

New Hampshire Medicaid Fee-for-Service Program Weight Management Criteria

Approval Date: June 29, 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
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

Requests for $Imcivree^{TM}$ <u>see page 4.</u>

Criteria for Approval

Adult

- 1. Patient is ≥ 16 years of age (Adipex®, phentermine, Lomaira™) or ≥ 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. $\geq 30 \text{ kg/m}^2$ with no risk factors; **OR**
 - b. $\geq 27 \text{ kg/m}^2$ 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
- 7. 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

- 1. Patient is ≥ 12 years of age and < 18 years of age (Saxenda®, Wegovy®, Xenical® only); **AND**
- 2. Body weight is > 60 kg AND initial BMI corresponds to 30 kg/m² 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).

Initial approval will be for 6 months.

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

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	



Table 2: Contraindications, Precautions, and Drug Interactions			
Drug	Contraindications	Precautions	Drug Interactions
phentermine/ topiramate	PregnancyGlaucomaHyperthyroidism	 Increase in heart rate Suicidal behavior and ideation Acute myopia and secondary angle closure glaucoma 	 MAOI 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 bupropion-containing products if the total daily dose of all bupropion-containing products is above the FDA maximum recommended dose
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 agonistInsulins
semaglutide	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 agonistInsulins

Criteria for Renewal

See below for renewal requests for $Imcivree^{TM}$.

- 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®, a six-month approval may be granted if a 4% weight reduction from baseline has been achieved.
- 2. 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.
- 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 ≥ 6 years of age; **AND**
- 2. Baseline BMI must be $\geq 30 \text{ kg/m}^2 \text{ or } \geq 95 \text{th percentile on pediatric growth chart; AND}$
- 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; \mathbf{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 ≥ 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
DUR Board	Revision	06/19/2023



Reviewed by	Reason for Review	Date Approved
Commissioner Designee	Approval	06/29/2023

