Qsymia® (phentermine/topiramate extended-release) – Expanded indication

- On June 24, 2022, the FDA approved Vivus' Qsymia (phentermine/topiramate extended-release), as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with an initial body mass index (BMI) in the 95th percentile or greater standardized for age and sex.

- Qsymia is also approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of:

    - 30 kg/m^2 or greater (obese), or
    - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

- Limitations of use for Qsymia include:

    - 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 drugs, over-the-counter drugs, and herbal preparations, have not been established.

- The approval of Qsymia for the expanded indication was based on a 56-week, randomized, double-blind, placebo-controlled study in 223 pediatric patients (12 to 17 years of age) with BMI ≥ 95th percentile standardized by age and sex. Patients were randomized to receive treatment with placebo, Qsymia 7.5 mg/46 mg, or Qsymia 15 mg/92 mg. The primary efficacy parameter was mean percent change in BMI.

    - At 56 weeks, the percent least-squares mean change from baseline in BMI was +3.3 kg/m^2 with placebo, -4.8 kg/m^2 (difference from placebo -8.1, 95% CI: -11.9, -4.3) with Qsymia 7.5 mg/46 mg, and -7.1 kg/m^2 (difference from placebo -10.4, 95% CI: -13.9, -7.0) with Qsymia 15 mg/92 mg.

- The most common adverse reactions (≥ 4% and greater than placebo) with Qsymia use in pediatric patients aged 12 years and older were depression, dizziness, arthralgia, pyrexia, influenza, and ligament sprain.

- The recommended dosage, titration, and administration of Qsymia in pediatric patients are as follows:

    - The recommended starting dosage is 3.75 mg/23 mg orally once daily for 14 days; after 14 days the recommended dosage should be increased to Qsymia 7.5 mg/46 mg orally once daily.
    - After 12 weeks of treatment with Qsymia 7.5 mg/46 mg, BMI reduction should be evaluated. If a patient has not experienced a reduction of at least 3% of baseline BMI, the dosage should be increased to 11.25 mg/69 mg orally once daily for 14 days; followed by an increase in the dosage to 15 mg/92 mg orally once daily.
    - After 12 weeks of treatment with Qsymia 15 mg/92 mg, BMI reduction should be evaluated. If a patient has not experienced a reduction of at least 5% of baseline BMI, Qsymia should be discontinued as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

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    - The rate of weight loss in pediatric patients should be monitored. If weight loss exceeds 2 lbs/week, dosage reduction should be considered.

- Refer to the Qsymia drug label for dosing and administration recommendations in adults.