KAISER PERMANENTE

Weight Management in Adults Screening and Intervention Guideline

Last guideline approval: December 2012

Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

Prevention

The following recommendations for prevention of overweight and obesity in adults are adapted from the 2010 Scottish Intercollegiate Guidelines Network (SIGN) guideline on managing obesity.

Nutrition

- Minimize intake of high-calorie foods (i.e., foods with significant fat and/or sugar content) by selecting low-calorie foods instead (i.e., fruits and vegetables).
- Learn and control portion sizes, and follow recommended numbers of servings for a healthy diet.
- Limit juice, soda, sports drinks, and other sweetened beverages, and drink water to satisfy thirst.
- Limit alcohol intake.

Healthy eating behaviors

- Eat regular family meals, including breakfast, without distractions (e.g., television) when possible.
- Limit meals eaten outside the home, especially those at fast-food restaurants. When eating out, include fruit and vegetable options.

Physical activity

- Engage in 30–60 minutes of moderate- to vigorous-intensity physical activity most days per week.
- Limit sedentary time (e.g., time spent using computer, playing video games, watching television).

Screening

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all adults for obesity, which is defined as a body mass index (BMI) of 30 or higher.

BMI is calculated by measuring weight in kilograms, then dividing by height in meters squared (kg/m2). BMI should be assessed at the following frequency:

- Every visit in primary and consultative care.
- Every hospital admission.

Waist circumference may be used, in addition to BMI, to refine assessment of risk of obesity-related comorbidities. Men with a waist circumference greater than 40 inches (greater than 102 cm) and women with a waist circumference greater than 35 inches (greater than 88 cm) are at increased risk for obesity-related health problems.

For additional information on BMI and waist circumference, see the CDC's Healthy Weight website (www.cdc.gov/healthyweight/assessing/). The site includes a BMI calculator (www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html).

Diagnosis

Table 1. Adult classification of weight by BMI	
Clinical classification	**BMI**
Underweight	Lower than 18.5
Normal weight	18.5–24.9
Overweight	25.0–29.9
Obesity	30.0–39.9
Morbid obesity	35.0 and higher **with** comorbidities [1] 40.0 and higher **without** comorbidities [1]
[1] Comorbidities include: dyslipidemia, diabetes, hypertension, coronary heart disease, sleep apnea, and severe osteoarthritis.	

BMI does not take into account the difference between lean and fat body mass. Therefore, it is possible for a healthy, muscular individual with low body fat to be classified as overweight or obese using the BMI formula (kg/m^2).

Interventions

Adults with a body mass index (BMI) of 30 or higher should be offered intensive, multicomponent behavioral interventions with a focus on both diet and physical activity (USPSTF 2012).

Weight loss can improve fasting glucose levels, type 2 diabetes, dyslipidemia, hypertension, coronary heart disease, obstructive sleep apnea, osteoarthritis, and degenerative joint disease (NIH 1998, WHO 2000).

Goals

Table 2. Recommended goals for adults	
Eligible population	**Goal**
BMI 18.5–24.9	Maintain weight.
BMI 25.0 or higher	For most patients, 5–10% weight loss over 6 months is a realistic initial goal. When the patient has reached and maintained the initial goal weight for 12 months or more, consider setting a new goal.

Strategies to help with weight loss

Table 3. Strategies to help adults with weight loss	
BMI	**Strategy**
BMI 30.0 to 39.9 **without** comorbidities	▪ Behavior change counseling (see following section) ▪ Lifestyle modifications (see page 7)
BMI 25.0 to 34.9 **with** comorbidities	▪ Behavior change counseling (see following section) ▪ Lifestyle modifications (see page 7) ▪ Consider a short trial of pharmacotherapy[1] (see page 9)
BMI 35.0 to 39.9 **with** comorbidities or BMI 40.0 or higher	▪ Behavior change counseling (see following section) ▪ Lifestyle modifications (see page 7) ▪ Consider a short trial of pharmacotherapy[1] (see page 9) ▪ Consider bariatric surgery (see page 10)
[1] Pharmacotherapy has limited efficacy, and most patients experience some side effects. Orlistat side effects include: abdominal pain, fecal leakage and urgency, flatulence, headache, back pain, and upper respiratory infection. Rare cases of severe liver injury have also been reported; however, a cause-and -effect relationship has not been established.	

Behavior change counseling using the 5A approach

Success in weight loss depends less on any specific intervention modality than on the delivery of personalized advice to patients, repeated in different forms by several sources over a long period (LeBlanc 2011, Glasgow 2003).

The use of a behavior change counseling approach such as the 5As may allow clinicians to support patients in making changes to eating and physical activity behaviors. The 5As—Ask, Advise, Assess, Assist, Arrange—are an adaptation of motivational interviewing.

Conversation 1a. Ask
Conversation 1b. Advise
Conversation 1c. Assess
Conversation 1d. Assist
Conversation 1e. Arrange

Conversation 1a. Ask Attempt to engage all overweight and obese patients in conversation about their weight.	
Talking points	▪ "Would it be OK if we take a few minutes to talk about your health and weight?" ▪ "What thoughts do you have about your weight?" ▪ "Has your weight kept you from doing things you wanted to do?" ▪ "What connection, if any, do you see between your [condition] and weight?" – "Would you like to have more information about this connection?" – "What have you tried to achieve a healthy weight?"

Conversation 1b. Advise
Urge all overweight and obese patients to lose weight. Advice should be delivered in a clear and personalized manner.

