Complete Summary

GUIDELINE TITLE

VA/DoD clinical practice guideline for screening and management of overweight and obesity.

BIBLIOGRAPHIC SOURCE(S)

Management of Overweight and Obesity Working Group. VA/DoD clinical practice guideline for screening and management of overweight and obesity. Washington (DC): Department of Veterans Affairs, Department of Defense; 2006. 117 p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Overweight and Obesity

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nursing
Nutrition
Pharmacology
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To describe the critical decision points in the management of obesity
- To provide a clear and comprehensive guideline incorporating current information and evidence based practice recommendations for practitioners throughout the Department of Defense and Veterans Health Administration system
- To improve local management of patients with obesity and improve patient outcome

TARGET POPULATION

Adults (age 18 years or older) with overweight or obesity who are eligible for care in the Veterans Affairs (VA) or Department of Defense (DoD) health care delivery system

Note: This guideline is not directed to the treatment of children, adolescents (less than age 18) or pregnant/lactating women.

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Measurement of height and weight ; calculation of body mass index (BMI)
2. Measurement of waist circumference
3. Determination of presence of obesity-associated health conditions
4. Promotion of healthy lifestyles in low-risk and normal weight patients
5. Annual screenings

Assessment

1. Medical history, physical examination, and laboratory tests (fasting lipid profile, liver function tests [LFTs], fasting glucose) as indicated

2. Social and psychological assessment
3. Assessment of patient readiness to lose weight
4. Incorporation of patient preferences in the treatment goals and plan

Treatment/Management

1. Initiation of interventions based on risk level and patient preference
2. Interventions that include diet therapy, increased exercise, and behavioral modification
3. Pharmacotherapy (orlistat, sibutramine) in combination with a reduced-calorie diet and exercise interventions
4. Bariatric surgery
5. Assessment of response to therapy and adjustment of therapy to meet treatment goals
6. Interventions for weight maintenance, relapse prevention (e. g. maintenance program, encouragement, medication), and follow-up
7. Motivation of overweight or obese patients who are not ready to undertake weight loss

MAJOR OUTCOMES CONSIDERED

- Incidence and severity of obesity-associated conditions
- Obesity related morbidity and mortality
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Formulating of Questions

The Working Group developed researchable questions and associated key terms after orientation to the scope of the guideline and to goals that had been identified by the Working Group. The questions specified (adapted from the Evidence-Based Medicine (EBM) toolbox, Center for Evidence-Based Medicine, [http://www.cebm.net]):

- **P**opulation – Characteristics of the target patient population
- **I**ntervention – Exposure, diagnostic, or prognosis
- **C**omparison – Intervention, exposure, or control used for comparison
- **O**utcome – Outcomes of interest

These specifications served as the preliminary criteria for selecting studies. Research questions focused on the following areas of inquiry: screening; risk

assessment; and treatment strategies for weight loss including diet, exercise and behavioral modification, drug therapy, and bariatric surgery.

Selection of Evidence

Published, peer-reviewed randomized controlled trials (RCTs) were considered to constitute the strongest level of evidence in support of guideline recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. Evidence-based systematic reviews were considered to be the strongest level of evidence as well as meta-analyses that included randomized controlled studies. The evidence selection was designed to identify the best available evidence to address each key question and ensured maximum coverage of studies at the top of the hierarchy of study types: evidence-based guidelines, meta-analyses, and systematic reviews. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and Evidence-based Practice Center (EPC) reports.

The search was performed using the National Library of Medicine's (NLM) Medline database. The terms "obesity", "weight gain", "body mass index" and "overweight" were used together with the following Boolean expressions and terms:

- Screening
- Lifestyle
- Caloric restriction, diet
- Behavioral therapy
- Anti-obesity agents
- Gastric bypass
- Patient education
- Human, adults

In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials (CCTR). For Medline/PubMed searches, limits were set for language (English), date of publication (1995 through 2004) and type of research (RCT, systematic reviews and meta-analysis).

Once definitive reviews or clinical studies that provided valid relevant answers to the question were identified, the search ended. The search was extended to studies/reports of lower quality (observational studies) only if there were no high-quality studies.

Exclusion criteria included reviews that omitted clinical course or treatment. Some retrieved studies were rejected on the basis of published abstracts, and a few were rejected after the researchers scanned the retrieved citation for inclusion criteria. Typical exclusions included studies with physiological endpoints or studies

of populations that were not comparable to the population of interest (e.g., studies of obesity in children). The bibliographies of the retrieved articles were hand-searched for articles that may have been missed by the computer search. Working Group members also contributed articles as part of the evidence gathering process.

The results of the search were organized and evidence reports as well as copies of the original studies were provided to the Working Group for further analysis.

Literature Review and Inclusion Criteria

As a result of the original and updated literature reviews, articles were identified for possible inclusion. These articles formed the basis for formulating the guideline recommendations. The following inclusion criteria were used for selecting randomized controlled trial studies:

- Articles published between 1995 and 2004, with some exceptions
- English language only
- Full articles only
- Age limited to adults greater than 18 years
- Randomized controlled trials only; no cross-over trials
- Minimum 6 months of follow-up
- Baseline body mass index (BMI) or body weight levels reported
- Key outcomes cited (decrease in body weight, BMI)

For some questions, special inclusion criteria (mostly related to minimum clinical trial size) were developed based upon research question content and available literature.

The literature search for the guideline update was validated by: (1) comparing the results to a search conducted by the independent research and appraisal team, (2) a review of the database by the expert panel, and (3) requesting articles pertaining to special topics from the experts in the Working Group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence (QE)

I	At least one properly done randomized controlled trial (RCT)
II-1	Well designed controlled trail without randomization

II-2	Well designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; *or* Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Net Effect of the Intervention

Substantial:	More than a small relative impact on a frequent condition with a substantial burden of suffering; *or* A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate:	A small relative impact on a frequent condition with a substantial burden of suffering; *or* A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small:	A negligible relative impact on a frequent condition with a substantial burden of suffering; *or* A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative:	Negative impact on patients; *or* No relative impact on either a frequent condition with a substantial burden of suffering, *or* an infrequent condition with a significant impact on the individual patient level.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Preparation of Evidence Tables (Reports) and Evidence Rating

A group of research analysts with experience in evidence-based appraisal independently read and coded each article that met inclusion criteria. The articles have been assessed for methodological rigor and clinical importance using the following criteria:

- Appropriateness of inclusion and exclusion criteria
- Concealment of allocation
- Blinding of patients, interventions and providers
- Objective method of data collection
- Valid method of data analysis
- Completeness and length of follow-up
- Appropriateness of outcome measures
- Statistical power of results

The information was synthesized and reported in a brief summary of the critical appraisal of each article that included the following components:

- Description of patient population
- Interventions
- Comparisons
- Outcomes
- Summary of results
- Analysis of findings
- Evidence appraisal
- Clinical significance

Quality of evidence ratings were assigned for each source of evidence using the grading scale presented in "Rating Scheme for the Strength of the Evidence" in this summary.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The development of the Screening and Management of Overweight and Obesity Guideline was initiated in January 2005 and continued through August 2005. The development process followed the steps described in "Guideline for Guidelines," an internal working document of Veterans Health Affairs' (VHA's) National Clinical Practice Guideline Council, which requires an on-going review of the work in progress. The Working Group of the VHA/Department of Defense (DoD) was charged to provide evidence-based action recommendations whenever possible;

hence, major clinical randomized controlled trials (RCTs) and observational studies published from 1995 through December 2004 in the areas of diagnosis and treatment of overweight and obesity were used.

