

Clinical Policy: Phentermine/Topiramate (Qsymia)

Reference Number: CP.CPA.336

Effective Date: 06.01.18

Last Review Date: 05.21

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Phentermine/topiramate (Qsymia[®]) is a combination of phentermine, which is a sympathomimetic amine anorectic, and topiramate, an antiepileptic drug.

FDA Approved Indication(s)

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.

Limitation(s) 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Qsymia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Weight Management** (must meet all):

1. Member meets one of the following (a or b):
 - a. BMI \geq 30 kg/m²;
 - b. BMI \geq 27 kg/m² with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age \geq 18 years;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
4. Dose does not exceed 15 mg/92 mg per day.

Approval duration: 12 weeks

B. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Weight Management (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. BMI ≥ 25 kg/m²;
3. Member is responding positively to therapy as evidenced by one of the following (a, b, or c):
 - a. If this is the first renewal request, member has lost $\geq 3\%$ of baseline body weight after 12 weeks on Qsymia 7.5 mg/46 mg, unless request is for a dose escalation;
 - b. If this is the second renewal request, member has lost $\geq 5\%$ of baseline body weight;
 - c. If this is a third or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
4. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
5. If request is for a dose increase, new dose does not exceed 15 mg/92 mg per day.

Approval duration:

First reauthorization – 12 weeks

Subsequent reauthorizations – 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMI: body mass index

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications / Boxed warnings

- Contraindication(s): pregnancy, glaucoma, hyperthyroidism, concomitant use or within 14 days of use of a monoamine oxidase inhibitor, or known hypersensitivity to sympathomimetic amines.
- Boxed warning(s): none reported

Appendix D: General Information

- BMI = 703 x [weight (lbs)/height (inches)²]
- Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.
- Qsymia is only available through the Qsymia REMS program due to teratogenic risk.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	<p>3.75 mg/23 mg PO QD for 14 days; then increase to 7.5 mg/46 mg PO QD for up to 12 weeks total; do not exceed 7.5 mg/46 mg dose for patients with moderate or severe renal impairment or patients with moderate hepatic impairment.</p> <p>If patient has not lost at least 3% of baseline body weight on 7.5 mg/46 mg, discontinue or escalate the dose, by increasing to 11.25 mg/69 mg PO QD for 14 days, followed by 15 mg/92 mg PO QD. If patient has not lost at least 5% of baseline body weight on Qsymia 15 mg/92 mg, discontinue Qsymia, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.</p>	15 mg/92 mg per day

VI. Product Availability

Capsules: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg

VII. References

1. Qsymia Prescribing Information. Mountain View, CA: Vivus Inc; October 2020. Available at: www.qsymia.com. Accessed February 12, 2021.
2. Jensen MD, Ryan DH, Apovian CM, 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.
3. 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): 42-362.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: split from CP.CPA.197 Weight Loss; removed requirement for documentation of baseline weight; for re-auth: removed “continuation in a formalized weight management program” as this is difficult to verify/enforce; added that BMI must be ≥ 25 kg/m ² ; references reviewed and updated.	02.12.18	05.18
2Q 2019 annual review: no significant changes; added contraindications; removed criteria for pregnancy test within 30 days since it has REMS; references reviewed and updated	02.05.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.05.20	05.20
Criteria added requiring documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy as per FDA label.	05.26.20	08.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.12.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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