Reference number(s)
794-C

Initial Prior Authorization with Quantity Limit
Qsymia
Weight Loss Management

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Qsymia	phentermine and topiramate extended-release

Indications

FDA-approved Indications

Qsymia is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:

- Adults and pediatric patients aged 12 years and older with obesity
- Adults with overweight in the presence of at least one weight-related comorbid condition

Limitations of Use

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Reference number(s)
794-C

Coverage Criteria

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ALL of the following criteria are met:

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced-calorie diet, AND increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
- If the patient is 18 years of age or older, then the patient meets ONE of the following:
    - The patient has a baseline body mass index (BMI) greater than or equal to 30 kg/m^2 [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.]
    - The patient has a baseline BMI greater than or equal to 27 kg/m^2 [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] In addition, the following criteria is met:
        - The patient has at least ONE weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia) [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.]
- If the patient is 12 to 17 years of age, then the following criteria is met:
    - The patient has a baseline BMI in the 95th percentile or greater standardized for age and sex [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.]

Reference number(s)
794-C

Continuation of Therapy

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ALL of the following criteria are met:

- If the patient is 18 years of age or older, then ONE of the following criteria is met:
  - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 15 mg/92 mg therapy and the following criteria is met:
    - The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 7.5 mg/46 mg therapy and ONE of the following criteria is met:
    - The patient has lost at least 3 percent of baseline body weight OR the patient has continued to maintain their initial 3 percent weight loss [ACTION REQUIRED: Documentation is required for approval.]
    - The patient's dose has been increased to Qsymia (phentermine/topiramate extended-release) 11.25 mg/69 mg AND will follow the recommended dose escalation schedule [ACTION REQUIRED: Documentation is required for approval.]
- If the patient is 12 to 17 years of age, then ONE of the following criteria is met:
  - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 15 mg/92 mg therapy and the following criteria is met:
    - The patient has experienced a reduction of at least 5 percent of baseline body mass index (BMI) OR the patient has continued to maintain their initial 5 percent BMI reduction [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has completed at least 12 weeks of Qsymia (phentermine/topiramate extended-release) 7.5 mg/46 mg therapy and ONE of the following criteria is met:
    - The patient has experienced a reduction of at least 3 percent of baseline BMI OR the patient has continued to maintain their initial 3 percent BMI reduction [ACTION REQUIRED: Documentation is required for approval.]
    - The patient's dose has been increased to Qsymia (phentermine/topiramate extended-release) 11.25 mg/69 mg AND will follow the recommended dose escalation schedule [ACTION REQUIRED: Documentation is required for approval.]

Reference number(s)
794-C

Quantity Limits Apply

Quantity Limit

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	Dosage	1 Month Limit	3 Month Limit
Qsymia (phentermine/topiramate extended-release)	3.75 mg / 23 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	7.5 mg / 46 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	11.25 mg / 69 mg	30 capsules / 25 days	90 capsules / 75 days
Qsymia (phentermine/topiramate extended-release)	15 mg / 92 mg	30 capsules / 25 days	90 capsules / 75 days

Duration of Approval (DOA)

- 794-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Qsymia [package insert]. Campbell, CA: Vivus LLC; September 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/28/2024).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. Circulation. 2014;129(suppl 2):S102-S138.

5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(2):342–362.
6. US Preventive Services Task Force. Interventions for High Body Mass Index in Children and Adolescents US Preventive Services Task Force Recommendation Statement. JAMA. 2024;Online ahead of print. doi: 10.1001/jama.2024.11146.