Guideline Development Process

The Offices of Quality and Performance and Patient Care Services, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Center Command of the DoD identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the VA and DoD that formed the Guideline Development Working Group. Working Group members included representatives of the following specialties: internal medicine, cardiology, surgery, endocrinology, medical nutrition therapy, social work, family practice, nursing, pharmacy, and healthcare systems management and policy.

As a first step, the guideline development groups defined a set of clinical questions within the area of the guideline. This ensured that the guideline development work outside the meeting focused on issues that practitioners considered important and produced criteria for the search and the protocol for systematic review and, where appropriate, meta-analysis.

The Working Group participated in an initial face-to-face meeting to reach consensus about the guideline algorithm and recommendations and to prepare a draft document. The draft continued to be revised by the Working Group at-large through numerous conference calls and individual contributions to the document. Following the initial effort, an editorial panel of the Working Group convened to further edit the draft document. Recommendations for the performance or exclusion of specific procedures or services were derived through a rigorous methodological approach that included the following:

- Determining appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction
- Reviewing literature to determine the strength of the evidence in relation to these criteria
- Formulating the recommendations and grading the level of evidence supporting the recommendation

Selection of Evidence

Each reference was appraised for scientific merit, clinical relevance, and applicability to the populations served by the Federal healthcare system. Recommendations were based on consensus of expert opinions and clinical experience only when scientific evidence was unavailable.

Recommendation and Overall Quality Rating

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group received an orientation and tutorial on the evidence U.S. Preventive Services Task

Force (USPSTF) 2001 rating process, reviewed the evidence and independently formulated Quality of Evidence ratings, a rating of Overall Quality (see "Rating Scheme for the Strength of the Evidence" in this summary), and a Strength of Recommendation (see "Rating Scheme for the Strength of the Recommendations" in this summary).

Lack of Evidence – Consensus of Experts

The majority of the literature supporting the science for these guidelines is referenced throughout the document and is based upon systematic reviews and technology assessment that serve as the basis for other evidence-based guidelines for overweight and obesity, and key RCTs and longitudinal studies published from 1995 through 2004. Following the independent review of the evidence, a consensus meeting was held to discuss discrepancies in ratings and formulate recommendations. Where existing literature was ambiguous or conflicting, or where scientific data was lacking on an issue, recommendations were based on the clinical experience of the Working Group. These recommendations are indicated in the evidence tables as based on "Working Group Consensus.").

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*
C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*
D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*

I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

COST ANALYSIS

Published cost analyses were reviewed in the preparation of the guideline.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Experts from the Veterans Administration (VA) and the Department of Defense (DoD) internal medicine, cardiology and primary care reviewed the final draft band their feedback was integrated into the final draft document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the screening and management of overweight and obesity are organized into 3 major modules. The algorithms, objectives and recommendations that accompany each module, and the evidence supporting the recommendations are presented below. The quality of evidence **(QE)** grading (I-III); overall quality (**Good, Fair, Poor**); and final grade of recommendations **(R)** (A-D, I) are provided for specific statements. These grades, along with "net effect of the interventions" are defined at the end of the "Major Recommendations" field.

Note: A list of all abbreviations is provided at the end of the "Major Recommendations" field.

Module A: Screening for Overweight and Obesity

Screening Algorithm

A. **Adult Person Enrolled in the Veterans Health Administration (VHA) or Department of Defense (DoD) Healthcare Systems**

Definition

Any adult eligible for care in the VHA or the (DoD) healthcare delivery system should be screened and if necessary, treated for overweight or obesity as described in this guideline.

B. **Obtain Height and Weight; Calculate Body Mass Index (BMI)**

Objective

Screen all adults for overweight or obesity.

Recommendations:

1. Adult patients should have their BMI calculated from their height and weight to establish a diagnosis of overweight or obesity. **[B]**
2. Obese patients (BMI $\geq$30 kg/m^2) should be offered weight loss treatment. **[B]** (See Module B: Treatment for Weight Loss and Weight Maintenance)
3. Overweight patients (BMI between 25 and 29.9 kg/m^2) or patients with increased waist circumference (>40 inches for men; >35 inches for women) should be assessed for the presence of obesity-associated conditions that are directly influenced by weight, to determine the benefit they might receive from weight loss treatment. **[B]**
4. Normal weight patients (BMI between 18.5 and 24.9 kg/m^2) should be provided with education regarding healthy lifestyle behaviors, advised of their BMI and their weight range margins, and instructed to return for further evaluation should those margins be exceeded. **[Expert Opinion]**

Classification	**BMI (kg/m^2)**	**Disease Risk with Normal Waist Circumference**	**Disease Risk with Excessive Waist Circumference**
Underweight	<18.5	-	-
Normal	18.5-24.9	-	-
Overweight	25.0-29.9	Increased	Moderate
Obese I	30-34.9	Moderate	Severe
Obese II	35.0-39.9	Severe	Very Severe
Obese III	$\geq$40	Very Severe	Very Severe

	Recommendation	**Sources of Evidence**	**QE**	**Overall Quality**	**SR**
1	Adult patients should have their BMI calculated from their height and weight.	McTigue et al., 2003 National Heart, Lung, and Blood Institute (NHLBI), 1998 U.S. Preventive Services Task Force (USPSTF), 2003 World Health Organization (WHO), 2000	I	Fair	B
2	Overweight adults (BMI between 25 and 29.9 kg/m^2) should be assessed for other risk factors to determine if they need treatment for overweight.	McTigue et al., 2003 NHLBI, 1998 Strawbridge et al., 2000 USPSTF, 2003 WHO, 2000	I	Fair	B
3	Obese patients should be	Heiat, Vaccarino, & Krumholz,	I	Good	B

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
	offered weight loss treatment.	2001 McTigue et al., 2003 NHLBI, 1998 WHO, 2000			

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

C. **Obtain Waist Circumference Measurement**

Objective

Assess person's body fat distribution.