Talking points

- "Adults who are overweight or obese can sometimes have difficulties with self-esteem and depression, and can experience a lower overall quality of life compared with adults who are not overweight."
- "Adults who are overweight or obese are more likely to have or to develop chronic conditions, including high blood pressure, high cholesterol, sleep apnea, osteoarthritis, cancer, type 2 diabetes, and liver disease."
- "I'm concerned that your BMI may contribute to your [condition]. As your doctor, I believe a healthy diet and exercise are important to your health."

Conversation 1c. Assess
Determine the patient's willingness to attempt to lose weight, including making a change to eating and/or physical activity at this time (e.g., within the next 30 days).

Talking points

- "On a scale of 0 to 10, how ready are you to consider making a healthy change in your eating or physical activity?" (Scale: 0 = not ready 5 = unsure 10 = ready)
- "How ready would you say you are to make this [specific change]?" (If high on readiness, 7–10, follow up with the next question.)
  - "How confident do you feel about making this change?" (This distinguishes those who are ready and confident from those who are ready and lacking in confidence.)
- "What are the three best reasons to make this change?"
- "How might you go about it, in order to succeed?"

Conversation 1d. Assist
Help the patient to move along the continuum of readiness to change.

Talking points

Not ready to change (0–3)
Leave the door open to further conversations.

- "Lots of people find it hard to consider making changes to their lifestyle. This may not be the right time for you. I'm here to help you, and when you're ready, I'd be happy to talk with you about how you might try to make some changes."
- "If you maintain your current weight and avoid further gains, you are taking a successful step toward staying healthy."

Unsure about change (4–6)
Explore ambivalence.

- "What do you like about the way things are now?"
- "What don't you like about the way things are now?"

Ask about the next step.

- "What would need to be different for you to feel you are ready to start eating healthier?"
- "What would need to be different for you to feel you are ready to start being more physically active?"
- "Is there anything you'd like to do between now and our next visit?"

Ready to change (7–10)
Strengthen commitment.

- "It's great to know that you are ready to change the way that you are eating."
- "What are the two most important reasons for you wanting to get more exercise?"

Facilitate action planning.

- "How might you go about making this change?"
- "What might get in your way?"
- "Could you plan around these roadblocks?"
- "What is your next step?"

If patient cannot or does not identify any next steps, try offering some suggestions. (See also "Healthy eating and active living," under "Lifestyle modifications.")

Conversation 1e. Arrange Arrange for follow-up contacts with the patient, either in person or by phone. Also provide an after-visit summary (e.g., **.avswt, .avswtcalories, .avswtprograms, .avswtfoodchoices, .avswtgetmoving**).	
Talking points	**Not ready to change** ▪ "When you are ready, I am here to support you. I look forward to your next visit. As part of your well visit care, I will continue to track your weight and height, and let you know how you are doing." ▪ "Even if you are not ready to make any changes, I'll plan on checking in with you about this in the future."
	Unsure about change "What information or resources would you be interested in as you consider healthy eating and getting active?"
	Ready to change "I am really glad that you are ready to start [walking, attending Weight Watchers meetings, etc.]."
	All patients ▪ "Would it be OK if one of my team checked back with you about this in the next couple of weeks?" ▪ "Let me or my team know how you are doing by secure message or by phone, or at your next visit."

Lifestyle modifications

Healthy eating and active living

These strategies can help adults manage their weight.

Healthy eating tips

- Drink more water and less soda or sugary drinks.
- Eat healthy snacks instead of processed foods (crackers, cookies), sweets, or candy.
- Limit meals eaten outside the home.
- Eat breakfast every morning.
- Remember that healthy changes do not mean that some foods or drinks are "off limits." Moderation is key. For example:
  - Split dessert with a friend or family member.
  - Drink half a can of soda.
  - Cut out one fast-food or restaurant meal a week.

For more information, see the U.S. Department of Health & Human Services' Dietary Guidelines for Americans website (www.health.gov/dietaryguidelines/) and the U.S. Department of Agriculture's Choose My Plate website (www.choosemyplate.gov/).

Nutritional advice

A healthy diet:

- Emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products.
- Includes protein such as lean meats, poultry, fish, beans, eggs, and nuts.
- Is low in saturated fats, trans fats, cholesterol (less than 200 mg per day), sodium (1,500–2,300 mg per day), and added sugars.
- Balances calorie intake from food and beverages with calories expended.

General recommendations for a balanced meal plan for weight loss include the following:

- Aim for cutting current calorie intake by 500 calories per day. This helps with moderate and sustainable weight loss of approximately 1 pound per week (3,500 calories = 1 pound).
- Protein: Range is 15–35% of daily calories.
  - General rule of approximately 0.8 grams of protein per kilogram of body weight. Eating too much protein often leads to weight gain due to excess calories.
  - Include some dairy protein or calcium fortified alternatives like soy to increase calcium content of the diet.
- Fat: Range is 25–35% of daily calories.
  - Reduce intake of saturated fats (i.e., those found in animal products, high-fat dairy, and plant oils such as palm and coconut oil).
  - Replace saturated fats with poly- and monounsaturated fats. These foods include nuts, olive oil, canola oil, safflower oil, fish, and avocado.
  - Eliminate or reduce trans fats. These are found in many snack foods, margarines, and deep-fried and packaged foods. (When labels list hydrogenated oils, the foods contain trans fats.)
- Carbohydrates: Range is 35–60% of daily calories.
  - Include 4–5 servings of fruit (total of 2 or more cups per day) and 4–5 servings of vegetables (total of 2½ or more cups per day).
  - Focus on whole-grain breads and cereals. The label on a whole-grain food specifically says “whole” (e.g., whole wheat).
  - Limit refined sugars, such as white bread and processed sweets (cookies, cake, donuts).
- Cholesterol: Reduce to fewer than 200 mg per day.
- Fiber: Get at least 20–35 grams per day. Increase fiber slowly to avoid gastrointestinal distress.

