State Medical Board of Ohio
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Prescribing Qsymia® and Belviq® for Chronic Weight Management
adopted August 15, 2013

Background

Qsymia® (phentermine and topiramate extended-release) and Belviq® (lorcaserin hydrochloride) are FDA-approved Schedule IV medications. They are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 or higher. The drugs may also be used for overweight adults with a BMI of 27 or higher and at least one weight-related condition such as high blood pressure, Type 2 diabetes, or high cholesterol.

Qsymia® and Belviq® are specifically designed for chronic weight management in adults. The Medical Board has received questions about how to prescribe Qsymia® and Belviq® in compliance with Rule 4731-11-04. Medical Board Rule 4731-11-04, Ohio Administrative Code (OAC), *Controlled substances: Utilization for weight reduction*, governs the use of Schedules III and IV controlled substances to assist in weight loss.

General requirements for prescribing controlled substances for weight reduction and management

Before starting treatment for weight reduction that includes a Schedule III or IV controlled substance, the physician has to

- Determine that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the use of controlled substances, and that the treatment has been ineffective.

- Obtain a thorough history, perform a thorough physical examination of the patient, determine that the patient has a BMI of at least thirty, or at least twenty-seven with comorbid factors, and rule out the existence of any recognized contraindications to the use of the controlled substance to be prescribed.

- Assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects from the medication.

When controlled substances are being utilized for weight reduction, the physician shall personally meet face-to-face with the patient, at a minimum, every 30 days, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances. (See 4731-11-04 (C)(1), OAC).

Q and A about Prescribing Qsymia® and Belviq® for Chronic Weight Management

Does the "12 week" treatment limitation apply to Qsymia® or Belviq® ?

No, it does not. Rule 4731-11-04(C)(2), OAC, requires the drug to be prescribed strictly in accordance with the FDA approved labeling. The instructions for the new drugs have more specific instructions for usage, but they are approved for "chronic weight management" and are not limited to use for "a few weeks." Therefore, the 12 week period is not applicable.

Does the requirement that the physician meet face-to-face with the patient at a minimum of every 30 days apply when prescribing Qsymia® or Belviq®?

Yes. Qsymia® and Belviq® are controlled substances. The physician must personally meet face-to-face with the patient, at a minimum, every 30 days, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

Can I prescribe Qsymia® or Belviq® to a patient who has been on phentermine for 12 weeks?

Yes. The patient may be switched to one of the new drugs after 12 weeks on phentermine if there is no interruption in treatment.

Also, the patient may be switched to one of the new drugs if treatment is interrupted for more than 7 days due to one or more of the following reasons (See Rule 4731-11-4(C)(3)):

- Illness /injury to the patient justifying a temporary cessation of treatment;
- Unavailability of the physician;
- Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability;
- The physician has determined, based on sound medical judgment, that an interruption of treatment was medically indicated

However, if a patient's treatment was interrupted for over 7 days for some other reason that those listed above, the patient may not begin treatment with one of the new drugs until 6 months after the last date the physician prescribed phentermine.

When does the "12 week" clock start if Qsymia® or Belviq® is discontinued and the patient is started on phentermine?

The "12 week" duration of treatment clock begins to run at the time the patient is started on phentermine.

Rule 4731-11-04(C)(3) provides that except for specified situations, a physician may not initiate treatment for weight loss with a controlled substance if the patient has received controlled substances for weight loss within the last 6 months. How is the 6 month period calculated?

The date the patient filled the last prescription is day one of the 6 month period during which the physician may not initiate a course of treatment using a controlled substance for weight loss.

How do you calculate the "12 week" clock if a patient is on phentermine, is switched to one of the new drugs, and then switched back to phentermine without an interruption in treatment?

In this scenario the total course of treatment on phentermine cannot exceed 12 weeks. For example, if the patient is on phentermine for four weeks, is switched to one of the new drugs for some period of time, then is switched back to phentermine, the second period on phentermine could not exceed eight weeks. (See Rule 4731-11-04(C)(4), OAC).

The FDA approved labeling for Qysmia® requires that the medication be titrated, starting at 3.75/23 mg for 14 days and then being increased to 7.5/46 mg for 12 weeks. May a physician provide a patient with a prescription for the 3.75/23 mg and the 7.5/46 mg at the first visit?

1. It is recommended that at the first visit the patient only be given the prescription for the 3.75/23 mg dosage for 14 days.

2. The physician should then have the patient return for an office visit within the 14 days to receive a prescription for the 7.5/46 mg dosage.

How is a physician able to prescribe Qysmia® and be in compliance with the weight-loss rule (Rule 4731-11-04, OAC)?

1. It is recommended that at the first visit the patient be given the prescription for the 3.75/23 mg dosage for 14 days.

2. The patient will then return for an office visit within the 14 days to receive a 30-day prescription for the 7.5/46 mg dosage.