Recommendations

1. For screening purposes, waist circumference should be obtained in patients with a BMI <30 kg/m^2 as a predictor of disease risk. **[C]**
2. The waist circumference measurement should be made with a tape measure placed above the iliac crest and wrapped in a horizontal fashion around the individual's abdomen at the end of a normal expiration.
3. Gender-specific cut-offs should be used as indicators of increased waist circumference. **[C]**
    - Men: waist circumference >40 inches (102 cm)
    - Women: waist circumference >35 inches (88 cm)

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Waist circumference should be obtained in patients with BMI <30 kg/m^2 as a predictor of disease risk.	NHLBI, 1998 Zhu et al., 2005	II-2	Fair	C
2	Gender-specific weight circumference (WC) cut-offs should be used as indicators of increased disease risk: Men >40 inches (102cm) Women >35 inches (88cm)	Janssen, Katzmarzyk, & Ross, 2002 NHLBI, 1998 WHO, 2000	III	Poor	C

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

D. **Determine Presence of Obesity-Associated Health Conditions that Increase Risk**

Objective

Identify patients who are overweight and who will benefit from weight loss treatment.

Recommendations

1. Weight loss treatment should be offered to overweight patients (BMI 25-29.9 kg/m^2) with one or more of the obesity-associated conditions that are directly influenced by weight loss (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea) **[B]**; or with degenerative joint disease (DJD). **[I]**

Table. Obesity-Associated Chronic Health Conditions

The presence of any of the following conditions that are directly influenced by weight warrants weight loss therapy:
Hypertension **Type 2 Diabetes** **Dyslipidemia** **Metabolic Syndrome *** **Obstructive Sleep Apnea** **Degenerative Joint Disease (DJD)**

*For a definition of Metabolic Syndrome, see the Table in Annotation L

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Overweight adults (BMI between 25 and 29.9 kg/m^2) should be assessed for other risk factors to determine if they need treatment for overweight.	McTigue et al., 2003 NHLBI, 1998 Strawbridge et al., 2000 USPSTF, 2003 WHO, 2000	I	Fair	B
2	Normal weight patients and overweight patients who do not have obesity-associated conditions should be educated to reinforce good lifestyle behaviors.	NHLBI, 1998 WHO, 2000	III	Poor	I

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

E. **Advise Patient to Maintain Weight and Prevent Weight Gain**

Objective

Promote healthy lifestyles in low-risk patients.

Recommendations

1. Overweight patients (BMI 25-29.9 kg/m^2) who do not have associated risk factors should be offered brief advice, encouraged to maintain or lose weight, and offered assistance in establishing reasonable weight loss goals as well as diet and exercise plans if they seek help in losing weight. **[I]**
2. Overweight patients without obesity-associated conditions should be provided with education regarding healthy lifestyle behaviors, be advised of their BMI and their weight range margins and instructed to return for further evaluation should those margins be exceeded. BMI and risk factors should be reassessed annually. **[Expert Opinion]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Brief advice for overweight adults (BMI 25-29.9 kg/m^2) without other associated risk factors assists in weight loss and/or weight maintenance.	Working Group Consensus	III	Poor	I

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

F. **Provide Brief Reinforcement and Lifestyle Education**

Objective

Promote healthy lifestyles for patients with normal weight.

Recommendations

1. Patients of normal weight should be praised, encouraged to maintain their normal weight, and educated regarding a healthy lifestyle to include: **[Expert Opinion]**
    - A balance between caloric intake and energy expenditure
    - A healthy diet emphasizing, whenever possible, fresh fruits and vegetables (see MyPyramid at http://www.mypyramid.gov)
    - Regular, moderately intense physical activity for more than 30 minutes, five or more days per week
    - Additional healthy lifestyle elements related to weight maintenance that may include tobacco use cessation, limited caffeine intake, sleep hygiene, and stress management

G. **Repeat Screening Annually**

Objective

Follow up patients with normal weight.

Recommendation

1. Screening for overweight and obesity should be performed at least annually. **[Expert Opinion]**

Module B: Treatment for Weight Loss and Weight Maintenance

Treatment Algorithm

Assessment

H. **Obese Person or Overweight with Obesity-Associated Condition(s)**

Definition

Patients who are obese, and patients who are overweight or have an elevated waist circumference with one or more obesity-associated conditions should be offered treatment for the reduction of body weight.

I. **Obtain Medical History, Physical Examination, and Laboratory Tests as Indicated**

Objective

Identify medical disorders that may cause or complicate obesity.

Recommendations

1. The clinical assessment of the overweight or obese patient should be done by the primary care provider. The assessment should include a basic medical history, a relevant physical examination, and laboratory tests as clinically indicated. The history should include age of onset or periods of rapid increase in body weight, precipitating factors, and maximum lifetime weight. **[Expert Opinion]**
2. The clinical assessment should rule out organic and drug related causes and identify health risks and/or the presence of weight-related conditions. **[Expert Opinion]**
3. In addition to a medical assessment, a social and psychological assessment may be indicated to identify barriers to participating in dietary or physical activity programs. The assessment may also include screening for behavioral health conditions that may hinder successful weight loss (i.e., depression, post-traumatic stress disorder, anxiety, bipolar disorder, addictions, binge eating disorder, bulimia, and alcoholism). **[Expert Opinion]**
4. A nutritional evaluation should include an assessment of current intake as well as the use of supplements, herbs, and over-the-counter weight loss aides. In addition, meal and snack patterns and problem eating behaviors need to be assessed. The weight and dieting history should include the age of onset of weight gain, number and types of diets and attempts, possible triggers of weight gains and losses, and range of weight change. **[Expert Opinion]**
5. Current levels of physical activity and sedentary lifestyle should be assessed, including exercise frequency, duration, and intensity as well

as the patient's motivation to increase physical activity. **[Expert Opinion]**

J. **Assess Patient's Readiness to Lose Weight**

Objective

Identify the patient who is ready and willing to attempt weight loss.

Recommendations

1. Readiness to lose weight should be assessed by direct inquiry. Those indicating an adequate readiness to lose weight (preparation or action stage) should proceed to treatment. Those not yet ready to lose weight (precontemplation or contemplation stage) should receive motivational counseling. **[Expert Opinion]**

K. **Reach Shared Decisions about Goals and Treatment Plan**

Objective

Incorporate patient preferences in the treatment goals and plan to optimize the patient's success in achieving and maintaining sustained weight loss.