Patients with nutrition-related comorbidities who are motivated to make dietary changes may be referred to a Registered Dietitian for individualized guidance on weight management. Nutrition-related comorbidities include diabetes, renal disease, heart disease, hypertension, hyperlipidemia, and gout. Patients who have demonstrated signs of eating disorders, such as binging, purging, and hiding food, should be referred to a Registered Dietitian and/or BHS.

Increasing physical activity

Engage in at least 30 minutes of moderate-intensity physical activity on most—preferably all—days of the week. For most people, greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or of longer duration. To maintain weight loss, 60 to 90 minutes of moderate-intensity physical activity per day is recommended.

Active living tips:

- Walk with family or pets after dinner.
- Play a team sport.
- Make the commute to work an active one (bus, walk, bike).
- Park farther from the store; get off the bus one stop early.
- Sign up for a dance class with a friend.

Decreasing sedentary activity

- Limit time spent watching television, using the computer, and playing video games to less than one hour a day.
- During long periods of sitting at work or home, get up once an hour and take a brisk 3-minute walk.
- Remember that making changes does not mean that certain activities are "off limits." Moderation is key. For example:
  - Watch 1 hour of TV a night instead of 2.
  - Play video games for 1 hour, then take an hour-long walk.

Diet and commercial weight-loss programs

Structured diet or weight-loss programs (e.g., Jenny Craig® and Weight Watchers®) may help with weight management. There are many popular programs, with varying levels of evidence on their effectiveness.

(Note that Weight Watchers program discounts are no longer available to members, so those who want to participate must pay retail rates.)

It is important for patients to avoid any programs that promise a "quick fix" or make unrealistic claims. When choosing a program—regardless of the type (in person, web based, or phone based)—patients should make sure it includes the following components:

- Focuses on long-term lifestyle change.
- Addresses both healthy eating and exercise.
- Sets realistic short-term goals (i.e., weight loss of 5–10% current total body weight).
- Promotes gradual weight loss (i.e., 0.5–2 lbs per week).
- Has a program to maintain goal weight once reached.
- Includes behavior modification (e.g., meal planning, food diary, etc.).

Successful weight management depends less on the diet or weight-loss program chosen than on the consistency and continuity of healthy nutritional choices throughout the patient's life. Be aware that some patients' diet-program choices may have adverse physiologic effects on blood glucose, blood pressure, and/or lipids.

Health coaching

Health coaching is a free, phone-based service available to all members aged 18 years and older. Health professionals, including nurses and dietitians, help members meet their goals in the areas of weight management, physical activity, and nutrition.

Pharmacotherapy

Use pharmacotherapy only as part of a comprehensive treatment program that includes healthy eating, physical activity, and behavioral change counseling. Pharmacotherapy has limited efficacy, and most patients experience some side effects. Very few studies of obesity medications have demonstrated sustained weight maintenance after discontinuation of the drug.

Although several weight-loss medications are available on the market, the only one recommended is orlistat. Side effects of orlistat include abdominal pain, fecal leakage and urgency, flatulence, headache, back pain, and upper respiratory infection. Orlistat, however, is not on the Drug Formulary.

Rare cases of severe liver injury have also been reported; however, a cause-and-effect relationship has not been established. See also the FDA Drug Safety Alert regarding severe liver toxicity and orlistat (www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213038.htm).

Table 4. Using orlistat to assist adults with weight loss

Eligible patients	Dosage forms	Initial dose	Maximum dose
BMI 30.0 or higher	120 mg (Rx)	120 mg three times daily	No additional benefit with dosages higher than 120 mg three times daily; safety and efficacy beyond 2 years is unknown.
BMI 25.0–29.9 **with** comorbidities	60 mg (OTC)	60 mg three times daily	

Pharmacologic options that are not recommended

The following medications are not recommended for weight loss, due to their potential side effects (increased heart rate and blood pressure) and potential for abuse:

- Dextroamphetamines (Dexedrine, ProCentra)
- Diethylpropion
- Methamphetamine (Desoxyn)
- Phendimetrazine (Bontril Slow-Release, Bontril PDM)
- Phentermine (Suprenza, Adipex-P)
- Benzphetamine (Didrex)

Metformin is not recommended for nondiabetic patients and is not FDA approved for weight loss, although diabetic patients taking metformin may experience modest weight loss.

Phentermine plus topiramate (Qsymia) and lorcaserin (Belviq) are not recommended for weight loss based on a March 2013 review by the Pharmacy and Therapeutics (P&T) Committee. Although the FDA approved both of these medications in 2012, P&T expressed concerns about the lack of data on long-term safety and clinical benefits, as well as about data showing significant weight gain after the drugs were discontinued.

Bariatric surgery

The consensus opinion of the guideline team is that clinicians should discuss behavioral weight-loss programs with patients considering bariatric surgery. Bariatric surgery may be an option for the individuals below. The following comorbidities and risk factors can be improved with surgery: impaired fasting glucose, type 2 diabetes, dyslipidemia, hypertension, coronary heart disease, obstructive sleep apnea, osteoarthritis, and degenerative joint disease (NIH 1998, WHO 2000).

