

## New Hampshire Medicaid Fee-for-Service Program

### Weight Management Criteria

Approval Date: January 26, 2023

### Medications

Brand Names	Generic Names	Dosage
Adipex-P®	phentermine	37.5 mg
Contrave®	naltrexone/bupropion	8 mg naltrexone/90 mg bupropion
Imcivree™	setmelanotide	10 mg/mL
Lomaira™	phentermine	8 mg
	phentermine	15 mg, 30 mg, 37.5 mg
Qsymia®	phentermine/topiramate	3.75/23 mg, 7.5/46 mg, 11.25/69 mg, 15/92 mg
Saxenda®	liraglutide	0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3 mg (6 mg/mL, 3 mL)
Wegovy®	semaglutide	0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL, 2.4 mg/0.75 mL
Xenical®	orlistat	120 mg

### Criteria for Approval

See below for requests for Imcivree™.

#### Adult

1. Patient is  $\geq 16$  years of age (Adipex®, phentermine, Lomaira™) or  $\geq 18$  years of age (all medications eligible); **AND**
2. Documented failure of at least a three-month trial on a low-calorie diet (1,200 kcal/day for women, 1,600 kcal/day for men); **AND**
3. A regimen of increased physical activity unless medically contraindicated by co-morbidity; **AND**
4. Baseline body mass index (BMI) must be:
  - a.  $\geq 30$  kg/m<sup>2</sup> with no risk factors; **OR**
  - b.  $\geq 27$  kg/m<sup>2</sup> with at least one very high-risk factor (see Table 1); **OR**
5. Waist circumference must be  $> 102$  cm for men and  $> 88$  cm for women with at least one very high-risk factor; **OR**
6. At least two other risk factors (see Table 1); **AND**

- No contraindications (disease state or current therapy) should exist unless the prescriber documents that benefits outweigh risks (see Table 2).

**Initial approval will be for 6 months.**

**Pediatric**

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

**Initial approval will be for 3 months.**

Table 1: Risk Factors	
<b>Very High Risk</b>	<ul style="list-style-type: none"> <li>Type 2 diabetes</li> <li>Established coronary heart disease</li> <li>Other atherosclerotic disease</li> <li>Sleep apnea</li> </ul>
<b>Other Risk Factors</b>	<ul style="list-style-type: none"> <li>Hypertension</li> <li>Dyslipidemia</li> <li>Impaired fasting glucose concentration</li> <li>Cigarette smoking</li> <li>Family history of premature heart disease</li> <li>Age (men <math>&gt; 45</math> years, women <math>&gt; 55</math> years or postmenopausal)</li> <li>Gynecologic abnormalities</li> <li>Osteoarthritis</li> <li>Gallstones</li> <li>Stress incontinence</li> </ul>

Table 2: Contraindications, Precautions, and Drug Interactions			
Drug	Contraindications	Precautions	Drug Interactions
<b>orlistat</b>	<ul style="list-style-type: none"> <li>Chronic malabsorption syndrome</li> <li>Cholestasis</li> <li>Pregnancy</li> </ul>	<ul style="list-style-type: none"> <li>Hx of hyperoxaluria or Ca oxalate nephrolithiasis</li> <li>Patients with deficiency of any fat-soluble vitamins</li> </ul>	
<b>phentermine</b>	<ul style="list-style-type: none"> <li>Hx of glaucoma</li> <li>Hx of hypertension (moderate to severe)</li> <li>Hx of hyperthyroidism</li> <li>Hx of cardiovascular disease</li> </ul>	<ul style="list-style-type: none"> <li>Hx of drug abuse</li> <li>Hx of anxiety disorders</li> <li>Hx of diabetes mellitus</li> <li>Hx of hypertension (mild)</li> </ul>	<ul style="list-style-type: none"> <li>Monoamine oxidase inhibitors (MAOI): contraindicated</li> </ul>

