BUPROPION/NALTREXONE (Contrave®1)
LORCASERIN (Belviq®1, Belviq XR®1)
PHENTERMINE/TOPIRAMATE ER (Qsymia®1)

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Obesity

BRAND (generic) NAMES:
- Belviq (lorcaserin) 10 mg, Belviq XR (lorcaserin) 20 mg
- Contrave (bupropion/naltrexone extended release) 90 mg/8 mg
- Qsymia (phentermine/topiramate extended-release) 3.75 mg/23 mg; 7.5 mg/46 mg; 11.25 mg/69 mg; 15 mg/92 mg

FDA-APPROVED INDICATIONS:
An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:
- 30 kg/m² or greater (obese) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related co-morbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes).

COVERAGE AUTHORIZATION CRITERIA:
INITIAL COVERAGE
Bupropion/naltrexone (Contrave), lorcaserin (Belviq, Belviq XR), or phentermine/topiramate extended-release (Qsymia) is initially covered for the following conditions:

1. Patient is 18 years of age or older; AND
2. The patient has a body mass index (BMI) ≥30 kg/m²; OR
3. The patient has a BMI ≥27 kg/m² and at least ONE of the following:
   a. Patient has two or more cardiovascular risk factors:
      i. LDL > 160 mg/dl;
      ii. HDL < 40 mg/dl;
      iii. hypertension;
      iv. smoking;
      v. impaired fasting glucose;
      vi. family history of premature coronary heart disease (CHD): CHD in male first degree relative < 55 years; CHD in female first degree relative < 65 years;
vii. Age (male > 45 years or female > 55 years or postmenopausal);  
**OR**  
b. Waist circumference > 40 inches in men or > 35 inches in women;  
**OR**  
c. Patient has one or more obesity-related co-morbidities (established CHD, other atherosclerotic diseases, type 2 diabetes, obstructive sleep apnea)  

4. Non-formulary medications included in this criterion are subject to a trial and failure of up to 2 formulary alternatives that are clinically appropriate to treat the same condition (see Non-formulary Exception Criterion for details).

*If approved, initial coverage will be for 6 months

### CONTINUATION COVERAGE (after 6 months of initial therapy)

Coverage of bupropion/naltrexone (Contrave), lorcaserin (Belviq, Belviq XR), or phentermine/topiramate extended-release (Qsymia) will be continued for the following conditions:

1. After initial approval, patient has lost at least 5% of their initial body weight (body weight immediately prior to starting therapy).
2. After each year of therapy, an additional 12 months of therapy will be approved if the member has maintained a weight loss of at least 5% of their initial body weight.

### WARNINGS AND PRECAUTIONS:

**Bupropion/naltrexone:**

- **Suicidal Behavior and Ideation:** Monitor for depression or suicidal thoughts. Discontinue Contrave if symptoms develop.
- **Risk of seizure** may be minimized by adhering to the recommended dosing schedule and avoiding coadministration with high-fat meal.
- **Increase in Blood Pressure and Heart Rate:** Monitor blood pressure and heart rate in all patients, especially those with cardiac or cerebrovascular disease.
- **Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction observed with naltrexone exposure.
- **Angle-closure glaucoma:** Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.
- **Use of Antidiabetic Medications:** Weight loss may cause hypoglycemia. Monitor blood glucose.

**Lorcaserin:**

- **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions:** The safety of coadministration with other serotonergic or antidopaminergic agents has not been established. Manage with immediate Belviq/Belviq XR discontinuation and provide...
supportive treatment.

- Valvular heart disease: If signs or symptoms develop consider Belviq/Belviq XR discontinuation and evaluate the patient for possible valvulopathy.
- Cognitive Impairment: May cause disturbances in attention or memory. Caution with use of hazardous machinery when starting Belviq/Belviq XR treatment.