Table 5. Recommendations for bariatric surgery to assist adults with weight loss

Eligible patients	Details
BMI 40.0 or higher	Roux-en-Y gastric bypass is the most commonly performed type of bariatric surgery. Other procedures include gastric banding[1] and vertical sleeve gastrectomy.
BMI 35.0 to 39.9 **with** comorbidities	

[1] Gastric banding is FDA approved for patients with BMI 30.0–34.9; however, there is insufficient evidence to determine the long-term efficacy and safety of the procedure in that population.

For information about patient eligibility, see Clinical Review Criteria: Bariatric Surgery and Referral Checklist.

Bariatric surgery candidates are required to complete a medical and psychological assessment (based on protocol and their particular health history), attend a mandatory pre-op class, and meet individually with one of the bariatric surgeons. For more information about the bariatric program, see What Happens After You Request Bariatric Surgery.

The bariatric team expects to follow patients for 5 years after surgery. Labs (e.g., complete blood count, vitamin B12) are done at yearly bariatric follow-ups, more frequently in the first 2 years. After 5 years, patients are referred back to their primary care physicians (PCPs) for yearly bariatric labs and follow-ups.

Patients are expected to continue seeing their PCPs for management of comorbidities and routine nonbariatric care.

Comorbidities

Hypertension and diabetes screening

Hypertension and diabetes are common comorbidities in overweight and obese adults. Screening recommendations for these conditions can be found in the Type 2 Diabetes Screening and Treatment Guideline and the Hypertension Diagnosis and Treatment Guideline.

Depression screening

Screen overweight and obese adults for depression by using the Patient Health Questionnaire (PHQ-9). Evidence suggests that patients with depression are less likely to be adherent to recommended management plans and less likely to be effective at self-management of chronic conditions. However, evidence also suggests that female depressed patients engaged in a group weight-loss program can lose just as much weight as non-depressed patients, with the added benefit of reduced depressive symptoms (Ludman 2009).

See the Adult Depression Screening, Diagnosis, and Treatment Guideline for additional guidance. Patients with major depression can be treated in primary care or offered a referral to Behavioral Health Services for counseling and/or drug therapy.

Sleep apnea screening not recommended

Routine screening for sleep apnea is not recommended because evidence is lacking regarding whom to screen and the effectiveness of treatment.

Evidence Summary

To develop the Adult Weight Management Guideline, the guideline team:

- Reviewed evidence using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.
- Adapted some recommendations from the following externally developed evidence-based guidelines:
  - Management of Obesity: A National Clinical Guideline, Scottish Intercollegiate Guidelines Network (SIGN), 2010 (www.sign.ac.uk/pdf/sign115.pdf).
  - Screening for and Management of Obesity in Adults, U.S. Preventive Services Task Force, 2012. (www.sign.ac.uk/pdf/sign115.pdf)

Commercial weight-loss programs

A 2005 systematic review of commercial weight-loss programs concluded that with the exception of Weight Watchers, the evidence to support use of the major commercial and self-help weight-loss programs is suboptimal (Tsai and Wadden 2005). The review identified one multicenter and two single-center randomized controlled trials totaling 551 subjects. The multicenter RCT (Heshka 2003) found significantly more weight loss after 1 and 2 years with Weight Watchers compared with a self-help intervention. The absolute difference in weight loss between groups was 3.0 kg after 1 year and 2.7 kg after 2 years.

The Dansinger (2005) RCT found that 4 popular diet programs (Weight Watchers, Atkins, Ornish, and the Zone) had similar efficacy. There was statistically significant weight reduction of 2–3 kg in each group at 1 year compared with baseline, but no significant between-group differences. The study also found a statistically significant association between dietary adherence and weight loss for each diet. Implications of the Dansinger study are that all of these popular diets can be effective if patients are able to adhere to them.

Behavior change counseling

The recommendations regarding behavior change counseling were adapted from the 2012 USPSTF guideline. They recommend that adults with a body mass index (BMI) of 30 or higher be offered intensive, multicomponent behavioral interventions with a focus on both diet and physical activity (USPSTF 2012).

Pharmacotherapy

Orlistat plus a reduced-calorie diet vs. placebo plus a reduced-calorie diet

Results from RCTs suggest that in obese adults, orlistat plus a lifestyle intervention may promote modest weight loss compared with placebo plus a lifestyle intervention; however, orlistat is associated with adverse events such as gastrointestinal problems. A 2003 Cochrane meta-analysis of RCTs found that compared with placebo, patients who took orlistat lost 4.25 kg more weight (Padwal 2003). Since the Cochrane meta-analysis, 3 RCTs and 1 meta-analysis evaluated the efficacy of orlistat alone or combined with diet and/or exercise for the treatment of obesity.

Three recent double-blind RCTs evaluated the safety and efficacy of orlistat (120 mg) plus a reduced-calorie diet with placebo plus a reduced calorie diet. The first study followed 254 obese patients with type 2 diabetes for 12 months and found that patients who received orlistat had significantly greater reductions in weight, BMI, and waist circumference compared with patients who received placebo. Patients who received orlistat reported more adverse events compared with patients who received a placebo. Adverse events included: flatulence, constipation, abdominal pain, fatty/oily evacuations, increased defecation, fecal urgency, and malaise (Derosa 2010).