3. Starting with the first prescription for the 7.5/46 mg dosage, the physician is required to personally meet face-to-face with the patient to evaluate the patient, at a minimum, every 30 days. (See Rule 4731-11-04(C)(4), OAC). As appropriate, the physician will write the patient another 30-day prescription as part of each office visit.

4. The FDA labeling requires the physician to evaluate the patient for weight loss of greater to or equal to 3% of baseline body weight at the end of 12 weeks on the 7.5/46 mg dosage. If at the conclusion of the 12-week period the patient has not lost at least 3% of baseline weight, the medication may be discontinued or the dosage increased by titration up to a 15/92 mg dosage.

5. If the dosage will be increased, the physician will prescribe a 14-day supply at the dosage of 11.25/69 mg. The patient should then return within the 14 days to receive a 30-day prescription at the 15/92 mg dosage.

6. Starting with the first prescription for the 15/92 mg dosage, the physician is required to personally meet face-to-face with the patient to evaluate the patient, at a minimum, every 30 days. (See Rule 4731-1-04(C)(4), OAC)

7. After 12 weeks at the 15/92 mg dosage, if the patient has not lost at least 5% of baseline body weight, the medication is required by FDA labeling to be discontinued. If the patient has lost at least 5% of baseline body weight, the medication may be continued.

8. As long as the patient remains on Qysmia®, the physician must meet face-to-face with the patient, at a minimum, every 30 days, and record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

Can Qsymia® or Belviq® be refilled?

There is no explicit prohibition in Rule 4731-11-04 against writing refills for one of the new drugs. But the physician is still required to personally meet face-to-face with the patient, at a minimum, every 30 days when controlled substances are being used for weight reduction. The physician must document in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances. (See Rule 4731-11-04 (C)(1), OAC). Therefore, in order to maintain compliance with the rule, the physician should require the patient to return every 30 days for the required face-to-face meeting with the physician and to receive a new prescription. The physician should not write multiple prescriptions with the notation, "Do not fill before ___," as this will discourage the patient from returning for the every 30 day face-to-face visit with the physician and mandatory evaluation of patient progress and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse.

Attachment: Rule 4731-11-04, Ohio Administrative Code

State Medical Board of Ohio
Chapter 4731-11, Ohio Administrative Code Controlled Substances

4731-11-04 Controlled substances: Utilization for weight reduction.

(A) A physician shall not utilize a schedule III or IV controlled substance for purposes of weight reduction unless it has an F.D.A. approved indication for this purpose and then only in accordance with all of the provisions of this rule.

(B) Before initiating treatment for weight reduction utilizing any schedule III or IV controlled substance:

(1) The physician shall determine through review of the physician's own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.

(2) The physician shall obtain a thorough history, perform a thorough physical examination of the patient, determine that the patient has a BMI of at least thirty, or at least twenty-seven with comorbid factors, and rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized.

(3) The physician shall assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.

(C) A physician may utilize a schedule III or IV controlled substance, that bears appropriate F.D.A. approved labeling for weight loss or the maintenance of weight loss, in the treatment of obesity only as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:

(1) The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

(2) The controlled substance is prescribed strictly in accordance with the F.D.A. approved labeling;

(a) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for "a few weeks", the total course of treatment using that controlled substance shall not exceed twelve weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule; and

(b) If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for maintenance of weight loss, that use cannot exceed the time period indicated as effective as reported in the clinical studies' information contained in the F.D.A. approved labeling. That time period includes any interruption in treatment permitted under paragraph (C)(3) of this rule.

(3) A physician shall not initiate a course of treatment utilizing a controlled substance for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. However, the physician may resume utilizing a

controlled substance following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:

(a) Illness of or injury to the patient justifying a temporary cessation of treatment; or

(b) Unavailability of the physician; or

(c) Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability; or

(d) If the physician utilizes a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" and based on sound medical judgment believes that an interruption of that treatment was medically indicated so long as its use is in accordance with paragraph (C) of this rule.

(4) After initiating treatment, the physician may elect to switch to a different controlled substance for weight loss based on sound medical judgment, but the total course of treatment for any combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.

(5) If the patient has continued to lose weight under the short term treatment, the physician may continue therapy utilizing a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" so long as its use is in accordance with paragraph (C) of this rule.

(6) The physician shall not initiate or shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:

(a) That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient's use of drugs or alcohol; or

(b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.

(7) The physician shall not initiate or shall discontinue utilizing all schedule III or IV controlled substances that do not bear F.D.A. Approved labeling which permits long-term use immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days; or

(b) That the patient has repeatedly failed to comply with the physician's treatment recommendations.

(8) The physician shall not utilize any schedule III or IV controlled substance for purposes of weight reduction in the treatment of a patient the physician knows or should know is pregnant.

4731-11-04 Controlled substances: Utilization for weight reduction.

(D) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in Division (B)(2) of section 4731.22 of the Revised Code; "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Effective: 11-17-86; 10-31-98; 6-30-00
Rule Review Date: 12/16/99, 6/30/05