

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

# **Pharmacy Medical Policy**

# **Drugs for Weight Loss and Cardiovascular Risk Reduction in Overweight and Obesity**

#### **Table of Contents**

- Policy: Commercial
- Policy History

References

- Policy: Medicare
- Information Pertaining to All Policies
- Forms

• Coding Information

# **Policy Number: 572**

BCBSA Reference Number: None

### **Related Policies**

Policy #621A Quality Care Dosing guidelines

# **Policy**

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

**Note:** All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

#### **Prior Authorization Information**

<ul><li>☑ Prior Authorization</li><li>☐ Step Therapy</li><li>☑ Quality Care Dosing</li></ul>		Pharmacy Operations:         Tel: 1-800-366-7778         Fax: 1-800-583-6289         Policy last updated       2/2025		
Pharmacy (Rx) or Medical (MED) benefit coverage  Policy applies to Commercial Members:  • Managed Care (HMO and POS),  • PPO and Indemnity  • MEDEX with Rx plan  • Managed Major Medical with Custom BCBSMA Formulary		To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.  Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043  Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration		

•	Comprehensive Managed Major Medical with Custom BCBSMA	
	Formulary	
•	Managed Blue for Seniors with Custom	
	BCBSMA Formulary	

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

	Formulary Information		
Drug	Standard		
	Formulary Status		
Contrave ® (naltrexone / bupropion)	PA Required		
Imcivree ™ (setmelanotide)	PA Required		
Saxenda ® (liraglutide)	PA Required		
Wegovy ™ (semaglutide)	PA Required		
Zepbound ™ (tirzepatide)	PA Required		

**Initiation** of **Zepbound** ™ (tirzepatide) or **Contrave**® (naltrexone HCl and bupropion HCl) for the treatment of obesity may be approved for up to 6 months when **all** of the following criteria are met:

- Members 18 years of age or older, AND
- Physician attestation or documentation that the member has already engaged in at least 6-month trial of a comprehensive weight loss plan that includes a reduced calorie diet, increased physical activity, and behavioral modifications prior to initiation of therapy, AND
- Physician attestation or documentation that the member will be using medication as an adjunct to a comprehensive weight management plan including a reduced-calorie diet, increased physical activity and behavioral modifications, AND
- For chronic weight management in patients,
  - o with an initial body mass index (BMI) of ≥ 30 kg/m<sup>2</sup>, **OR**
  - ≥ 27 kg/m² in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

**Initiation** of **Saxenda** <sup>®</sup> (liraglutide), or **Wegovy** <sup>TM</sup>\*\* (semaglutide) for the treatment of obesity may be approved for up to 6 months when **all** of the following criteria are met:

- Members 12<sup>%, #</sup> years of age or older, AND
- Physician attestation or documentation that the member has engaged in a 6-month trial of a comprehensive weight loss plan that includes a reduced calorie diet, increased physical activity, and behavioral modifications prior to initiation of therapy.
- Physician attestation or documentation that the member will be using medication as an adjunct to a comprehensive weight management plan including a reduced-calorie diet, increased physical activity and behavioral modifications, AND
  - For chronic weight management in patients, with an initial body mass index (BMI) of ≥ 30 kg/m² (obese), OR
  - For age >=18 years: ≥ 27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes), OR
  - For age (12-18 years): Documentation that the members initial BMI > 95th percentile standardized for age and sex.
  - o (Physician must include Baseline BMI and Baseline Weight and BMI % for pediatrics)

Continuation of therapy for Contrave® (naltrexone HCl and bupropion HCl), Saxenda® (liraglutide),

<sup>%</sup> Saxenda ® (liraglutide) Is FDA approved for 12 years of age or older and body weight above 60 kg.
# - Wegovy ™ (semaglutide) Is FDA approved for 12 years of age or older with an initial BMI at the 95th percentile or greater standardized for age and gender.

#### Continuation of Contrave, Saxenda, Wegovy, or Zepbound

**Contrave** (naltrexone \ bupropion), **Saxenda** (liraglutide), **Wegovy™** (semaglutide), or **Zepbound ™** (tirzepatide) may be approved for up to an additional 12 months of therapy when **all** of the following criteria are met:

- Documentation of significant weight loss\*, after initiation of therapy, AND
- Documentation that the member is adherent to therapy and has been tolerating the recommended maintenance dose of medication for at least 3 consecutive months, AND
- Documentation that the member continues with a comprehensive weight management plan including a reduced-calorie diet, increased physical activity and behavioral modifications.

\*Note: Contrave® (naltrexone \ bupropion) requires documented weight loss of at least 5% of baseline body weight after the initiation of treatment (first 12 weeks of treatment), OR must demonstrate continued weight loss, OR maintain the plateau weight at least 5% below baseline.

**Saxenda**® (liraglutide) requires documented weight loss of at least 4% of baseline body weight after the initiation of treatment (first 16 weeks of treatment), **OR** must demonstrate continued weight loss, **OR** maintain the plateau weight achieved with diet, exercise treatment.

Wegovy™ (semaglutide) requires documented weight loss of at least 5% of baseline body weight after the initiation of treatment (first 16 weeks of treatment), OR must demonstrate continued weight loss, OR maintain the plateau weight achieved with diet, exercise treatment AND requires the member to be on the 2.4mg dose or 1.7mg dose.

**Zepbound** ™ (tirzepatide) requires documented weight loss of at least 5% of baseline body weight after the initiation of treatment (first 20 weeks of treatment), **OR** must demonstrate continued weight loss, **OR** maintain the plateau weight achieved with diet, exercise treatment and requires the member to be on the 5mg dose, 10mg dose or 15mg dose.

**Initiation** of **Imcivree** ™(setmelanotide) may be approved for up to 4 months when **all** of the following criteria are met:

- Diagnosis of obesity, defined as:
   Adult patients (>= 18 years old): BMI of ≥30 kg/m² OR Pediatric patients 2 years of age or older
   AND
- Obesity is due to a homozygous or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing including Documentation demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or Variants of Uncertain Significant (VUS).
  - Proopiomelanocortin (POMC)
  - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
  - Leptin receptor (LEPR),

#### OR

• Documentation of monogenic or syndromic obesity due to Bardet-Biedl syndrome.

Continuation of Imcivree ™(setmelanotide) ) may be approved when all of the following criteria are met:

#### First Renewal Criteria for Consideration for Imcivree

- Documentation of response to therapy, as evidenced by:
  - At least a 5% reduction in baseline body weight OR
  - o At least a 5% reduction in baseline BMI for patients with continued height growth potential
- Demonstration of treatment adherence
   Approvals may be granted for up to 4 additional months

#### Subsequent Renewal Criteria for Consideration for Imcivree

- Documentation of maintained response to therapy, as evidenced by:
  - o Maintenance of at least a 5% reduction in body weight relative to baseline OR

- Maintenance of at least a 5% reduction in baseline BMI for patients with continued height growth potential
- Demonstration of treatment adherence
   Approvals may be granted for up to 12 additional months.

\*\*\*Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and step criteria below are met

#### Wegovy for cardiovascular risk reduction in obesity or overweight

**We may cover Wegovy** <sup>®</sup> (semaglutide) to reduce the risk of major adverse cardiovascular events [MACE] (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) when **all** of the following criteria are met:

- 1.) Patient needs to be 45 years or older, AND
- 2.) Patient has established cardiovascular disease defined as one (1) of the following:
  - a.) Prior MI
  - b.) Prior Stroke
  - c.) Symptomatic Peripheral Artery Disease (PAD) as evidenced by one (1) of the following:
    - i.) Current intermittent claudication with Ankle-Brachial Index (ABI) test <0.85 (at rest)
    - ii.) Prior peripheral arterial revascularization procedure
    - iii.) Prior amputation due to Atherosclerotic Cardiovascular Disease (ASCVD)

