

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

WEIGHT LOSS MANAGEMENT

**BRAND NAME
(generic)**

**QSYMIA
(phentermine and topiramate extended-release)**

Status: CVS Caremark Criteria

Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients 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 comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia

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 and over-the-counter drugs and herbal preparations have not been established.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has completed at least 12 weeks of Qsymia 15 mg/92 mg therapy AND
 - The patient lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.
- OR**
- The patient has completed at least 12 weeks of Qsymia 7.5 mg/46 mg therapy AND
 - The patient lost at least 3 percent of baseline body weight OR the patient has continued to maintain their initial 3 percent weight loss. Documentation is required for approval.
- OR**
- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult
- AND**
- 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
- AND**
- The patient has a body mass index (BMI) greater than or equal to 30 kilogram per square meter
- OR**
- The patient has a body mass index (BMI) greater than or equal to 27 kilogram per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)
- AND**
- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine)

REFERENCES

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