The second trial evaluated the efficacy of orlistat (120 mg) plus a reduced-calorie diet compared with placebo plus a reduced-calorie diet in 166 obese patients with hypercholesterolemia. Compared with patients who received placebo, patients who received orlistat had significantly greater reductions in weight and BMI (de Castro 2009).

The third RCT, which included 131 subjects, evaluated whether a 24-week weight-loss program with orlistat (60 mg 3 times daily) in overweight subjects would produce greater changes in visceral adipose tissue compared with placebo. Results from this study suggest that adding orlistat to diet and exercise significantly reduced visceral adipose tissue compared with diet and exercise alone (-0.59 kg vs. -0.37 kg, P<0.05). Results from this study should be interpreted with caution as it was funded and conducted by the manufacturer and there were several methodological limitations. Additionally, 76% of subjects in the orlistat group experienced GI side effects (Smith 2011).

Adverse events with orlistat

With regard to adverse events, a recent meta-analysis that included 15 studies and 6,590 subjects estimated the risk of discontinuation due to adverse events in trials of orlistat (120 mg). Findings from this study indicate that compared with patients receiving placebo, adverse-event dropout rates were significantly higher in patients receiving orlistat (Risk Difference 0.03, 95% CI 0.01 to 0.04, NNH 39). Gastrointestinal problems were the most commonly reported adverse events (Johnasson 2009).

Phentermine plus topiramate (Qsymia)

Results from 2 RCTs and an extension study suggest that the combination of phentermine plus topiramate may lead to significantly greater reductions in weight compared with placebo after 1 year; however, there is insufficient evidence to determine the long-term safety and efficacy of this medication. Additionally, the trials were conducted among a highly selected group of patients, which limits generalizability.

The first RCT was the EQUIP study. This trial followed 1,267 overweight and obese adults for 56 weeks to evaluate the safety and efficacy of two different doses of phentermine plus topiramate (15/92 mg or 3.75/23 mg) plus a lifestyle intervention compared with placebo plus lifestyle interventions. Results from this study suggest that compared with placebo, subjects taking phentermine plus topiramate had significantly greater reductions in mean body weight; in addition, significantly more subjects lost 5% or more of their baseline body weight. There was no significant difference in serious adverse events. Patients in the 15/92 group experienced more paresthesia, dry mouth, constipation, and dysgeusia compared with the placebo group. A limitation of the study is generalizability, as the majority of patients included in the study were white women. Additionally, 40% of patients did not complete the study (Allison 2012).

Mean change from baseline to 56 weeks in body weight outcomes (Allison 2012)

	15/92	3.75/23	Placebo
		Mean (95% CI)	
Change in weight (%)	-10.92%*† (-10.2 to -1.7)	-5.10%* (-4.0 to -6.2)	-1.55% (-0.8 to -2.3)
		Number (%)	
5% weight loss or more	332*† (66.7%)	105* (44.9%)	86 (17.3%)

*P<0.001 compared with placebo.
†<0.001 compared with 3.75/23.

The CONQUER study, an RCT that followed 2,487 overweight and obese adults with at least 2 comorbidities for 56 weeks, evaluated the safety and efficacy of two different doses of phentermine plus topiramate (15/92 mg or 7.5/46 mg) plus a lifestyle intervention compared with placebo plus a lifestyle intervention. Compared with placebo, subjects treated with phentermine plus topiramate had significantly greater reductions in mean body weight, and significantly more subjects lost 5% or more of their baseline body weight. There was no significant difference in serious adverse events. The most commonly occurring adverse events in patients treated with phentermine plus topiramate were dry mouth, paresthesia, constipation, dysgeusia, and dizziness. A limitation of the study is that the majority of patients included in the study were white women. Results from this study are not generalizable to patients with depression, type 1 diabetes, type 2 diabetes taking medication other than metformin, patients with blood pressure greater than 160/100 mm Hg, or triglycerides greater than 4.52 mmol/L. Additionally, 38% of subjects did not complete the study (Gadde 2012).

Change from baseline to 56 weeks (Gadde 2012)

	15/92	7.5/46	Placebo
		Mean (95% CI)	
Change in weight (%)	-9.8%* (-10.4 to -9.3)	-7.8%*(-8.5 to -7.1)	-1.2% (-1.8 to -0.7)
		Number (%)	
5% weight loss or more	687* (70%)	303* (62%)	204 (21%)

*P<0.0001 compared with placebo.

The SEQUEL study was the only trial that evaluated the safety and efficacy of phentermine plus topiramate for longer than one year. This study was a 52-week extension study of the CONQUER study. Results from the SEQUEL suggest that while subjects generally maintained the weight that they had lost in the first year, treatment with phentermine plus topiramate for an additional year did not result in clinically significant additional weight loss. This study has several limitations. Selection bias is highly likely as only centers with high enrollment and high retention rates were eligible to participate, and patients who stopped taking the drug for more than 4 weeks were excluded. Additionally, more subjects in the 15/92 group were lost to follow-up than in the other two groups (Garvey 2012).

Lorcaserin (Belviq)

Results from 4 RCTs suggest that lorcaserin may lead to significantly greater reductions in weight compared with placebo after 1 year; however, there is insufficient evidence to determine the long-term safety and efficacy of this medication. Additionally, the trials were conducted among a highly selected group of patients, which limits generalizability.

The first RCT evaluated the safety and efficacy of lorcaserin in 469 obese adults without comorbidities. Results from this study suggest that after 12 weeks of treatment patients taking lorcaserin experienced significantly greater weight reductions compared with placebo. The most frequent adverse events were headache, nausea, and dizziness. Results from this study should be interpreted with caution as it does not address long-term safety and efficacy (Smith 2009).

