

Weight Management Agents

Pharmacy Benefit Drug Policy

Drug Details

Medications	Quantity Limit
CONTRAVE ER (<i>bupropion-naltrexone</i>)	May be subject to quantity limit
QSYMIA (<i>phentermine-topiramate</i>)	
XENICAL (<i>orlistat</i>)	
SAXENDA (<i>liraglutide</i>)	
WEGOVY (<i>semaglutide</i>)	
ZEPBOUND (<i>tirzepatide</i>) <i>subcutaneous injection</i>	

Condition(s) listed in policy (*see coverage criteria for details*)

- Chronic weight management

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Providers must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

1. For Wegovy request for chronic weight management:

Initial Authorization
<ul style="list-style-type: none"> • Age is consistent with the FDA labeled indication (Patient is 12 years of age or older), and • Being used as adjunct to a reduced calorie diet and increased physical activity, and • Chart documentation of one of the following:

- a. Current BMI of ≥ 30 kg/m², **or**
- b. Current BMI of ≥ 27 kg/m² and patient has one of the following conditions: hypertension, diabetes, coronary artery disease, dyslipidemia, stroke, osteoarthritis, metabolic syndrome, prediabetes, PCOS, NASH, or patient has sleep apnea currently being treated with CPAP, **or**
- c. *For pediatric patients (age 12 to 17 years):* Current BMI ≥ 95 th percentile using growth chart assessments,

and

- Documentation that patient has participated in a comprehensive lifestyle intervention consisting of reduced calorie diet, increased physical activity and behavioral modification for at least 6 months within the past year, **and**
- Patient had been evaluated by a physician to rule out other underlying endocrine causes of obesity, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Not being used in combination with another GLP-1 agent (e.g., Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Dose does not exceed 2.4 mg once weekly

Coverage Duration: 7 months

1st Reauthorization

- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- One of the following:
 - Patient demonstrates at least 5% weight loss from baseline, **and** Patient has been on maintenance dose (1.7mg or 2.4mg once weekly) for 3 months or longer, **or**
 - Patient is still being titrated to target dose (maintenance dose of 1.7mg or 2.4 mg once weekly),
 - AND
- Not being used in combination with another GLP-1 agent (e.g., Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 2.4 mg once weekly.

Coverage Duration: 6 months

Subsequent Reauthorization

- Patient continues to respond to treatment, **and**
- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Patient’s weight has not returned to baseline and is not below ideal body weight (IBW), **and**
- Not being used in combination with another GLP-1 agent (e.g. Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 2.4 mg once weekly

Coverage Duration: 6 months

2. For Zepbound request for chronic weight management:

Initial Authorization

- Age is consistent with the FDA labeled indication (Patient is 18 years of age or older), **and**
- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Chart documentation of one of the following:
 - d. Current BMI of ≥ 30 kg/m², **or**
 - e. Current BMI of ≥ 27 kg/m² and patient has one of the following conditions: hypertension, diabetes, coronary artery disease, dyslipidemia, stroke, osteoarthritis, metabolic syndrome, prediabetes, PCOS, NASH, or patient has sleep apnea currently being treated with CPAP**and**
- Documentation that patient has participated in a comprehensive lifestyle intervention consisting of reduced calorie diet, increased physical activity and behavioral modification for at least 6 months within the past year, **and**
- Patient had been evaluated by a physician to rule out other underlying endocrine causes of obesity, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**

- Not being used in combination with another GLP-1 agent (e.g., Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Dose does not exceed 15 mg once weekly

Coverage Duration: 4 months

1st Reauthorization

- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- One of the following:
 - Patient demonstrates at least 5% weight loss from baseline, **or**
 - Patient is still being titrated to a higher maintenance dose (up to max of 15 mg once weekly),**AND**
- Not being used in combination with another GLP-1 agent (e.g., Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 15 mg once weekly.

Coverage Duration: 6 months

Subsequent Reauthorization

- Patient continues to respond to treatment, **and**
- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Patient's weight has not returned to baseline and is not below ideal body weight (IBW), **and**
- Not being used in combination with another GLP-1 agent (e.g. Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Saxenda), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 15 mg once weekly.