#### **AND**

- 3.) Patient is receiving Standard Of Care (SOC) treatment as appropriate (please provide examples of all that apply):
  - a.) Antiplatelet agent (Aspirin or P2Y12 inhibitor [common ones include clopidogrel and prasugrel)
  - b.) Lipid lowering drug (Statin, ezetimibe, fibrate, and/or PCSK-9 inhibitor)
  - c.) Antihypertensive (beta blocker, ACE-I, ARB)

#### AND

4.) Patient is not New York Heart Association (NYHA) class IV heart failure,

#### AND

5.) Patient has a BMI > 27.

If approved the APPROVAL duration - 6 Months.

#### Renewal Criteria for Wegovy for MACE

We may renew coverage of Wegovy ® if **ALL** the following criteria are met:

- 1. Individual continues to meet initial approval criteria, AND
- 2. Individual is adherent to therapy, as evidenced by claims records demonstrating > 80% fill rate, AND
- 3. Individual has not developed Type 2 Diabetes (T2D) or New York Heart Association (NYHA) class IV Heart failure (HF), **AND**
- 4. Member remains on Standard of Care (SOC) therapies for Cardiovascular Disease (CVD).

RE-AU	THORIZ#	NOITA	duratio	n – 12	months

\*\*Requests based exclusively on the use of samples will not meet continuing coverage criteria. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We do not cover these medications for conditions not listed above unless otherwise specified in other medical policies.

# **CPT Codes**

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

#### **CPT Codes**

There is no specific CPT code for this service.

#### **Individual Consideration**

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043

Phone: 1-800-366-7778 Fax: 1-800-583-6289 We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

# **Policy History**

Policy history			
Date	Action		
2/2025	Updated to add Imcivree 's new age indication.		
7/2024	Updated title of the policy and Wegovy's new Cardiovascular indication.		
5/2024	Clarified Coverage.		
11/2023	Updated to add Zepbound <sup>™</sup> to the policy.		
9/2023	Updated to add new age update for Wegovy <sup>™</sup> and to require additional documentation		
	and updated significant weight loss for Wegovy and the length of approvals were also		
	updated and updated IC to align with 118E MGL § 51A.		
7/2023	Reformatted Policy.		
11/2022	Updated to add new indication for Imcivree ™.		
1/2022	Updated both initial authorization length and continuation authorization length.		
7/2021	Updated to add Wegovy ™ to the policy.		
4/2021	Updated to add Imcivree <sup>™</sup> to the policy.		
1/2021	Updated to remove Belviq ® and Belviq XR® as FDA withdrew them from the market and		
	update age for Saxenda®.		
1/2020	Updated to make Belviq <sup>®</sup> and Belviq XR <sup>®</sup> not covered.		
6/2017	Updated address for Pharmacy Operations.		
12/2016	Updated to Add Belviq XR®		
6/2016	Updated FDA approved Saxenda® dosing.		
12/2015	Updated to add Contrave® and Saxenda®.		
8/2014	Coding information clarified.		
1/2014	Implementation of policy.		
9/2013	Pharmacy and Therapeutics Committee review.		

# References

- 1. Belvig ® [package insert]. Eisai Inc., Woodcliff Lake, NJ 07677
- 2. Contrave ® [package insert]. Takeda Pharmaceuticals America, Inc., La Jolla, CA -2014
- 3. Saxenda ® [package insert]. Novo Nordisk Inc., Plainsboro, NJ –Jan 2015
- 4. Imcivree ™ [package insert]. Rhythm Pharmaceuticals, Inc., Boston, MA–Dec 2020
- 5. Wegovy ™ [package insert]. Novo Nordisk Inc., Plainsboro, NJ –June 2021.
- 6. Zepbound <sup>™</sup> [package insert]. Lilly USA, LLC., Indianapolis, IN-Nov 2023.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: <a href="http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf">http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf</a>