FAQ’s regarding short-term weight loss anorexiants

Rule 4731-11-04, Ohio Administrative Code

1. What are short-term anorexiants?

Short-term anorexiants are those medications in Schedule III or IV that are intended to be used for weight-loss purposes and have FDA-approved labeling indicating that they can be used “for a few weeks.”

2. Can I prescribe or dispense short-term anorexiants for longer than 12 weeks in a row?

No. The FDA-approved labeling for most schedule III and IV anorexiants mentions prescribing for “a few weeks”. Ohio Administrative Code (OAC) Rule 4731-11-04(C)(2)(A) clarifies that labeling requirement to mean twelve weeks.

3. Can those 12-weeks use of schedule III and IV short-term anorexiants be interrupted for any reason?

Yes, IF:
- your patient’s illness or injury justifies a temporary cessation of treatment;
- you are unavailable; or
- your patient is unavailable, and your patient notifies you about that unavailability.

4. Can I prescribe schedule III and IV short-term anorexiants off label that I intend be used for weight loss?

No. OAC Rule 4731-11-04(C)(2) requires that schedule III and IV short-term anorexiants used for weight loss can only be employed consistent with FDA labeling.

5. Can I prescribe or dispense a short-term anorexiant during the first patient visit?

It depends. OAC Rule 4731-11-04(B)(1) requires that you do the following prior to beginning treatment with schedule III and IV short-term anorexiants:

- review your own records of any prior treatment of that patient for weight loss;
- review records of any prior treatment by another treating physician or weight-loss program, if available;
- determine that the patient has made a substantial good-faith effort to lose weight without utilizing short-term anorexiants;
- determine that those prior good-faith efforts included caloric restriction, nutritional counseling, behavior modification, and exercise;
- determine that those prior good-faith efforts were ineffective;
- obtain a thorough history;
- perform a thorough physical examination;
- determine that the patient has a body mass index (BMI) of at least 30 or a BMI of at least 27 with comorbid factors;
- determine that there are no signs in the patient of drug or alcohol abuse;
- determine whether there are any contraindications for the use of schedule III or IV short-term anorexiants in the patient;
- determine whether there are any adverse side effects for the use of schedule III or IV short-term anorexiants in the patient; and
- determine that the patient has not used a schedule III or IV short-term anorexiant within the prior six months.

OAC Rule 4731-11-02(D) requires that you document all of the above in the patient record. If you have completed all of the above, then, if appropriate, you may begin prescribing or dispensing schedule III or IV short-term anorexiants.

6. What if my patient has not made a prior substantial good-faith effort to lose weight by caloric restriction, nutritional counseling, behavior modification, and exercise without utilizing schedule III or IV short-term anorexiants? Can I start prescribing or dispensing schedule III or IV short-term anorexiants at the first visit?

No. Your patient must have made a substantial good-faith effort to lose weight by caloric restriction, nutritional counseling, behavior modification, and exercise and that effort must have proved ineffective, before you can prescribe or dispense a schedule III or IV short-term anorexiant.

7. Can I allow my physician assistant to see the patient instead of me after the first visit?

No. OAC Rule 4731-11-04(C)(1) requires that you personally see the patient at least every 30 days.

8. Do I have to document the patient’s weight in the chart on every visit related to weight loss?

Yes.

9. Does my patient have to lose weight over every 30-day period that I prescribe or dispense schedule III or IV short-term anorexiants?

No. If your patient fails to lose weight after the first 30-day period, you may, if medically indicated, continue to treat that patient for an additional 30 days by prescribing a different schedule III or IV short-term anorexiant. If the patient loses weight after the switch to a different anorexiant, you may continue to prescribe or dispense that anorexiant month by month IF the patient continues to lose weight every month.

10. Are there any reasons that require me to stop utilizing schedule III or IV short-term anorexiants for treating a patient for weight loss?

Yes. You must stop utilizing schedule III or IV short-term anorexiants to treat a patient IF:
- your patient fails to lose weight at any visit except as described in FAQ number 8 above;
- your patient has a history of, or shows a propensity for, alcohol or drug abuse;
- your patient has made any false or misleading statement to you relating to the patient's use of drugs or alcohol;
- your patient has consumed or disposed of any controlled substance other than in strict compliance with your directions;
- your patient has repeatedly failed to comply with your treatment recommendations; or
- if you know, or should know, that your patient is pregnant.

11. 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. Does this require a six-month pause before switching a patient from Qsymia® to a short-term weight loss drug?

No. Although Qsymia® is a controlled substance, it is FDA-approved for chronic weight management instead of weight loss. A patient who has been on Qsymia® or another chronic weight management drug may be switched to a short-term weight loss drug without a six-month break.

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