Coverage Duration: 6 months

3. For Saxenda request for chronic weight management:

Initial Authorization
<ul style="list-style-type: none"> • Age is consistent with the FDA labeled indication (Patient is 12 years of age or older), and • Being used as adjunct to a reduced calorie diet and increased physical activity, and • Chart documentation of one of the following: <ul style="list-style-type: none"> a. Current BMI of ≥ 30 kg/m², or b. Current BMI of ≥ 27 kg/m² and patient has one of the following conditions: hypertension, diabetes, coronary artery disease, dyslipidemia, stroke, osteoarthritis, metabolic syndrome, prediabetes, PCOS, NASH, or patient has sleep apnea currently being treated with CPAP, or f. <i>For pediatric patients (age 12 to 17 years):</i> Current BMI corresponding to 30 kg/m² for adults by international cutoff, and • Patient had been evaluated by a physician to rule out other underlying endocrine causes of obesity, and • Patient has not undergone bariatric surgery within the previous 12 months, and • Not being used in combination with another GLP-1 agent (e.g., Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Wegovy), and • Not being used in combination with another weight loss agent, and • Documentation that patient has participated in a comprehensive lifestyle intervention within the past year consisting of reduced calorie diet, increased physical activity and behavioral modification for at least 6 months, and • Dose does not exceed 3 mg per day <p><u>Coverage Duration:</u> 16 weeks</p>
1 st Reauthorization
<ul style="list-style-type: none"> • Patient demonstrates at least 5% (1% for pediatric patients) weight loss from baseline, and • Being used as adjunct to a reduced calorie diet and increased physical activity, and

- Not being used in combination with another GLP-1 agent (e.g. Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Wegovy), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 3 mg per day.

Coverage Duration: 6 months

Subsequent reauthorization

- Patient continues to respond to treatment, **and**
- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Patient’s weight has not returned to baseline and is not below ideal body weight (IBW), **and**
- Not being used in combination with another GLP-1 agent (e.g. Adlyxin, Bydureon, Byetta, Ozempic, Soliqua, Rybelsus, Trulicity, Victoza, Xultophy, Mounjaro, Wegovy), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed 3 mg per day.

Coverage Duration: 6 months

4. For Contrave, Qsymia, or Xenical request for chronic weight management:

Initial Authorization

- Age is consistent with the FDA labeled indication,

Contrave ER	18 years of age or older
Xenical	12 years of age or older
Qsymia	12 years of age or older

and

- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Chart documentation of one of the following:

- a. Current BMI of $> 30 \text{ kg/m}^2$, **or**
- b. Current BMI of $> 27 \text{ kg/m}^2$ and patient has one of the following conditions: hypertension, diabetes, coronary artery disease, dyslipidemia, stroke, osteoarthritis, metabolic syndrome, prediabetes, PCOS, NASH, or patient has sleep apnea currently being treated with CPAP, **or**
- c. *For Qsymia requests for patients between 12 to 17 years of age::* Current BMI ≥ 95 th percentile using growth chart assessments (See Additional Information, Table 2),

and

- Patient had been evaluated by a physician to rule out other underlying endocrine causes of obesity, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Not being used in combination with another weight loss agent, **and**
- Documentation that patient has participated in a comprehensive lifestyle intervention within the past year consisting of reduced calorie diet, increased physical activity and behavioral modification for at least 6 months, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration:

Contrave ER: 16 weeks

Qsymia: 7 months

Xenical: 3 months

1st Reauthorization

- Patient demonstrates at least 5% weight loss from baseline, **and**
- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed FDA label maximum

Coverage Duration: 6 months

Subsequent Reauthorization

- Patient continues to respond to treatment, **and**

- Being used as adjunct to a reduced calorie diet and increased physical activity, **and**
- Patient’s weight has not returned to baseline and is not below ideal body weight (IBW), **and**
- Not being used in combination with another weight loss agent, **and**
- Patient has not undergone bariatric surgery within the previous 12 months, **and**
- Dose does not exceed FDA label maximum

Coverage Duration: 6 months

Additional Information:

Table 1: Dosing Limits

Drug	FDA label maximum
Contrave	32 mg/360 mg daily in two divided doses
Qsymia	15 mg/92 mg daily
Saxenda	3 mg per day
Wegovy	2.4 mg once weekly
Xenical	360 mg daily in three divided doses

Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age	Body mass index 30kg/m ²	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

Table 3: BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 Years and Older

Age	95 th percentile BMI Value	
	Males	Females
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

References

1. Product Information: CONTRAVE(R) oral extended-release tablets, naltrexone HCl and bupropion HCl oral extended-release tablets. Currax Pharmaceuticals LL, Morristown, NJ. 2021.
2. Product Information: QSYMIA® oral extended-release capsules, phentermine topiramate oral extended-release capsules. VIVUS LLC (per FDA), Campbell, CA, 2022.
3. Product Information: SAXENDA(R) subcutaneous injection, liraglutide subcutaneous injection. Novo Nordisk Inc (per manufacturer), Plainsboro, NJ, 2022.
4. Product Information: WEGOVY(R) subcutaneous injection, semaglutide subcutaneous injection. Novo Nordisk Inc (per manufacturer), Plainsboro, NJ, 2022.
5. Product Information: XENICAL® oral capsules, orlistat oral capsules. Roche Laboratories Inc, Nutley, NJ, 2022.
6. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. *Endocr Pract*, 2016;22 Suppl 3:1-203. doi: 10.4158/EP161365.GL.

Policy Update

Date of Last Annual Review: 2Q23

Date of last revision: 01/03/2024

Changes from previous policy version:

- Zepbound added to policy

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*