Qsymia®
(phentermine and topiramate extended-release capsules) CV

Prescriber Dosing and Management Checklist

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

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

Identify Appropriate Patients

☐ Adults and pediatric patients aged 12 and older with obesity or adults with overweight with at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia

☐ Must NOT be pregnant, trying to get pregnant, or unable/unwilling to comply with contraceptive guidance

☐ Must not have glaucoma

☐ Must not have hyperthyroidism

☐ Must not be using monoamine oxidase inhibitors (MAOIs) or have used them within 14 days

☐ Must not have known hypersensitivity or idiosyncrasy to the sympathomimetic amines

Start

Write 2 prescriptions:

- Qsymia 3.75 mg/23 mg (starting dose) for the first 14 days
- Qsymia 7 .5 mg/46 mg (recommended dose) after the first 14 days
- Once daily, in the morning, with or without food
- Moderate hepatic impairment or moderate/severe renal impairment: dose should not exceed 7 .5 mg/46 mg
- Suggested follow-up: 2–8 weeks

Instruct patients to begin Qsymia treatment as follows:

1. Take only one 3.75 mg/23 mg† capsule each morning for the first 14 days of treatment.
2. AFTER the first 14 days of 3.75 mg/23 mg treatment is complete, take one 7.5 mg/46 mg† capsule each morning.
3. Do NOT take 3.75 mg/23 mg and 7.5 mg/46 mg at the same time.

Counsel Patients

Counsel patients at each visit to:

- Consistently use contraception to avoid pregnancy because of the increased risk of teratogenicity, if the patient is of reproductive potential. Refer these patients to the *Risk of Birth Defects with Qsymia®* patient brochure
- Modify their lifestyle, eat properly, and engage in regular physical activity
- Not share Qsymia with anyone else
- Report any symptoms of concern

Monitor Patients

- Monitor all patients at each visit for:
- Weight, status of comorbidities, and achievement of goals
- Adjustments/modifications to concomitant medications
- Use of effective contraception, if applicable. Test for pregnancy on a monthly basis if patient is of reproductive potential
- Heart rate: discontinue for sustained elevations
- Emergent/worsening depression, suicidal thoughts or behaviors
- Important side effects (e.g., cognitive dysfunction, glaucoma, metabolic acidosis, kidney stones)
    - Consider lowering dose or discontinuing medication for patients who experience important side effects

After 12 weeks at recommended dose of 7.5 mg/46 mg†:

- If weight loss less than 3%, discontinue Qsymia or escalate the dose
- To escalate dose, write 2 prescriptions:
    - Qsymia 11.25 mg/69 mg (titration dose) for 14 days
    - Qsymia 15 mg/92 mg after 14 days
- Qsymia 3.75 mg/23 mg and Qsymia 11.25 mg/69 mg are for titration purposes only
- Instruct patients to escalate the Qsymia dose as follows:
    1. Take only one 11.25 mg/69 mg† capsule each morning for 14 days of dose escalation.
    2. AFTER the 14 days of dose escalation with 11.25 mg/69 mg is complete, take only one 15 mg/92 mg† capsule each morning.
    3. Do NOT take 11.25 mg/69 mg and 15 mg/92 mg at the same time.

After additional 12 weeks following dose escalation to 15 mg/92 mg:

- If weight loss less than 5% after 12 weeks, discontinue treatment

- Discontinue Qsymia 15 mg/92 mg gradually by taking a dose every other day for at least 1 week prior to stopping altogether, due to the possibility of precipitating a seizure with abrupt cessation of the drug

Important Safety Information

Qsymia (phentermine and topiramate extended-release capsules), CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors (MAOIs); or in patients with hypersensitivity or idiosyncrasy to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Pregnancy testing is recommended before initiating Qsymia treatment in patients who can become pregnant and monthly during Qsymia therapy. Advise patients who can become pregnant of the potential risk to a fetus and to use effective contraception during Qsymia therapy.

Topiramate, a component of Qsymia, increases the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Qsymia in patients who experience suicidal thoughts or behaviors. Qsymia is not recommended in patients with a history of suicidal attempts or active suicidal ideation.

Acute angle closure glaucoma has been reported in patients treated with topiramate, a component of Qsymia. Symptoms include acute onset of decreased visual acuity and/or eye pain. Symptoms typically occur within 1 month of initiating treatment with topiramate but may occur at any time during therapy. The primary treatment to reverse symptoms is immediate discontinuation of Qsymia.

Visual field defects (independent of elevated intraocular pressure) have been reported in clinical trials and in postmarketing experience in patients receiving topiramate. In clinical trials, most of these events were reversible after topiramate discontinuation. If visual problems occur at any time during treatment, consider discontinuing Qsymia.

Qsymia can cause mood disorders, including depression and anxiety, as well as insomnia. Qsymia can cause cognitive dysfunction (e.g., impairment of concentration/attention, difficulty with memory, and speech or language problems, particularly word-finding difficulties).

Since Qsymia has the potential to impair cognitive function, patients should be cautioned about operating hazardous machinery, including automobiles.

Qsymia is associated with a reduction in height velocity (centimeters of height gained per year) in obese pediatric patients 12 to 17 years of age. Monitor height velocity in pediatric patients treated with Qsymia. Consider dosage reduction or discontinuation of Qsymia if pediatric patients are not growing or gaining height as expected.

Hyperchloremic, non-anion gap, metabolic acidosis has been reported in patients treated with Qsymia. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing Qsymia.

Qsymia can cause an increase in serum creatinine. The changes in serum creatinine (and measured GFR) with short-term Qsymia treatment appear reversible with treatment discontinuation, but the effect of chronic treatment on renal function is not known. If persistent elevations in creatinine occur while taking Qsymia, reduce the dose or discontinue Qsymia.

Serious skin reactions (Stevens-Johnson Syndrome [SJS] and Toxic Epidermal Necrolysis [TEN]) have been reported in patients receiving topiramate. Qsymia should be discontinued at the first sign of a rash, unless the rash is clearly not drug related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed, and alternative therapy should be considered.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, in adults include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. Common side effects in pediatric patients aged 12 years and older at ≥4% and greater than placebo include depression, dizziness, arthralgia, pyrexia, influenza, and ligament sprain.

VIVUS