- Psychiatric Disorders, including euphoria and dissociation: Do not exceed recommended dose of 10 mg twice daily.
- Monitor for depression or suicidal thoughts. Discontinue if symptoms develop.
- Use of Antidiabetic Medications: weight loss may cause hypoglycemia. Monitor blood glucose. Belviq/Belviq XR has not been studied in patients taking insulin.
- Priapism: Patients should seek emergency treatment if an erection lasts >4 hours. Use Belviq/Belviq XR with caution in patients predisposed to priapism.

**Phentermine/Topiramate Extended-Release:**
- Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. Qsymia is available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS).
- Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease.
- Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue Qsymia if symptoms develop.
- Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue Qsymia.
- Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms.
- Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment.
- Metabolic Acidosis: Measure electrolytes before/during treatment.
- Elevated Creatinine: Measure creatinine before/during treatment.
- Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment.

**CONTRAINDICATIONS:**

**Bupropion/naltrexone:**
- Uncontrolled hypertension
- Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- Use of other bupropion-containing products
- Chronic opioid use
- During or within 14 days of taking monoamine oxidase inhibitors (MAOI)
- Known allergy to any of the ingredients in Contrave
- Pregnancy

**Lorcaserin:**
- Pregnancy
Phentermine/Topiramate Extended-Release:

- Pregnancy
- Glaucoma
- Hyperthyroidism
- During or within 14 days of taking monoamine oxidase inhibitors
- Known hypersensitivity or idiosyncrasy to sympathomimetic amines

REFERENCES:

Bupropion/naltrexone (Contrave extended release) Prescribing Information. Takeda Pharmaceuticals America, Inc. September 2014.


Lorcaserin (Belviq) product information. Eisai Inc. Woodcliff Lake, NJ.

Lorcaserin (Belviq XR) product information. Eisai Inc. Woodcliff Lake, NJ.

Phentermine/topiramate extended-release (Qsymia) product information. VIVUS Inc. by Catalent Pharma Solutions, LLC. Winchester, KY


POLICY IMPLEMENTATION/UPDATE INFORMATION

September 2016: Reviewed for Essential Formulary; non-formulary verbiage added. Added new to market Belviq XR.

May 2015: Historical Revision
Non-Discrimination and Accessibility Notice

Discrimination is Against the Law

• Blue Cross and Blue Shield of North Carolina (“BCBSNC”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

• BCBSNC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

BCBSNC:

▪ Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)

▪ Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

• If you need these services, contact Customer Service 1-888-206-4697, TTY and TDD, call 1-800-442-7028.

• If you believe that BCBSNC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
  ➢ BCBSNC, PO Box 2291, Durham, NC 27702, Attention: Civil Rights Coordinator-
    Privacy, Ethics & Corporate Policy Office, Telephone 919-765-1663, Fax 919-287-5613, TTY 1-888-291-1783 civilrightscoordinator@bcbsnc.com

• You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

• This Notice and/or attachments may have important information about your application or coverage through BCBSNC. Look for key dates. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call Customer Service 1-888-206-4697.

ATTENTION: If you speak another language, language assistance services, free of charge, are available to you. Call 1-888-206-4697 (TTY: 1-800-442-7028).


注意：如果您講廣東話或普通話，您可以免費獲得語言援助服務。請致電 1-888-206-4697 (TTY: 1-800-442-7028).

МЕЛОВА: Если вы говорите нан русском языке, то вам доступны бесплатные услуги перевода. Звоните по номеру 1-888-206-4697 (телетайп: 1-800-442-7028).

ध्यान दें: यदि आप हिंदी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। 1-888-206-4697 (TTY: 1-800-442-7028) पर कॉल करें।

โปรดทราบ: ทุกอย่างกำลังเกิดขึ้น แต่ ทางบริษัทผู้ถือสิทธิ์ทางผลิตภัณฑ์ ได้จัดทำขึ้น แบบมีผลบังคับใช้ทันที โปรด 1-888-206-4697 (TTY: 1-800-442-7028)。

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。1-888-206-4697（TTY: 1-800-442-7028）まで、お電話にてご連絡ください。