Drug Quantity Management – Per Rx
Weight Loss – Qsymia® (phentermine and topiramate extended-release capsules)

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Product Identifier(s)

108580

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Qsymia. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Qsymia® (phentermine and topiramate extended-release capsules)	3.75 mg/23 mg extended-release capsules	30 capsules	30 capsules
	7.5 mg/46 mg extended-release capsules	30 capsules	90 capsules
	11.25 mg/69 mg extended-release capsules	30 capsules	30 capsules
	15 mg/92 mg extended-release capsules	30 capsules	90 capsules

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Qsymia 3.75 mg/23 mg capsules

1. If the individual is initiating or restarting therapy, approve a one-time override for 46 capsules at retail and home delivery.

Qsymia 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg capsules

No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Qsymia, an appetite suppressant, is indicated as an adjunct to reduced-calorie diet and increased physical activity for **chronic weight management** in:[1]

- Adults with an initial body mass index (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).
- Pediatric patients ≥ 12 years of age with BMI in the 95th percentile or greater standardized for age and sex.

Dosing

Qsymia should be taken orally once daily (QD) in the morning with or without food.[1] The recommended starting dose is 3.75 mg/23 mg QD for 14 days, then increase to 7.5 mg/46 mg QD.

After 12 weeks of treatment with a dose of 7.5 mg/46 mg QD, weight loss/BMI reduction should be evaluated.[1] If an adult has not lost ≥ 3% of their baseline body weight or a pediatric patient has not experienced a ≥ 3% reduction of their baseline BMI, increase the dose of Qsymia to 11.25 mg/69 mg QD for 14 days, followed by 15 mg/92 mg QD.

After 12 weeks of treatment with a dose of 15 mg/92 mg QD, weight loss/BMI reduction should be evaluated.[1] If an adult has not lost ≥ 5% of their baseline body eight or a pediatric patient has not experienced a ≥ 5% reduction of their baseline BMI, discontinue Qsymia, as it is unlikely that the patient will achieve and sustained clinically meaningful weight loss with continued treatment. Discontinuation of Qsymia 15 mg/92 mg should occur gradually by taking Qsymia 15 mg/92 mg once every other day for at least 1 week prior to stopping altogether, due to the possibility of precipitating a seizure.

The rate of weight loss should continue to be monitored in pediatric patients. If the weight loss exceeds 2 pounds (0.9 g) per week, a dose reduction should be considered.[1]

Use of Qsymia should be avoided in patients with end-stage renal disease on dialysis.[1] The maximum dose of Qsymia is 7.5 mg/46 mg QD in patients with severe or moderate renal impairment. Use of Qsymia should also be avoided in patients with severe hepatic impairment. The maximum dose of Qsymia is 7.5 mg/46 mg QD in patients with moderate hepatic impairment. The dose in patients with mild renal impairment or mild hepatic impairment is the same as for patients with normal renal/hepatic function.

Availability

Qsymia extended-release capsules are available in four strengths of phentermine/topiramate: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, and 15 mg/92 mg.[1]

References

1. Qsymia® capsules [prescribing information]. Mountain View, CA: Vivus; June 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
New Policy	--	08/17/2022