Change in weight from baseline to 12 weeks (Smith 2009)

	Placebo	10 mg once daily	15 mg once daily	10 mg BID
		Mean (SE)		
Change in weight (kg)	-0.4 kg (0.3)	-2.0 kg (0.3)	-2.5 kg (0.3)	-3.3 kg (0.3)
		Difference (treatment – placebo) (95% CI)		
Difference	Ref.	-1.5 (-2.2 to -0.9)	-2.1 (-2.7 to -1.4)	-2.9 (-3.5 to -2.2)

The BLOOM study, an RCT that followed 3,182 patients for 1 year, evaluated the safety and efficacy of lorcaserin (10 mg twice daily) plus lifestyle intervention for weight loss compared with placebo. Patients who remained in the trial at the end of year 1 were eligible to continue the study for a second year. In year 2, patients who received placebo continued receiving it; patients who received lorcaserin during year 1 were randomly assigned to continue receiving lorcaserin or to receive placebo. Results from this trial suggest that after 1 year of treatment patients in the lorcaserin group experienced significantly greater weight reductions compared with placebo.

Changes in efficacy end points (baseline to year 1)* (Smith 2010)

	Lorcaserin	Placebo	P-value
5% weight loss or more			
Patients (%)	47.5%	20.3%	<0.001
Change in weight (kg)	-5.8 kg ± 0.2	-2.2 kg ± 0.1	<0.001
10% weight loss or more			
Patients (%)	22.6%	7.7%	<0.001

* Plus-minus values are means ± SE.

At year 2, the proportion of patients with a 5% or more reduction in baseline body weight at year 1 who maintained the reduction at year 2 was greater in those who continued to receive lorcaserin compared with those who received placebo (67.9% vs. 50.3%, P<0.001). However, mean weight increased in all groups from year 1 to year 2.

Changes in weight at year 2 (Smith 2010)

	Baseline to Year 2			Year 1 to Year 2		
	P/P	L/L	L/P	P/P	L/L	L/P
Change in weight (Mean ± SE)	-2.43 kg ± 0.28	-5.56 kg ± 0.31	-3.30 kg ± 0.42	+1.00 kg ± 0.16	+2.53 kg ± 0.19	+4.76 kg ± 0.31

Abbreviations: P/P=patients received placebo in year 1 and year 2; L/L= patient received lorcaserin in year 1 and year 2; L/P= patients received lorcaserin in year 1 and placebo in year 2.

The most commonly occurring adverse events in the lorcaserin group were headache, upper respiratory infection, nasopharyngitis, dizziness, and nausea. At 1 year, FDA-defined valvulopathy developed in 2.3% of patients in the placebo group, and 2.7% of patients in the lorcaserin group. At year 2, the rate of valvulopathy was 2.7% in the placebo group, and 2.6% in the lorcaserin group. No severe mitral or aortic insufficiency was reported. The study had several limitations. Results are not generalizable to patients with a BMI over 45, diabetes, or binge-eating disorders. The rate of discontinuation at year 1 was nearly 50%. As the incidence of valvulopathy was below pretrial estimates, the trial may be underpowered to assess this endpoint (Smith 2010).

The BLOSSOM trial, an RCT that followed 4,004 overweight and obese subjects for 1 year, evaluated the safety and efficacy of two different doses of lorcaserin (10 mg twice daily and 10 mg once daily) plus lifestyle intervention compared with placebo plus lifestyle intervention. Results from this study suggest that patients treated with lorcaserin 10 mg twice daily lost significantly more weight compared with lorcaserin 10 mg once daily and placebo. Patients treated with lorcaserin 10 mg once daily also lost significantly more weight compared with placebo. The most commonly occurring adverse events in the lorcaserin groups were headache, upper respiratory infection, nausea, dizziness, and fatigue. After 1 year, 2.0% of patients in the lorcaserin twice daily group, 1.4% in the lorcaserin once daily group, and 2.0% in the placebo group developed FDA-defined valvulopathy. Limitations of this trial include a high rate of loss to follow-up, and less than 80% power to determine echocardiographic safety endpoint. Additionally, results are not generalizable to patients with diabetes or pharmacologically treated depression (Fidler 2011).

Mean change in weight from baseline to 1 year (Fidler 2011)

	Lorcaserin twice daily	Lorcaserin once daily	Placebo
	Number (%)		
5% weight loss or more	737* (47.2%)	310*† (40.2%)	385 (25.0%)
10% weight loss or more	353* (22.6%)	134*† (17.4%)	150 (9.7%)
	Mean (SD)		
Change in weight (kg)	-5.8 kg * (6.4)	-4.7 kg *† (6.4)	-2.9 kg (6.4)
Change in weight (%)	-5.8 %* (6.3)	-4.7 %*† (6.3)	-2.8% (6.3)

*P<0.001 compared to placebo.
†P<0.01 lorcaserin once daily vs. lorcaserin BID.

