MEDICAL MUTUAL®

Drug Policy

Policy:	Weight Loss - Contrave and Qsymia Contrave (naltrexone/bupropion) Qsymia (phentermine/topiramate) ER	Annual Review Date: 07/18/2024 Last Revised Date: 07/18/2024

OVERVIEW

Qsymia and **Contrave** are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

Contrave

The recommended maintenance dose of Contrave is achieved at Week 4. Response to therapy should be evaluated after 12 weeks at the maintenance dosage (Week 16, if dosed according to the prescribing information). If a patient has not lost ≥ 5% of baseline body weight, discontinue Contrave, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Qsymia

Response to therapy should be evaluated by Week 12. If a patient has not lost ≥ 3% of baseline body weight, discontinue Qsymia or escalate the dose. If a patient has not lost ≥ 5% of baseline body weight after an additional 12 weeks of treatment on the escalated dose, discontinue Qsymia as directed as it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

POLICY STATEMENT

This policy involves the use of Qsymia and Contrave. Prior authorization is recommended for pharmacy benefit coverage of Qsymia and Contrave. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of **Contrave** is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Weight Loss.** Approve for the duration noted if the patient meets one of the following criteria (A or B):

A. Initial Therapy. Approve for 4 months if the patient meets the following criteria (i, ii, iii, and iv):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient meets one of the following (a or b):
  - **a)** At baseline, the patient had a body mass index (BMI) ≥ 32 kg/m^2 [documentation required]; OR
  - **b)** At baseline, the patient had a BMI ≥ 27 kg/m^2 [documentation required] and at least TWO of the following weight-related comorbidities [documentation required]: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); AND

  Note: This refers to baseline prior to use of any pharmacologic weight loss therapy.
- **iii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
- **iv.** Contrave will be used concomitantly with a behavioral modification program and a reduced calorie diet; AND
- **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.

A) Patient is Continuing Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
Note: For a patient who has not completed 4 months of initial therapy, criterion (1A) must be met (do not use continuation criteria if the initial 4 months were not completed).
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient meets one of the following:
  - **a)** At baseline, the patient had a BMI ≥ 32 kg/m^2 [documentation required]; OR
  - **b)** At baseline, the patient had a BMI ≥ 27 kg/m^2 [documentation required] and at least TWO of the following weight-related comorbidities [documentation required]: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); AND

  Note: This refers to baseline prior to use of any pharmacologic weight loss therapy.
- **iii.** Contrave will be used concomitantly with a behavioral modification program and a reduced calorie diet; AND
- **iv.** Patient has lost ≥ 5% of baseline body weight [documentation required]; AND
- **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.

II. Coverage of **Qsymia** is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Weight Loss, Adult.** Approve for the duration noted if the patient meets one of the following criteria (A or B):

   A. Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):
   - **i.** Patient is ≥ 18 years of age; AND
   - **ii.** Patient meets one of the following:
     - **a)** At baseline, the patient had a body mass index (BMI) ≥ 32 kg/m^2 [documentation required]; OR
     - **b)** At baseline, the patient had a BMI ≥ 27 kg/m^2 [documentation required] and at least TWO of the following weight-related comorbidities [documentation required]: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); AND

     Note: This refers to baseline prior to use of any pharmacologic weight loss therapy.
   - **iii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
   - **iv.** Qsymia will be used concomitantly with a behavioral modification program and a reduced calorie diet; AND
   - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.

   B. Patient is Continuing Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
   Note: For a patient who has not completed 6 months of initial therapy, criterion (1A) must be met (do not use continuation criteria if the initial 6 months were not completed).
   - **i.** Patient is ≥ 18 years of age; AND
   - **ii.** Patient meets one of the following:
     - **a)** At baseline, the patient had a BMI ≥ 32 kg/m^2 [documentation required]; OR
     - **b)** At baseline, the patient had a BMI ≥ 27 kg/m^2 [documentation required] and at least TWO of the following weight-related comorbidities [documentation required]: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); AND

     Note: This refers to baseline prior to use of any pharmacologic weight loss therapy.
   - **iii.** Qsymia will be used concomitantly with a behavioral modification program and a reduced calorie diet; AND
   - **iv.** Patient has lost ≥ 5% of baseline body weight [documentation required]; AND
   - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.

2. **Weight Loss, Pediatric.** Approve for the duration noted if the patient meets one of the following criteria (A or B):
   - **A.** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):
     - **i.** Patient is ≥ 12 years of age and < 18 years of age; AND
     - **ii.** Patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex [documentation required]; AND
     - **iii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iv.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
     - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
   - **B.** Patient is Continuing Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
     Note: For a patient who has not completed 6 months of initial therapy, criterion (2A) must be met (do not use continuation criteria if the initial 6 months were not completed).
     - **i.** Patient is ≥ 12 years of age and < 18 years of age; AND
     - **ii.** Patient had an initial BMI of ≥ 95th percentile for age and sex [documentation required]; AND
     - **iii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
     - **iv.** Patient has had a reduction in BMI of ≥ 5% from baseline (prior to the initiation of Qsymia) [documentation required]; AND
     - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Qsymia and Contrave have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with Other Weight Loss Medications.** Concomitant use with other medications intended for weight loss is not recommended. Of note, examples of medications FDA-approved for weight loss include phentermine, benzphetamine, diethylpropion, phendimetrazine, Contrave, Qsymia, orlistat 120 mg (Xenical, authorized generic), Saxenda (liraglutide subcutaneous injection), Wegovy (semaglutide subcutaneous injection), and Zepbound (tirzepatide subcutaneous injection). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation

supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Qsymia® capsules [prescribing information]. Mountain View, CA: Vivus, Inc.; June 2022.
2. Contrave® tablets [prescribing information]. Morristown, NJ: Nalpropion/Currax; April 2021.
3. Phentermine/topiramate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 11 July 2024. Accessed on 16 July 2024.
4. Naltrexone hydrochloride/bupropion hydrochloride. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 10 July 2024. Accessed on 16 July 2024.