Recommendations

1. The clinical team, together with the patient, should reach shared decisions regarding the treatment program. **[Expert Opinion]**
    - The clinical team should convey to the patient that obesity is a chronic disease that will require lifelong treatment
    - The clinical team should suggest the personalized preferred treatment options based on disease risk and patient characteristics (e.g., describe to the patient/caregiver the treatment options, including behavioral modification, diet and activity patterns, prognosis, estimated length and frequency of therapy, and expectations)
    - The patient should describe his or her needs, preferences, and resources and assist the team in determining the optimal environment for therapy and preferred interventions
    - The patient and the clinical team together should reach conclusions on the goals of therapy and preferred treatment plan

2. The patient's family/caregiver may participate in the treatment process and should be involved in assisting the patient with changing lifestyle, diet and physical activity patterns. **[Expert Opinion]**
3. Patient education should be provided in an interactive and written format. The patient should be given an information packet that includes printed material on subjects such as preferred foods to eat or foods to avoid, healthy lifestyle tips, support group information, and available audio/visual programs on weight loss. **[Expert Opinion]**

4. A detailed treatment plan needs to be documented in the medical record to provide integrated care. **[Expert Opinion]**

Treatment For Weight Loss

L. Initiate Interventions Based on Risk Level and Patient Preferences

Objective

Stratify patients according to risk and provide weight loss treatment accordingly.

Recommendations

1. Weight loss therapy should be tailored to risk level based on calculated BMI and based upon the balance of benefits and risks and patient preferences. **[C]**
2. Patients who may benefit from weight loss should be offered interventions to improve their diet, increase exercise, and change related behaviors to promote weight loss. **[A]**
3. Weight loss interventions should combine dietary therapy, increased physical activity, and behavioral modification strategies rather than utilizing one intervention alone. **[A]**
4. A reasonable initial goal of weight loss therapy (intervention) is a 10 percent reduction in body weight. **[B]**
5. Drug therapy in combination with a reduced-calorie diet and exercise interventions should be considered for obese patients (BMI $\geq$30 kg/m^2) or overweight patients (BMI $\geq$27 kg/m^2) with an obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). **[B]**
6. Bariatric surgery to reduce body weight, improve obesity-associated comorbidities, and improve quality of life may be considered in adult patients with a BMI $\geq$40 kg/m^2 and those with a BMI $\geq$35 kg/m^2 with at least one obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). **[B]**
7. There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have documented coronary artery disease (CAD). **[I]** However, there is good evidence that drug and surgical weight loss interventions may improve cardiovascular risk factors, such as hypertension, dyslipidemia, and diabetes mellitus. **[A]**
8. There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have degenerative joint disease (DJD). However, physical activity and diet may improve physical function and chronic pain in patients with DJD. **[I]**

Table. Indications for More Intensive Weight Loss Therapy

The presence of the following conditions, directly influenced by weight loss, warrants consideration of more intensive therapy with drugs or surgery:

Hypertension **Type 2 Diabetes** **Dyslipidemia** **Metabolic Syndrome** **Obstructive Sleep Apnea**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss with diet, exercise, and behavioral modification is recommended for patients with a BMI $\geq$25 kg/m^2 and hypertension.	NHLBI, 1998 Appel et al., 2003	I	Good	A
2	Orlistat is associated with lowering blood pressure as a secondary effect of weight loss in patients with a BMI $\geq$27 kg/m^2 and hypertension.	Sharma & Golay, 2002	I	Good	B
3	Bariatric surgery is effective in lowering blood pressure in patients with a BMI $\geq$35 kg/m^2 and hypertension.	Buchwald et al., 2004 Sjostrom et al., 2004	I	Fair	B
4	Sibutramine has been shown to raise blood pressure in patients with a BMI $\geq$27 kg/m^2.	Arterburn, Crane, & Veenstra, 2004	I	Good	D

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss with diet, exercise, and behavioral modification is recommended in patients with a BMI $\geq$25 kg/m^2 and diabetes.	Tuomilehto et al., 2001 The Diabetes Prevention Program, 2002	I	Good	A
2	Orlistat and sibutramine modestly improve glycemic control in patients with a BMI $\geq$27 kg/m^2 and type 2 diabetes.	Didangelos et al., 2004 Hanefeld & Sachse, 2002 Kelley et al., 2002 Miles et al., 2002 Torgerson et al., 2004	I	Fair	B
3	Bariatric surgery improves glycemic control or resolves diabetes in patients with a BMI $\geq$35 kg/m^2.	Buchwald et al., 2004	I	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss is recommended in all patients with a BMI $\geq$25 kg/m^2 with dyslipidemia.	"Third Report," 2002 NHLBI, 1998	I	Good	A
2	Orlistat and sibutramine improve lipid levels in patients with a BMI $\geq$27 kg/m^2 with dyslipidemia.	Dujovne et al., 2001 Hutton & Fergusson, 2004 Klein, 2004 Lucas, Boldrin, & Reaven, 2003 Micic et. al., 1999	I	Good	B
3	Bariatric surgery improves triglycerides in patients with a BMI $\geq$35 and dyslipidemia.	Buchwald et al., 2004 Sjostrom et al., 2004	I	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

Diagnosis of Metabolic Syndrome *["Third Report,", 2002]*

Three or more of the following risk factors indicate metabolic syndrome:	Defining Level
Abdominal Obesity:	Waist Circumference (WC):
Men*	Greater than 102 cm (>40 in)
Women	Greater than 88 cm (>35 in)
Triglycerides	Greater than or equal to 150 mg/dL
HDL cholesterol:	
Men	Less than 40 mg/dL
Women	Less than 50 mg/dL
Blood pressure	Greater than or equal to 130/85 mmHg
Fasting glucose	Greater than or equal to 110 mg/dL

*Some men can develop multiple metabolic risk factors when the WC is only marginally increased (e.g., 37-39 inches [94-102 cm]). Such persons may have a strong genetic contribution to insulin resistance. They should benefit from changes in life habits, similarly to men with categorical increases in WC.

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss is recommended in all patients with a BMI $\geq$25 kg/m^2 with metabolic syndrome.	"Third Report," 2002 NHLBI, 1998	I	Good	A
2	Orlistat improves the components of the metabolic syndrome in patients with a BMI $\geq$27 kg/m^2.	Didangelos et al., 2004 Lindgarde, 2000	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss is recommended in patients with a BMI $\geq$25 kg/m^2 with sleep apnea.	Carmelli et al., 2000 Kansanen et al., 1998 Smith et al., 1985 Suratt et al., 1992	II-3	Fair	B
2	The use of orlistat and sibutramine has not been adequately studied in obese or overweight patients with sleep apnea.	N/A	N/A	N/A	I
3	Bariatric surgery is recommended in morbidly obese patients with sleep apnea.	Buchwald et al., 2004 Dixon, Schacter, & O'Brien, 2001 Karason et al., 2000 Maggard et al., 2005 O'Brien et al.,2002	II-2	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document) N/A = Not Applicable

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Weight loss is recommended in all obese or overweight patients with lower extremity DJD.	Christensen, Astrup, & Bliddal, 2005 Felson et al., 1992 Messier et al., 2004 Rejeski et al., 2002	I	Poor	C

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

Weight Maintenance and Follow-Up

M. Is Patient Losing Weight?

Objective

Assess response to therapy and progress toward weight loss goals.

