VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

QSYMIA™ (phentermine and topiramate)

Effective Date: 10.23.12
Date Developed: 10/15/12 by Albert Reeves MD Last Approval Date: 01/26/16, 01/24/17
Unarchived: 1/22/19
(Archived Date: 1/1/18, 1/22/19)

QSYMIA™ is an anorexiant; anticonvulsant, miscellaneous; sympathomimetic

Pre-Authorization Criteria:

VCHCP will authorize **QSYMIA** ™ for FDA indicated treatment for chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either an initial body mass index (BMI) of ≥30 kg/m^2 **or** an initial BMI of ≥27 kg/m^2 and at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).

QSYMIA ™ is non formulary.

VCHCP requires that **QSYMIA** ™ be prescribed by providers in a contracted weight loss program.

Dosing:

The recommended starting dose is 3.75mg/23mg taken daily, in the morning, for 14 days, then increased to 7.5mg/46mg capsule daily.

- After 12 weeks, response to therapy should be carefully evaluated for discontinuation, no change or dose increase, up to15 mg/92mg daily.
- Response to therapy needs to be re-evaluated after an additional 12 weeks (week 26) if the patient was on the higher dose to determine if weight loss benchmarks have been achieved.
- In the event of discontinuation of the 15 mg/92mg dose due to lack of response or adverse events, *Qsymia* should be gradually decreased by taking a dose every other day for at least a week to prevent possible seizure.

26) Note: *Qsymia* is also available in 3.75 mg/23 mg and 11.25 mg/69 mg, but these doses are for titration purposes only.

Warnings/Precautions

1. The requirement for frequent dosing adjustments, interruption or discontinuation of therapy and clinical monitoring to decrease the potential for drug toxicity and increase the probability for beneficial treatment outcomes:

- The FDA approved *Qsymia* with a Risk Evaluation and Mitigation Strategy (REMS), which consists of elements to assure safe use (ETESU) that include prescriber training, pharmacy certification, and pregnancy monitoring.

    i. *Qsymia* can cause fetal harm and is Pregnancy Category X.

    ii. The purpose of the REMS is to educate prescribers and their patients about the increased risk of birth defects associated with first trimester exposure to *Qsymia,* the need for pregnancy prevention, and the need to discontinue therapy if pregnancy occurs.

    iii. Females of reproductive potential should have a negative pregnancy test before starting *Qsymia* and monthly thereafter during *Qsymia* therapy.

    iv. Unlike other CIV's that may be filled for up to 90 days (depending on the state) at retail, *Qsymia* can only be dispensed every 30 days due to the need for pregnancy monitoring.

2. Contraindications include: Pregnancy, MAO Inhibitors within 14 days
3. Breastfeeding is possibly unsafe
4. Monitor the following:

- Pregnancy at baseline and monthly
- Chemistry profile at baseline then periodically
- Heart rate and Blood Pressure at baseline then periodically
- Behavior changes and suicidality

REFERENCES

QSYMIA TM(phentermine and topiramate extended-release capsules)

Manufactured by:
VIVUS, Inc 1172 Castro Street Mountain View, CA 94040 USA

US Patent Numbers: 7,056,890 and 7,553,818

Revision History:

Date Reviewed/No Updates: 01.16.13 by A. Reeves MD

Date Approved by P&T Committee: 10.23.12; 01.29.13

Date Reviewed/No Updates: 01.28.14 by C. Sanders MD

Date Approved by P&T Committee: 01.28.14

Date Reviewed/No Updates: 01.13.15 by C. Sanders, MD

Date Approved by P&T Committee: 01.27.15

Date Reviewed/No Updates: 01.26.16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 01.26.16

Date Reviewed/No Updates: 01.24.17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 01.24.17

Date Reviewed/No Updates/Date Unarchived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – excluded from Formulary effective 1/1/18
1/22/19	Yes	Catherine Sanders, MD; Robert Sterling, MD	Unarchived – Formulary Exclusion – For Exception Review Use Only Annual Review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI