDIOL)

Drug Class:

Available dosage forms: *Prior Authorization Required*

- **Royaldee, Capsule, 30 mcg**

Length of Authorization:

- Initial = 3 months; Renewal = 1 year

Coverage Criteria:

Initial Requests

- Diagnosis of secondary hyperparathyroidism in adult with stage 3 or 4 chronic kidney disease; **AND**
- Serum total 25-hydroxyvitamin D level less than 30 ng/mL (document level); **AND**
- Serum calcium level below 9.8 mg/dL (document level); **AND**
- Previous treatment, intolerance or contraindication to generic calcitriol and paricalcitol or doxercalciferol

Renewal Requests

- Intact parathyroid hormone (PTH) is above treatment goal; **AND**
- Serum total 25-hydroxyvitamin D level less than 100 ng/mL (document level); **AND**
- Serum calcium level below 9.8 mg/dL (document level)

IMCIVREE (SETMALANOTIDE)

Drug Class:

Available dosage forms: *Prior Authorization Required*

- **Imcivree (setmelanotide), Vial, 10 mg/ml**

Length of Authorization:

- Initial requests 16 weeks; renewal up to 12 months

Coverage Criteria:

Initial Requests

- Patient is ≥ 2 years of age; **AND**
- Genetic testing demonstrates homozygous or compound heterozygous mutations in one of the following genes: POMC, PCSK1, or LEPR; **AND**
- The genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance;

-OR-

- Patient has a diagnosis of Bardet-Biedl Syndrome; **AND**
 - If patient ≥ 18 years of age: body mass index (BMI) ≥ 30 kg/m² ; **OR**
 - If patient is 2 to 17 years of age: BMI ≥ 95 th percentile for age and sex;

-AND-

- Prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders.

Renewal Requests

- Patient has achieved a weight loss of $\geq 5\%$ of baseline weight; **OR**
- Patient has achieved at least a 5% reduction in baseline BMI for patients with continued growth potential.