**Table 2: Contraindications, Precautions, and Drug Interactions**

Drug	Contraindications	Precautions	Drug Interactions
<b>phentermine/ topiramate</b>	<ul style="list-style-type: none"> <li>▪ Pregnancy</li> <li>▪ Glaucoma</li> <li>▪ Hyperthyroidism</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increase in heart rate</li> <li>▪ Suicidal behavior and ideation</li> <li>▪ Acute myopia and secondary angle closure glaucoma</li> </ul>	<ul style="list-style-type: none"> <li>▪ MAOI</li> <li>▪ Oral contraceptive</li> <li>▪ Non-potassium sparing diuretic</li> <li>▪ CNS depressants including alcohol</li> </ul>
<b>naltrexone/bupropion</b>	<ul style="list-style-type: none"> <li>▪ Uncontrolled hypertension</li> <li>▪ Seizure disorders</li> <li>▪ Anorexia nervosa or bulimia</li> <li>▪ Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs</li> <li>▪ Chronic opioid use</li> </ul>	<ul style="list-style-type: none"> <li>▪ Suicidal thoughts and ideation</li> </ul>	<ul style="list-style-type: none"> <li>▪ MAOI</li> <li>▪ Opioid analgesics</li> <li>▪ Concurrent use of other bupropion-containing products if the total daily dose of all bupropion-containing products is above the FDA maximum recommended dose</li> </ul>
<b>liraglutide</b>	<ul style="list-style-type: none"> <li>▪ Pregnancy</li> <li>▪ Personal or family Hx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2</li> </ul>	<ul style="list-style-type: none"> <li>▪ Suicidal behavior and ideation</li> <li>▪ Acute pancreatitis</li> <li>▪ Acute gallbladder disease</li> <li>▪ Renal impairment</li> </ul>	<ul style="list-style-type: none"> <li>▪ GLP-1 receptor agonist</li> <li>▪ Insulins</li> </ul>
<b>semaglutide</b>	<ul style="list-style-type: none"> <li>▪ Personal or family Hx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2</li> </ul>	<ul style="list-style-type: none"> <li>▪ Suicidal behavior and ideation</li> <li>▪ Acute pancreatitis</li> <li>▪ Acute gallbladder disease</li> <li>▪ Renal impairment</li> </ul>	<ul style="list-style-type: none"> <li>▪ GLP-1 receptor agonist</li> <li>▪ Insulins</li> </ul>

## Criteria for Renewal

See below for renewal requests for Imcivree™.

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. See **Special Approval Instructions** below for weight loss requirements.

## Special Approval Instructions

1. Patients  $\geq 16$  years of age:
  - a. After six months of therapy, a six-month approval may be granted if a 5% weight reduction from baseline has been achieved. (exception noted below)
    - i. If renewal request is for Saxenda<sup>®</sup>, a six-month approval may be granted if a 4% weight reduction from baseline has been achieved.
2. Pediatric patients  $\geq 12$  years of age:
  - a. After 3 months of therapy, patient must have had a reduction in body weight of at least 1% from baseline.
3. After lapses of therapy, additional trials may be approved if criteria requirements are met.
4. Phentermine may not be approved for therapy beyond nine months.

## Criteria for Approval (Imcivree™ only)

1. Patient must be  $\geq 6$  years of age; **AND**
2. Baseline BMI must be  $\geq 30$  kg/m<sup>2</sup> **or**  $\geq 95$ th 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.

## Criteria for Renewal (Imcivree™ only)

1. First approval will be for four months; **AND**
2. After four months of therapy, patient must have lost at least 5% of the baseline body weight (or  $\geq 5\%$  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).

## Criteria for Denial

Prior approval will be denied if the approval criteria are not met.

## References

Available upon request.

## Revision History

Reviewed by	Reason for Review	Date Approved
Pharmacy and Therapeutic Committee	New	09/2001
Pharmacy and Therapeutic Committee	Pursuant to Chapter 281, NH law 2001	10/2002
Pharmacy and Therapeutic Committee	Revision	03/24/2005
Commissioner	Approval	04/15/2005
Pharmacy and Therapeutic Committee	Revision	04/16/2009
Commissioner	Approval	05/12/2009
DUR Board	Revision	06/18/2012
Commissioner	Approval	07/10/2012
	New drug to market	09/02/2014
DUR Board	Revision	05/12/2015
Commissioner	Approval	06/30/2015
DUR Board	Revision	05/31/2016
Commissioner	Approval	06/18/2016
DUR Board	Revision	03/20/2017
Commissioner	Approval	06/08/2017
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020
DUR Board	Revision	12/15/2020
Commissioner	Approval	02/24/2021
DUR Board	Revision	12/02/2021
Commissioner Designee	Approval	01/14/2022
DUR Board	Revision	12/13/2022
Commissioner Designee	Approval	01/26/2023