Recommendations

1. Patients on diet, exercise, and behavioral therapy who have lost on average 1 to 2 pounds per week should continue with their current treatment until their weight loss goal is achieved. **[B]**
2. Patients who have lost on average less than 1 pound per week should have their adherence to therapy assessed and treatment plan reevaluated. **[I]**

3. Obese patients with a BMI $\geq$30 kg/m^2, and overweight patients with a BMI $\geq$27 kg/m^2 and obesity-associated chronic health conditions who fail to achieve adequate weight loss through non-pharmacologic interventions may be candidates for pharmacotherapy with orlistat or sibutramine. **[B]** (See Module C, Section C-4 Pharmacotherapy.)

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	An energy deficit of 500-1,000 calories can lead to weight loss of 1 to 2 pounds per week.	"Diet programs," 2004 NHLBI, 1998	I	Good	B
2	A reasonable time to achieve a 10% reduction in body weight is 6 months of therapy.	NHLBI, 1998	I	Good	B
3	Patients who have lost on average 1 pound or more per week should continue with their current treatment.	NHLBI, 1998	II	Fair	B
4	Use of medications for maintenance.	See Module C, Section C-4: Pharmacotherapy			

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

N. Congratulate and Initiate Relapse Prevention/Maintenance

Objective

Continue the necessary interventions to maintain the weight loss and prevent weight gain.

Recommendations

1. Patients who have met their weight loss goals or have stopped losing weight and are ready to sustain current weight loss should be offered a maintenance program consisting of diet, physical activity, and behavioral support. Weight status should be reevaluated and diet and physical activity should be adjusted so that energy balance is maintained (energy intake is equal to energy expenditure). **[B]**
2. Providers should continue to maintain contact with patients providing on-going support, encouragement, and close monitoring during the maintenance phase of weight loss to prevent weight regain. **[B]**
3. Patients who achieve their weight loss goal with a combination of medication, diet, and exercise may be considered candidates to include their medication as a component of their weight maintenance program with continued monitoring of effectiveness and adverse effects. **[B]** (See Module C, Section C-4 Pharmacotherapy recommendations below.)

4. Lifelong follow-up after bariatric surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. **[I]**
5. There is no established optimum visit length or duration between maintenance visits, but it seems reasonable to establish a minimum of quarterly follow-up (every three months) for the sustainment of weight loss and more frequently if the patient requests it. **[I]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Continued contact with patients providing on-going support, encouragement, and monitoring to prevent weight regain.	NHLBI, 1998	II	Fair	B
3	A maintenance program of diet, physical activity, and behavioral support should be offered beginning at 6 months.	NHLBI, 1998 Tremblay, Doucet, & Imbeault, 1999	II-2	Fair	B
4	Emphasize working with patients to solve problems that impede weight management.	NHLBI, 1998 Perri et al., 1988, 2001 Tremblay Doucet, & Imbeault , 1999 Wing & Phelan, 2005	II-2	Fair	B

Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

O. **Assess Adherence and Modify Treatment**

Objective

Assess the patient's progress toward treatment goals and determine adjustments as needed.

Recommendations

1. Adherence to weight loss programs should be assessed by periodically measuring the patient's BMI and waist circumference and providing feedback. **[Expert Opinion]**
2. Patients should be encouraged to record activities by using food logs, exercise logs, and personal diaries to provide structure and allow the provider to identify compliance or relapse issues. **[B]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Provide patient with objective evidence of goal attainment.	Marlatt & Gordon, 2000 Wadden, 1999	II-2	Fair	B
2	Analysis/reinforcement of food logs, exercise records,	DiLillo, Siegfried,& Smith-West, 2003	II	Poor	B

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
	and personal diaries confirms compliance.	NHLBI, 1998			

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

P. **Reinforce Knowledge, Motivation, Skills, and Support**

Objective

Motivate overweight or obese patients who are presently not ready to undertake weight loss to do so in the future.

Recommendations

1. Motivational interviewing techniques should be utilized to motivate patients to improve their dietary habits. **[B]**
2. Motivational interviewing techniques should be considered to motivate patients to increase their physical activity. **[Expert Opinion]**
3. Patients who may benefit from weight loss but are not willing to attempt to lose weight at this time should receive brief, non-judgmental motivational counseling designed to increase their motivation to lose weight. This counseling should include discussion about: **[Expert Opinion]**
    - Relevance: connection between overweight and current symptoms, disease, and medical history
    - Risks: risks of continued overweight status, tailored to individual risk/relevance of cardiovascular disease or exacerbation of pre-existing disease
    - Rewards: potential benefits for losing excess weight to patients' medical, financial, and psychosocial well-being
    - Roadblocks: barriers to losing weight, with options and strategies to address patient's barriers
    - Repetition: reassess willingness to lose weight at subsequent visits; repeat intervention for unmotivated patients at every visit

Module C: Interventions for Weight Loss

C-1 **Diet Therapy**

Recommendations

<u>Weight Loss</u>

1. Dietary interventions should be individually planned, in conjunction with physical activity, to create a caloric deficit of 500 to 1,000 kcal/day. Such negative energy balance may lead to a weight loss of 1 to 2 pounds per week. **[B]**

Selection of Specific Diets

2. Dietary programs should at a minimum reduce the usual caloric intake by 500 to 1,000 kcal/day to achieve modest weight loss. **[B]**
3. Low-calorie diets (LCDs) should generally include 1,000 to 1,200 kcal/day for women and 1,200 to 1,600 kcal/day for men and should include the major nutrients in appropriate proportions (see Appendix C, Table C-1 in the original guideline document). **[B]**
4. Very-low-calorie diets (VLCDs) that restrict calories to less than 800 kcal/day [15 kcal/kg ideal body weight] are not recommended for weight loss, but may be used short term (12 to 16 weeks) under medical supervision. **[B]**
5. Low-fat intake (20 to 30 percent of total calories/day), as part of low-calorie diets (LCDs), can be recommended to induce weight loss and should be recommended for patients with cardiovascular disease or lipid abnormalities. **[B]**
6. Low-carbohydrate diets (less than 20 percent of total calories) may be used for short-term weight loss, but are not recommended for long-term dieting or weight maintenance. **[B]**
7. Low-carbohydrate diets can be recommended to reduce serum triglyceride levels for overweight patients with mixed dyslipidemia. **[B]**
8. Low-carbohydrate diets are not recommended for patients with hepatic or renal disease or for patients with diabetes who are unable to monitor blood glucose. **[C]**
9. Low-calorie diets (LCDs) or very low-calorie diets (VLCDs) may include meal replacements (e.g., bars and shakes). **[A]**
10. There is insufficient evidence to recommend for or against a diet limited to foods with a glycemic index less than 55 as a means of producing weight loss. **[C]**