The BLOOM-DM trial, an RCT that followed 604 overweight and obese subjects with type 2 diabetes for 1 year, evaluated the safety and efficacy of two different doses of lorcaserin (10 mg twice daily and 10 mg once daily) plus lifestyle intervention compared with placebo plus lifestyle intervention. Results from this study suggest that patients treated with lorcaserin lost significantly more weight compared with placebo. The most common adverse events with a greater incidence in the lorcaserin group than the placebo group were headache, back pain, nasopharyngitis, and nausea. At week 24, 4 (1.9%) patients in the placebo group, 3 (3.9%) in the lorcaserin once daily group, and 5 (2.5%) in the lorcaserin twice daily group had FDA-defined valvulopathy that was not present at baseline. At week 52, 1 (0.5%) patient in the placebo group, 2 (2.5%) in the lorcaserin once daily group, and 6 (2.9%) in the lorcaserin twice daily group had FDA-defined valvulopathy that was not present at baseline. Limitations of this trial include a high rate of loss to follow-up, limited statistical power to assess echocardiographic safety endpoint, and that after 8 months recruitment was stopped in the lorcaserin 10 mg once daily group due to lower than

anticipated enrollment. Additionally, results are not generalizable to patients with diabetes taking medications other than metformin or a sulfonylurea (O'Neil 2012).

Mean change in weight from baseline to 1 year (O'Neil 2012)

	Placebo	Lorcaserin twice daily	Lorcaserin once daily
		Number (%)	
5% weight loss or more	40 (16.1%)	94* (37.5%)	42* (44.7%)
10% weight loss or more	11 (4.4%)	41* (16.3%)	17* (18.1%)
		Mean ± SE	
Change in weight (kg)	-1.6 kg ± 0.4	-4.7 kg* ± 0.4	-5.0 kg * ± 0.6
Change in weight (%)	-1.5 %± 0.4	-4.5%* ± 0.4	-5.0%* ± 0.5

* P<0.001 compared to placebo.

Bariatric surgery

For treatment of obesity in patients

A recent Clinical Evidence review addressed the effects of bariatric surgery in adults with morbid obesity. Findings from this review suggest that bariatric surgery may result in weight loss that is greater than 20% of body weight, and that this weight loss is largely maintained for 10 years. This conclusion was based on results from two RCTs and three cohort studies that included 3,757 participants. Limitations of the evidence included the inclusion of observational studies and that the majority of participants in the studies were young, white women. There was insufficient evidence to determine the most effective and least harmful surgical method. Adverse events included nutritional and electrolyte abnormalities, GI symptoms, and surgical complications. There was a small risk of perioperative death, which on average was less than 0.28% within 30 days. Furthermore, there is evidence from observational studies that surgery appears to improve long-term survival compared with nonsurgical treatment (DeLaet 2011).

For patients with a BMI of 30.0–35.0, the literature evaluating the safety and efficacy of bariatric surgery is limited and consists mainly of small observational studies. The peer-reviewed studies submitted to the FDA by Allergan and the results from a recent Kaiser Permanente Medical Technology Assessment Team are summarized below.

Randomized controlled trials

The first RCT followed 80 patients with a BMI of 30.0–35.0 for 2 years to determine whether surgical therapy for obesity achieves better weight loss compared with medical therapy. Patients randomized to the surgical intervention received laparoscopic adjustable gastric banding (LAP-BAND® System). The medical therapy intervention included the use of behavior modification, very-low-calorie diet, and pharmacotherapy with education and professional support on appropriate eating and exercise behaviors. At 6 months there was no significant difference in weight loss between the two treatment groups. After 6 months, patients in the medical therapy group regained weight while patients in the surgical treatment group continued to lose weight (O'Brien 2006).

Weight loss at baseline, 6, 12, 18, and 24 months (O'Brien 2006)

	Baseline	**6 mo**	**12 mo**	**18 mo**	**24 mo**
BMI (kg/m^2)			Mean (95% CI)		
Surgical	33.7 (32.9 to 34.4)	28.9 (28.1 to 29.7)	27.0 (26.2 to 27.8)	26.7 (25.9 to 27.5)	26.4 (25.6 to 27.2)
Medical	33.5 (32.7 to 34.3)	28.7 (27.9 to 29.6)	29.9 (29.1 to 30.8)	30.9 (30.0 to 31.8)	31.5 (30.6 to 32.4)
P-Value	0.88	0.73	Lower than 0.001	Lower than 0.001	Lower than 0.001

The second RCT followed 60 subjects for 2 years and examined whether surgically induced weight loss resulted in better glycemic control and less need for diabetic medications than conventional diabetes therapy focused on weight loss through lifestyle changes. Compared with the conventional therapy group, subjects in the surgery group were more likely to achieve remission of type 2 diabetes, have better glycemic control, and have significantly more weight loss. The study was not powered for safety, to detect differences in mortality or cardiovascular

events, or to detect multiple outcome measures. This trial was restricted to participants with newly diagnosed diabetes and therefore is not generalizable to patients with a longer history of diabetes. Additionally, only 13 patients had a BMI between 30.0 and 35.0 (Dixon 2008).

Observational studies

Results from these studies should be interpreted with caution as they are small observational studies. Except for the study conducted by Choi and colleagues, which included patients with a BMI of 30.0–35.0 with 1 or more comorbidities (22 patients) or 35.0–40.0 with no comorbidities (44 patients), all of the studies included patients with a BMI lower than 35. It should be noted that the majority of patients included in these studies were female (Angrisani 2004, Choi 2010, Sultan 2009, Parikh 2006).

