Clinical Policy: Phentermine/Topiramate (Qsymia)

Reference Number: CP.CPA.336
Effective Date: 06.01.18
Last Review Date: 05.24
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, a sympathomimetic amine anorectic, and topiramate, an antiepileptic drug.

FDA Approved Indication(s)

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

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, b, or c):
   a. BMI ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 with at least one indicator of increased cardiovascular risk (e.g., controlled hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
   c. If age is between 12 and 17 years: BMI ≥ 95th percentile standardized for age and sex (*see Appendix D*);
2. Age ≥ 12 years;
3. Documentation supports member's participation in a weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a weight loss program for at least 6 months;

b. Will continue to be actively enrolled in a weight loss program adjunct to therapy;
4. Dose does not exceed 15 mg/92 mg per day.

Approval duration: 12 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Weight Management (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. 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 ≥ 3% of baseline body weight (adults) or baseline BMI (pediatrics) 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 ≥ 5% of baseline body weight (adults) or baseline BMI (pediatrics);
   c. If this is a third or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy;
4. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

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; use during or within 14 days of taking monoamine oxidase inhibitors; known hypersensitivity to phentermine, topiramate, or other components of Qsymia or idiosyncrasy to the sympathomimetic amines
- Boxed warning(s): none reported

Appendix D: General Information

- BMI = 703 x [weight (lbs)/height (inches)^2]
- Qsymia is only available through the Qsymia REMS program due to teratogenic risk.
- BMI cut-offs (95th percentile) for obesity by age and sex for pediatric patients aged ≥ 12 years:

	95th Percentile BMI Value	
Age (in years)	**Male**	**Female**
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3

	95th Percentile BMI Value	
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	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. • After 12 weeks of treatment with Qsymia 7.5 mg/46 mg, evaluate weight loss for adults or BMI reduction for pediatric patients aged 12 years and older. If an adult patient has not lost at least 3% of baseline body weight or a pediatric patient has not experienced a reduction of at least 3% of baseline BMI, increase 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. • Monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 lbs (0.9 kg)/week, consider dosage reduction.	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. Campbell, CA: Vivus Inc; September 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/022580s025lbl.pdf. October 3, 2024.

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.
4. Grunvald E, Shah R, Hernaez R et al. AGA clinical practice guidelines on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198-1225.
5. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity [published online ahead of print, 2023 Jan 9]. Pediatrics. 2023;e2022060640.
6. Data Table of BMI-for-Age Charts. CDC National Center for Health Statistics. Available at: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm. Accessed February 16, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.21.22	05.22
RT4: updated criteria to reflect FDA approved pediatric extension to age ≥ 12 years; for indicators of increased cardiovascular risk, removed coronary artery/heart disease and clarified hypertension should be "controlled".	07.11.22	
Template changes applied to other diagnoses/indications and continued therapy section.	09.28.22	
2Q 2023 annual review: removed continued therapy criterion of BMI ≥ 25 kg/m^2; references reviewed and updated.	01.11.23	05.23
2Q 2024 annual review: for documentation of weight loss program, added members has been actively enrolled for at least 6 months to initial criteria and added a weight loss program that also involves behavioral modification as supported by ACC/AHA guidelines; references reviewed and updated.	01.17.24	05.24
RT4: Updated FDA approved indication(s) section to reflect re-wording of labeled indication	09.24.24	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.