Commercial Diets

11. Patients should be encouraged to adhere to a specific diet, as adherence to any diet plan from a variety of programs (e.g., Atkins, Ornish, Weight Watchers, and Zone) has been shown to be the most important factor in achieving weight reduction. **[B]**

Table. Definitions of Common Diets

Diet Approach	Content (% of total calories)		
	Fat	**Carbohydrates**	**Protein**
Very-low carbohydrates (High-fat)	55–65	<20 (<100g)	25–30
Low carbohydrates (Moderate-fat)	20–30	30–40	25–30
Moderate-fat, balanced nutrient reduction (Low-calorie)	20–30	55–60	15–20
Low-fat	11–19	>65	10–20

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	An energy deficit of 500-1,000 kcal/day will lead to weight loss of 1 to 2 pounds per week.	"Diet programs," 2004 NHLBI, 1998	I	Fair	B
2	Energy deficit (calories in vs. calories out), rather than macronutrient composition is the major determinant of weight loss.	Avenell et al., 2004 Freedman, King, & Kennedy, 2001 "Diet programs," 2004 McTigue et al., 2003	I	Fair	B
3	No single type of diet has been shown to be more effective than the others.	Avenell et al., 2004 Dansinger et al., 2005 "Diet programs," 2004 McTigue et al., 2003	I	Fair	B
4	**LCDs** may result in moderate weight loss for patients that adhere to the diet program (3 to 18 months).	Avenell et al., 2004 "Diet programs," 2004 McTigue et al., 2003 NHLBI, 1998	I	Good	A
5	**VLCDs** (less than 800 kcal/day) produce greater initial weight loss than other forms of calorie restriction at 12 to 16 weeks.	Wadden & Stunkard, 1986; Wadden et al., 1994 Williams et al., 1998 Wing et al., 1994	I	Good	B
6	**VLCDs** should be monitored under medical supervision.	"Very low-calorie diets," 1993	III	Poor	C
7	Greater initial weight loss induced without changes in lifestyle (e.g., **VLCD**) may improve long-term weight maintenance.	Anderson et al., 2001	I	Fair	I
8	**Low-fat** diets produce a caloric deficit and lead to modest weight loss at 3 to 6 months. Greater weight loss is observed in patients with greater baseline weights.	NHLBI, 1998	I	Good	A
9	**Low-fat**, calorie restricted diets may lead to weight loss and reduction in Low density lipoprotein (LDL) cholesterol for patient with dyslipidemia.	"Third Report," 2002 NHLBI, 1998	I	Fair	B
10	**Low-carbohydrate** diets result in more rapid short-term (6 months) weight loss than low-fat LCDs. **Low-carbohydrate** diets may reduce serum triglyceride levels and improve High density	Bravata et al., 2003 Brehm et al., 2003 Foster et al., 2003 Samaha et al., 2003	I	Fair	B

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
	lipoprotein cholesterol (HDL-C) in patients with mixed dyslipidemia.				
11	**Low-carbohydrate** diets are contraindicated in patients with renal or hepatic disease and patients with diabetes that cannot monitor their blood sugars.	Working Group Consensus	III	Poor	I
12	**Meal replacements** are safe to promote weight loss in conjunction with LCDs and VLCDs.	Bowerman et al., 2001 Flechtner-Mors et al., 2000 Heymsfield et al., 2003 Noakes et al., 2004	I	Good	A
13	The evidence is insufficient to substantiate the recommendation of a diet based on the **glycemic index**, without caloric reduction.		III	Poor	I
14	Low-**energy**-dense diets can help lower calorie intake without reducing food volume and lead to weight loss.	McCrory et al., 2000 Rolls & Bell, 2000	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

C-2 **Physical Activity**

Recommendations

1. Weight loss interventions should include exercise to promote weight loss **[A]**, maintain weight loss **[A]**, decrease abdominal obesity **[B]**, improve cardiovascular fitness **[A]**, improve cardiovascular outcomes **[A]**, and decrease all-cause and cardiovascular mortality **[B]**.
2. Home fitness/lifestyle activities or structured supervised programs may be effectively used to produce a caloric expenditure leading to weight loss. **[A]**
3. Moderate levels of physical activity should be performed at least 30 minutes most days of the week. **[B]**
4. Physical activity may include short intermittent bursts (10 minutes or longer) as well as longer continuous exercise. **[A]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	***Physical Activity/Exercise should occur to*:**				
	a. Promote weight loss	NHLBI, 1998 Ross et al., 2000	I	Good	A
	b. Maintain weight loss	Miller et al., 1997	I	Good	A
	c. Decrease abdominal	NHLBI, 1998	I	Fair	B

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
	obesity				
	d. Improve cardiovascular fitness	NHLBI, 1998	I	Good	A
	e. Reduce cardiovascular risk factors	Bassuk & Manson, 2004 NHLBI, 1998	I	Good	A
	f. Decrease all-cause and cardiovascular mortality	Blair et al., 1995 Lee, Blair, & Jackson, 1999 Paffenbarger et. al., 1993	II-2	Fair	B
2	Lifestyle physical activities (home fitness programs) are just as effective in promoting weight loss as structured supervised exercise programs.	Anderson et al., 1999 Fogelholm et al.,2000	I	Good	A
3	Moderate levels of physical activity should be performed at least 30 minutes most days of the week.	Jakicic et al., 2001 NHLBI, 1998 Saris et al., 2003	I	Fair	B
4	Short intermittent bursts of physical activity are just as effective as longer continuous exercise.	Frick et al., 2001 Jakicic et al., 1999	I	Good	A

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

C-3 **Behavioral Modification Strategies**

Recommendations

1. Behavioral modification interventions to improve adherence to diet and physical activity should be given to overweight or obese individuals. **[B]**
2. Behavioral modification interventions should be provided at a higher intensity when possible for greater effectiveness. Higher intensity is defined as more than one personal contact per month for the first three months (individual or group setting). Less frequent intervention may be an ineffective and inefficient use of manpower. **[B]**
3. Multiple behavioral modification strategies should be used in combination for greater effectiveness. **[A]**
4. Behavioral modification intervention should be delivered in a group format when possible rather than individually. **[B]**
5. For individuals unable or unwilling to participate in weight loss treatment in person, telephone or internet-based behavioral modification intervention may be considered. **[B]**
6. Behavioral modification intervention should be continued on a long-term basis to promote maintenance of weight loss. **[B]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Behavioral modification interventions add effectiveness to diet and exercise interventions in promoting weight loss.	Avenell et al., 2004 ICSI, 2005 McTigue et al., 2003 NHLBI, 1998 Wadden & Butryn, 2003	I	Fair	B
2	Behavioral modification interventions with greater intensity are more effective than those with less intensity in promoting weight loss.	NHLBI, 1998 McTigue et al., 2003	I	Fair	B
3	Combined behavioral modification strategies are more effective than a single behavioral modification strategy in promoting weight loss.	NHLBI, 1998	I	Good	A
4	Group-based behavioral modification counseling is more effective than individual counseling in promoting weight loss.	Renjilian et al., 2001	I	Fair	B
5	Telephone and internet behavioral treatment is effective in promoting weight loss.	Boucher et al., 1999 Harvey-Barino et al., 2004 Jeffery et al., 2003 Tate, Jackvony, & Wing, 2003	I	Fair	B
6	Continued behavioral modification interventions are effective in sustaining weight loss.	Jeffery et al., 2000 Latner et al., 2002 McTigue et al., 2003 NHLBI, 1998 Perri et al., 1988 Perri et al., 2001 Wadden & Butryn, 2003	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

