Pharmacy Medical Policy
Drugs for Weight Loss

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Coding Information
- Policy History
- Information Pertaining to All Policies
- References
- Forms

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
- Prior Authorization
- Step Therapy
- Quality Care Dosing
- Rx
- MED

Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Policy last updated 7/1/2023

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
<th>Standard</th>
<th>Formulary Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrave® (naltrexone / bupropion)</td>
<td>PA Required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imcivree™ (setmelanotide)</td>
<td>PA Required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saxenda® (liraglutide)</td>
<td>PA Required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wegovy™ (semaglutide)</td>
<td>PA Required</td>
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</tr>
</tbody>
</table>

**Initiation of Contrave® (naltrexone HCl and bupropion HCl), Saxenda® (liraglutide) or Wegovy™ (semaglutide) may be approved for up to 20 weeks when all of the following criteria are met:**
- Members 18 years of age or older, **AND**
- As an adjunct to a reduced-calorie diet and increased physical activity, **AND**
- For chronic weight management in patients,
  - with an initial body mass index (BMI) of ≥ 30 kg/m² (obese), **OR**
  - ≥ 27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes), **AND**
  - Documentation that the member has been and is currently following a dietary and behavior modification program for weight loss.
  - Saxenda® (liraglutide) is FDA approved for 12 years of age or older and body weight above 60 kg.

**Continuation of therapy for Contrave® (naltrexone HCl and bupropion HCl), Saxenda® (liraglutide) or Wegovy™ (semaglutide) may be approved for up to an additional 6 months of therapy when all of the following criteria are met:**
- Demonstrate significant weight loss*, after initiation of therapy, **AND**
- Adhering to a reduced-calorie diet, **AND**
- Adhering to increased physical activity, **AND**
- Third party documentation, if applicable, is included with the request for continuing treatment, **AND**

*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 achieved with diet, exercise.

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 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 and requires the member to be on the 2.4mg 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: BMI of ≥30 kg/m² **OR**
  - Pediatric patients: ≥95th percentile using growth chart assessment, **AND**
- Members 6 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:
  - Proopiomelanocortin (POMC)
- Proprotein convertase subtilisin/kexin type 1 (PCSK1)
- Leptin receptor (LEPR), AND
  - Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or Variants of Uncertain Significant (VUS).
  - Documentation of monogenic or syndromic obesity due to Bardet-Biedl syndrome, AND
  - Members 6 years of age or older

Continuation of therapy for 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
  - At least a 5% reduction in baseline BMI for patients with continued 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:
  - Maintenance of at least a 5% reduction in baseline body weight OR
  - Maintenance of at least a 5% reduction in baseline BMI for patients with continued 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**

Coverage Criteria, for initiation and continuation of therapy shall include: Weight, Height, BMI, Weight History, Systolic/ Diastolic BP, For Diabetics HbA1c, Ruled out weight gain due to drug therapy (e.g., anti-psychotics, TZDs, others), Addition of drug therapy is clinically indicated for Member currently adhering to diet modification and exercise program, and pharmacy prescription claims history of treatment for comorbid conditions (e.g., antihypertensive, diabetes, dyslipidemia).

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review. We do not cover conditions not listed above.**

**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**
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>11/2022</td>
<td>Updated to add new indication for Imcivree™.</td>
</tr>
<tr>
<td>1/2022</td>
<td>Updated both initial authorization length and continuation authorization length.</td>
</tr>
<tr>
<td>7/2021</td>
<td>Updated to add Wegovy™ to the policy.</td>
</tr>
<tr>
<td>4/2021</td>
<td>Updated to add Imcivree™ to the policy.</td>
</tr>
<tr>
<td>1/2021</td>
<td>Updated to remove Belviq® and Belviq XR® as FDA withdrew them from the market and update age for Saxenda®.</td>
</tr>
<tr>
<td>1/2020</td>
<td>Updated to make Belviq® and Belviq XR® not covered.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>12/2016</td>
<td>Updated to Add Belviq XR®</td>
</tr>
<tr>
<td>6/2016</td>
<td>Updated FDA approved Saxenda® dosing.</td>
</tr>
<tr>
<td>12/2015</td>
<td>Updated to add Contrave® and Saxenda®.</td>
</tr>
<tr>
<td>8/2014</td>
<td>Coding information clarified.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Implementation of policy.</td>
</tr>
<tr>
<td>9/2013</td>
<td>Pharmacy and Therapeutics Committee review.</td>
</tr>
</tbody>
</table>

References

2. Contrave® [package insert]. Takeda Pharmaceuticals America, Inc., La Jolla, CA -2014

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: