

Introduction

Overweight and obesity are defined as excessive fat accumulation that can be diagnosed by several measures, including body mass index (BMI), body-fat percentage, and/or waist circumference (download the free Obesity Algorithm[®] at www.obesityalgorithm.org for more information). Obesity is recognized as a chronic disease deserving of consistent, long-term medical treatment, which can include pharmacotherapy. Therefore, it is the position of the Obesity Medicine Association (OMA) that pharmacotherapy may be used for patients affected by obesity, but only in a comprehensive obesity management program that includes a thorough medical evaluation and support for lifestyle change.

Background

Indications for pharmacotherapy are currently defined by the U.S. Food & Drug Administration (FDA) according to BMI. OMA believes that this definition is too narrow in scope and should be expanded to include the presence of excess adiposity by any of the commonly used measures of excess body fat. The chronic nature of the disease necessitates targeting not only the primary outcome of improved weight and body composition, but also maintenance of these improvements and prevention of weight regain. OMA believes that the use of pharmacotherapy should be based upon the scientific evidence available, FDA guidance, current standards of care and the clinical judgment of the practicing clinician. Currently, the options for treatment may include FDA-approved prescription anti-obesity medications such as phentermine, diethylpropion, phendimetrazine, Xenical (orlistat), Qsymia (phentermine + topiramate extended release), Belviq (lorcaserin), Contrave (naltrexone + bupropion), and Saxenda (liraglutide).

Evidence

The prescribing practices of trained obesity medicine physicians are based upon the scientific literature, expert opinion and the clinical needs of the individual patient. In medical obesity treatment, a relatively young scientific field where science is advancing rapidly, routine prescribing practices of obesity medicine physicians may have moved forward from the most recent published guidelines or FDA labeling. Components of comprehensive treatment may additionally include some or all of the following: support visits, nutritional interventions, intensive behavioral therapy, exercise programs, skilled medical management, anti-obesity medications, and/or bariatric surgery.

As obesity is a chronic disease with a high risk of relapse when treatment is discontinued, treatments that are offered must be appropriate for chronic use. This applies for support visits, nutritional interventions, behavioral programs, exercise programs, medical care, anti-obesity medications, and even surgery. Pharmacotherapy for the treatment of obesity should be prescribed only by licensed health care professionals qualified by training and experience to treat obesity. Consider the treatment of hypertension or hyperlipidemia: if medical treatment is administered, the disease state is improved. However, if the treatment is stopped, the disease relapses or recurs. Due to enhanced medical knowledge, the indications for treatment of hypertension and hyperlipidemia have changed significantly in the past 50 years. The original National Cholesterol Education Program guidelines recommended treatment only if the LDL cholesterol was high enough. New guidelines from the American Heart Association recommend treatment for individuals at high risk for heart disease, regardless of the level of LDL.¹

Purpose

Similarly, we now see a clinical change in how anti-obesity medications are used. The original labeling of anti-obesity medications directed that they should only be used short-term. Unfortunately, use in this way is not effective in the long run for chronic disease management and should not be encouraged. The new generation of drugs are labeled for use by the FDA for chronic use, provided that the individual is of initial appropriate risk to be placed on the medication and demonstrates adequate weight loss.^{ii,iii}

It is the position of OMA that anti-obesity medications, both of the older and newer generations, may be used for long-term weight control, similar to the use of anti-hypertensives, anti-diabetics, and lipid lowering treatments. This belief is grounded in several facts:

- Several medications have been on the U.S. market for more than 50 years and there has been no evidence of harm when prescribed appropriately by trained practitioners whether used short or long-term.
- Some new anti-obesity drugs have been studied and found to be safe and effective for up to a two-year period.^{iv} There is no reason to believe that the older anti-obesity drugs would have any additional risk compared to that which was found with the new anti-obesity drugs, particularly in light of the fact that three of the new drugs contain older medications, and one includes phentermine.
- These medications, when added to a properly supervised intensive behavioral program, significantly improve the odds of achieving a 5-10% weight loss (or more), which has been recognized by the National Institutes of Health and the Institute of Medicine as reducing the health risks of obesity—particularly reducing the risk of developing type 2 diabetes.
- Approximately 80% of patients with obesity who lose weight return to their previous weight due to metabolic changes. These adaptations may include increases in appetite as well as decreased energy expenditure. This biologic propensity for regain explains the necessity of persistent treatment to prevent relapse.

Summary

Because the increased health risks associated with overweight and obesity occur without threshold, we believe that there should be no absolute contra-indications for the use of pharmacotherapy for obesity based on BMI, body-fat percentage, or waist circumference. Because overweight and obesity are chronic medical conditions, there should be no time limitation on the use of any existing pharmacotherapy for obesity. Patients undergoing long-term pharmacotherapy should be monitored as recommended by the FDA in the first 12 weeks of therapy for efficacy and side effects, followed by continued monitoring that is individualized to a patient's needs and disease state and appropriate for the level of risk of the medication(s) being used, so that medications and dosages may be adjusted for optimum treatment. Since obesity is a chronic illness similar to diabetes and hypertension, therapy (including pharmacotherapy) should be continued as long as required, provided patient treatment benefit exceeds treatment risk. Chronic use of all approved medications for the treatment of obesity may be used if the risk-benefit ratio is favorable in the judgment of the treating physician.

About Obesity Medicine Physicians

Obesity medicine physicians dedicate a portion or all of their practices to the treatment of obesity. They perform a medical evaluation that typically includes a patient history, physical exam, laboratory work,

EKG monitoring, and body composition measurements. They also provide medical supervision for lifestyle changes (i.e., nutrition, physical activity, behavior, and medication). Obesity medicine physicians certified by the American Board of Obesity Medicine have been acknowledged to meet professional proficiency and testing standards. OMA recognizes that obesity is a chronic medical disease including the possibility of lifelong treatment.

ⁱ Stone NJ et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association/American Heart Association Task Force on Practice Guideline."Circulation November 12, 2013.

ⁱⁱ <https://www.qsymia.com/pdf/prescribing-information.pdf>

ⁱⁱⁱ http://www.belviq.com/pdf/Belviq_Prescribing_information.pdf

^{iv} <http://www.clinicaltrials.gov/ct2/show/NCT00553787?term=NCT00553787&rank=1>

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