C4 **Pharmacotherapy**

Recommendations

1. Adult patients with a BMI greater than 30 kg/m^2 or a BMI greater than 27 kg/m^2 with obesity-associated conditions may be considered for pharmacotherapy in combination with a reduced-calorie diet, increased physical activity and behavioral therapy. **[B]**
2. Patients who do not respond to medication with a reasonable weight loss should be evaluated for adherence to the medication regimen and adjunctive therapies or considered for an adjustment of dosage. **[I]**
3. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the use of medication should be discontinued. **[I]**

Orlistat

4. Orlistat may be considered to reduce body weight **[B]** and improve obesity-associated cardiovascular risk factors **[C]**.
5. Patients who have lost 5 percent or more of their body weight after 12 weeks of treatment or lost an average of 1 pound or more per week with orlistat should continue their current treatment, as they are more likely to experience sustained weight loss. **[B]**
6. Orlistat may be considered as a component of weight maintenance programs for up to 4 years. **[B]**
7. Patients prescribed orlistat should take a multiple vitamin that includes fat soluble vitamins. **[Expert Opinion]**

Sibutramine

8. Sibutramine may be considered to reduce body weight **[B]** and improve glycemic and lipid parameters **[C]**.
9. Patients who have lost an average of 1 pound or more per week during the first 4 weeks of therapy with sibutramine should continue treatment, barring any intolerable side effects. **[Expert Opinion]**
10. Patients who fail to lose 4 pounds after 4 weeks treated with sibutramine should have their adherence assessed and, if appropriate, an increase in the dose for an additional 4-week trial. **[I]**
11. Sibutramine may be considered as a component of weight maintenance programs for up to 2 years. **[B]**
12. Sibutramine should be discontinued if it is not efficacious in helping the patient to lose or maintain weight loss. **[B]**
13. Sibutramine should be used with caution as it can elevate blood pressure and heart rate. **[A]**
14. Adult patients with uncontrolled hypertension, cardiovascular disease, or a history of myocardial infarction (MI) or stroke should not include sibutramine as a part of their weight loss program due to the increased risk of harm. **[D]**
15. Sibutramine should be avoided in patients taking selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors (MAOIs), triptans, pseudoephedrine, and other agents that affect serotonin. **[D]**

	Recommendation	**Sources of Evidence**	**QE**	**Overall Quality**	**SR**		
					Weight	**CV risk**	**Morbidity Mortality**
1	Pharmacotherapy may be considered for BMI greater than 30 kg/m^2 or a BMI greater than 27 kg/m^2 with one or more obesity related risk factors.	Apfelbaum et al., 1999 Arterburn, McDonell, & Hedrick, 2004 James et al., 2000 Li et. al., 2005 McTigue et al., 2003 O'Meara et al., 2002 Shekelle et al., 2004 Torgerson et al., 2004	I	Fair	B	C	I
2	Orlistat may be considered to reduce body weight and improve obesity-	Lindegarde, 2000 Padwal, Li, & Lau, 2004 Shekelle et al., 2004	I	Fair	B	C	I

	Recommendation	Sources of Evidence	QE	Overall Quality	SR		
					Weight	CV risk	Morbidity Mortality
	associated cardiovascular risk factors.						
3	Patients who have lost greater than or equal to 5% of their body weight after 12 weeks of treatment with orlistat are more likely to experience sustained improvement.	Rissanen et al., 2003	II-2	Fair	B	C	I
4	Orlistat may be considered as a component of weight maintenance programs for up to 4 years.	Padwal, Li, & Lau, 2004 Shekelle et al., 2004 Torgerson et al., 2004	I	Fair	B	C	B (new onset diabetes)
5	Sibutramine may be considered to reduce body weight and improve glycemic and lipid parameters.	Arterburn, Crane, & Veenstra, 2004 Arterburn, McDonell, & Hedrick, 2004 McTigue et al., 2003 Padwal, Li, & Lau, 2004 Shekelle et al., 2004	I	Fair	B	C	I
6	Sibutramine may be considered as a component of weight maintenance program for up to 2 years.	Arterburn, Crane, & Veenstra, 2004 Arterburn, McDonell, & Hedrick, 2004 Padwal, Li, & Lau, 2004 Shekelle et al., 2004	I	Fair	B	C	I
7	Sibutramine should be used with caution as it can elevate blood pressure and heart rate.	Arterburn Crane, & Veenstra, 2004 Arterburn, McDonell, & Hedrick, 2004 Padwal, Li, & Lau, , 2004	I	Good	A		
8	Avoid sibutramine in adult patients with uncontrolled hypertension, cardiovascular disease, and history of MI or stroke due to the increased risk of harm.	Arterburn Crane, & Veenstra, , 2004 Arterburn, McDonell, & Hedrick, 2004 Padwal, Li, & Lau., 2004	II-3	Fair	D		

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

C-5 **Bariatric Surgery**

Recommendations

1. Adult patients with extreme obesity (BMI 40 kg/m^2 or more) or severe obesity (BMI 35 kg/m^2 or more with one or more obesity-associated chronic health condition) may be considered for bariatric surgery to reduce body weight **[A]**, improve obesity-associated comorbidities **[B]**, and improve quality of life **[B]**.
2. Roux-en-y Gastric Bypass (RYGB) is recommended as the bariatric procedure with the most robust evidence for inducing sustained weight loss **[B]** for patients with BMI greater than 40 kg/m^2.
3. There is insufficient evidence to recommend for or against the routine use of bariatric surgery in those over 65 years of age and patients with a substantial surgical risk. **[I]**
4. Providers should engage all patients who are candidates for bariatric surgery in a detailed discussion of the benefits and potential risks of bariatric procedures. **[I]**
5. Relative contraindications to bariatric surgery that are supported only by expert consensus include:
    - Unstable coronary artery disease, severe pulmonary disease, portal hypertension or other conditions that can compromise anesthesia or wound healing
    - Patients who are unable to comprehend basic principles of surgery or follow-up postoperative instructions
    - Patients having had multiple abdominal operations, complicated incisional hernias
    - Patients who have illnesses that greatly reduce life expectancy and/or are unlikely to be improved in their medical condition by surgically-induced weight reduction (e.g., cancer).

