DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Weight Loss – Phentermine and Topiramate Drug Quantity Management Policy – Per Rx
- Qsymia® (phentermine and topiramate extended-release capsules – Vivus, generic)

REVIEW DATE: 08/05/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Phentermine/topiramate extended-release (Qsymia, generic) is indicated as an adjunct to reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:[7]
- Adults and pediatric patients ≥ 12 years of age with obesity; and
- Adults with overweight in the presence of at least one weight-related comorbid condition.

Dosing

Phentermine/topiramate extended-release 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/body mass index (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 phentermine/topiramate extended-release 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 phentermine/topiramate extended-release, as it is unlikely that the patient will achieve and sustained clinically meaningful weight loss with continued treatment. Discontinuation of phentermine/topiramate extended-release 15 mg/92 mg should occur gradually by taking phentermine/topiramate extended-release 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 phentermine/topiramate extended-release should be avoided in patients with end-stage renal disease on dialysis.[1] The maximum dose of phentermine/topiramate extended-release is 7.5 mg/46 mg QD in patients with severe or moderate renal impairment. Use of phentermine/topiramate extended-release should also be avoided in patients with severe hepatic impairment. The maximum dose of phentermine/topiramate extended-release 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 in bottles of 30 capsules each: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, and 15 mg/92 mg.[1]

POLICY STATEMENT

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. "One-time" approvals are provided for 30 days in duration.

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, generic)	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

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Phentermine and topiramate 3.75 mg/23 mg extended-release capsules (Qsymia, generic)

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

Phentermine and topiramate 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg extended-release capsules (Qsymia, generic)

No overrides recommended.

REFERENCES

1. Qsymia® capsules [prescribing information]. Campbell, CA: Vivus; September 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/23/2023
Annual Revision	No criteria changes.	09/03/2024
Annual Revision	The title of the policy was changed from "Weight Loss – Qsymia Drug Management Policy – Per Rx" to "Weight Loss – Phentermine and Topiramate Drug Management Policy – Per Rx". Generic phentermine and topiramate extended-release capsules were added to the policy. The same quantity limits and override apply to the generic product as apply to the brand product. The Policy Statement was clarified to note that "one-time" approvals are provided for 30 days in duration.	08/05/2025