Efficacy of LAP-BAND in patients with BMI below 35

Author (year)	Design	Sample size	Follow-up	Baseline BMI	Final BMI
				Mean ± SD	
Angrisani (2004)	Retrospective	N=210	60 months	33.9 ± 1.1	28.2 ± 0.9
Choi (2010)	Prospective	N=66	18 months	36.1 ± 2.6	Not reported
Parikh (2006)	Prospective	N=93	36 months	32.7 (range 30-34)	27.3 ± 3.7
Sultan (2009)	Prospective	N=53	24 months	33.1 ± 1.7	25.8 ± 3.1

Safety of LAP-BAND in patients with BMI below 35

Author (year)	Adverse events
Angrisani (2004)	▪ Death from sepsis following gastric perforation (1 patient) ▪ Gastric pouch dilation (11 patients) ▪ Tube-port leak (4 patients) ▪ Intragastric migration (2 patients)
Choi (2010)	▪ Band slippage (2 patients) ▪ Erosion (1 patient) ▪ Port site seroma (1 patient)
Parikh (2006)	▪ Band slippage (3 patients) ▪ Hiatal hernia (2 patients) ▪ Tubing break (1 patient) ▪ Placed ports deeper because patients became too slender (2 patients)
Sultan (2009)	▪ Band slippage (1 patient) ▪ Band obstructions (2 patients) ▪ Esophagitis (2 patients) ▪ Port leaks (2 patients)

Kaiser Permanente Medical Technology Assessment

The object of the assessment was to evaluate the evidence on the safety and efficacy of laparoscopic gastrointestinal banding surgery (LAP-BAND) in patients with a BMI of 30.0–35.0 and diabetes, and patients with a BMI higher than 35 and lower than 40 with no comorbidities. The Kaiser Permanente Review was based on two RCTs and five case-series. These were the same trials submitted to the FDA plus an additional case-series. Kaiser Permanente also found that the evidence was of insufficient quality and quantity to determine the safety and efficacy of LAP-BAND in these populations (Kaiser Permanente 2011).

For treatment of diabetes

A review by the Kaiser Permanente Medical Technology Assessment Team addressed the safety and efficacy of bariatric surgery for the treatment of diabetes and the BMI threshold/range for patient selection. Kaiser Permanente's recommendations were based mainly on evidence from case series and cohort studies. As stated by the Kaiser Permanente team, the validity and applicability of the findings are challenged as the majority of the included studies had small sample sizes, insufficient or lack of controls, short duration of follow-up, and unclear or incomplete reporting. In addition, definitions for the diagnosis of diabetes, impaired glucose levels, metabolic syndrome, resolution or remission of disease, and

complications or adverse events were not consistent across studies. The results from the Kaiser Permanente review are presented below (Kaiser Permanente 2010).

Short-term effectiveness

There is fair to good evidence that bariatric surgery leads to short-term improvement in measures of type 2 diabetes mellitus as compared with conventional management. Depending on the type of bariatric procedure performed, it was found that approximately 40–100% of patients experienced diabetes resolution with surgery.

Long-term effectiveness

The evidence is of insufficient quality, quantity, and consistency from RCTs to determine the long-term (greater than 2 years) effect of bariatric surgery on type 2 diabetes mellitus and risk management of other comorbidities.

Safety

The evidence is of insufficient quality, quantity, and consistency to determine the safety of bariatric surgery for type 2 diabetes mellitus patients. Deaths, adverse events, and some complications are rare events and, therefore, it is unlikely that the current evidence provides reliable estimates because most of the studies were of limited size, duration, and highly heterogeneous, depending on type of procedure performed.

BMI threshold/range for effectiveness

There is fair to good evidence that bariatric surgery in type 2 diabetes mellitus patients with BMI 35 or higher is effective for improving diabetes and other health outcomes. However, the evidence is of insufficient quality, quantity, and consistency to draw a definitive conclusion on the effectiveness of surgery in type 2 diabetes mellitus patients with BMI lower than 35. Additionally, the evidence is of insufficient quality and quantity to make a determination on the safety and efficacy of laparoscopic gastric banding for adult patients with BMI higher than 35 and lower than 40 without comorbidities.

Since the Kaiser Permanente review, two RCTs evaluated the safety and efficacy of bariatric surgery for the treatment of type 2 diabetes. The first study included 150 subjects and evaluated the safety and efficacy of intensive medical therapy alone or in combination with surgical treatment (gastric bypass or sleeve gastrectomy) as a means of improving glycemic control in obese patients with type 2 diabetes. Results from this study suggest that significantly more patients treated with bariatric surgery combined with intensive medical therapy achieved glycemic control (HbA1c 6% or lower) compared with intensive medical therapy alone (gastric bypass 42%, sleeve gastrectomy 37%, intensive medical therapy 12%). The results should be interpreted with caution, as the durability and long-term safety are unknown and the study was conducted at a single center with one surgeon performing all of the procedures (Schauer 2012).

The second study included 60 subjects with type 2 diabetes and evaluated the effects of bariatric surgery on type 2 diabetes compared with medical therapy. Results from this study suggest that patients who underwent bariatric surgery (gastric bypass or biliopancreatic diversion) had better glycemic control than patients who received medical therapy (gastric bypass 75%, biliopancreatic diversion 95%, medical therapy 0%). This study had several limitations, including: small sample size, dissimilar baseline characteristics, and that the study took place at a single center (Mingrone 2012).

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Guideline Development Process and Team

Development process

To develop the Adult Weight Management Guideline, the guideline team reviewed evidence in the following areas: commercial weight-loss programs, behavior change counseling, pharmacotherapy, and bariatric surgery. The guideline team also adapted some recommendations from externally developed evidence-based guidelines.

This edition of the guideline was approved for publication by the Guideline Oversight Group in December 2012.

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