6. Lifelong medical follow-up after surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. **[I]**

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1	Bariatric surgery (RYGB, AGB, & VBG) to promote substantial long-term (3 years) weight loss in patient with BMI $\geq$40 or BMI $\geq$35 with comorbid conditions.	ECRI, 2004 Maggard et al., 2005 Shekelle et al., 2004	I	Good	B
2	Bariatric surgery (RYGB, AGB, & VBG) to improve or resolve comorbid conditions.	Buchwald et al., 2004 ECRI, 2004 Sjostrom et al., 2004	I	Fair*	B
3	Bariatric surgery (RYGB, AGB, & VBG) to improve quality of life.	ECRI, 2004 Karlsson, Sjostrom, & Sullivan, 1998 Shekelle et al., 2004	I	Fair*	B
4	Bariatric surgery to improve long-term (greater than 5	Christou et al., 2004 Flum & Dellinger, 2004	II-2	Poor	I

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
	years) survival.				
5	RYGB to promote greater weight loss than VBG or AGB	Buchwald et al., 2004 ECRI, 2004 Maggard et al., 2005 Shekelle et al., 2004	I	Fair	B
6	Bariatric surgery in those over 65 years of age has higher risk of mortality	ECRI, 2004 Shekelle et al., 2004	II-3	Fair	I
7	Preoperative requirements or effective means to prepare patients for surgery.	Expert Opinion Saltzman et al,, 2005	III	Poor	I
8	Contraindication for bariatric surgery.	Expert Opinion	III	Poor	I

*Evidence quality was rated as fair, because few studies reported these outcomes consistently, and few studies were designed to examine the impact of surgery on these outcomes.

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A in the original guideline document)

AGB = Adjustable gastric band; RBG vertical banded gastroplasty

Definitions:

Evidence Rating System

Quality of Evidence (QE)

I	At least one properly done randomized controlled trial (RCT)
II-1	Well designed controlled trail without randomization
II-2	Well designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; *or* Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Net Effect of the Intervention

Substantial:	More than a small relative impact on a frequent condition with a substantial burden of suffering; *or* A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate:	A small relative impact on a frequent condition with a substantial burden of suffering; *or* A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small:	A negligible relative impact on a frequent condition with a substantial burden of suffering; *or* A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative:	Negative impact on patients; *or* No relative impact on either a frequent condition with a substantial burden of suffering, *or* an infrequent condition with a significant impact on the individual patient level.

Strength of the Recommendation

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*

C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*
D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*
I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

Abbreviations and Acronyms List

AGB - Adjustable Gastric Band

BMI - Body Mass Index

CAD – Coronary artery disease

DoD - Department of Defense

DJD - Degenerative Joint Disease

EBM - Evidence-Based Medicine

HDL-C - High Density Lipoprotein Cholesterol

LCD - Low-Calorie Diet

LDL – Low density Lipoprotein

MAOI - Monoamine Oxidase Inhibitors

MI - Myocardial Infarction

RYGB - Roux-en-y Gastric Bypass

SSRI - Selective Serotonin Reuptake Inhibitor

VHA – Veterans Health Administration

VBG - Vertical Banded Gastroplasty

VLCD - Very-Low-Calorie Diet

WC - Waist Circumference

CLINICAL ALGORITHM(S)

Algorithms are provided for:

- Screening for Overweight and Obesity
- Treatment for Weight Loss and Weight Maintenance

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline is supported by the literature in a majority of areas, with evidence-based tables and references throughout the document. The evidence consists of key clinical randomized controlled trials and longitudinal studies in the area of weight loss and weight maintenance therapy. Where existing literature is ambiguous or conflicting, or where scientific data are lacking on an issue, recommendations are based on the expert panel's opinion and clinical experience. The guideline contains a bibliography and discussion of the evidence supporting each recommendation.

The quality of the evidence supporting individual recommendations is given for selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Weight loss improves blood pressure, cholesterol, glycemic control, and obstructive sleep apnea and reduces incident hypertension and type 2 diabetes. Modest weight loss among overweight and obese adults will reduce the incidence and severity of diabetes, a chronic condition that is linked to significant morbidity, mortality, and healthcare costs.

POTENTIAL HARMS

- Continuing a very low calorie diet (VLCD) for a long period may not be safe.
- Potential adverse effects and precautions for drug therapy used in dyslipidemia are provided in Table F-1 in Appendix F of the original guideline document.
- There are significant drug or nutrient interactions with anti-obesity agents. See Table F-3 in Appendix F in the original guideline document for a list of known drug interactions to date.

- Bariatric surgery may be associated with stricture of gastrojejunonstomy, gastrointestinal bleeding, marginal ulcer, bowel obstruction, and complications of the *LapBand*. See Appendix G of the original guideline document for details.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Low-carbohydrate diets are contraindicated in patients with renal or hepatic disease and patients with diabetes that cannot monitor their blood sugars.
- The use of sibutramine with a monoamine oxidase inhibitor (MAOI) is contraindicated.
- Sibutramine is contraindicated in patients with uncontrolled hypertension and in patients who have a major eating disorder (anorexia nervosa or bulimia nervosa).
- Women who are pregnant or who are considering pregnancy in the next two years should not be considered candidates for bariatric surgery.
- Relative contraindications to bariatric surgery that are supported only by expert consensus include:
    - Unstable coronary artery disease, severe pulmonary disease, portal hypertension or other conditions that can compromise anesthesia or wound healing
    - Patients who are unable to comprehend basic principles of surgery or follow-up postoperative instructions
    - Patients having had multiple abdominal operations, complicated incisional hernias
    - Patients who have illnesses that greatly reduce life expectancy and/or are unlikely to be improved in their medical condition by surgically-induced weight reduction (e.g., cancer).

QUALIFYING STATEMENTS

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- The Department of Veterans Affairs (VA) and The Department of Defense (DoD) guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care, and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.
- Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.
- Clinical practice guidelines, which are increasingly being used in health care, are seen by many as potential solutions to inefficiency and inappropriate variations in care. Guidelines should be evidenced-based as well as based upon explicit criteria to ensure consensus regarding their internal validity.

However, it must be remembered that the use of guidelines must always be in the context of a health care provider's clinical judgment in the care of a particular patient. For that reason, the guidelines may be viewed as an educational tool analogous to textbooks and journals, but in a more user-friendly format.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Clinicians can use the algorithms to determine appropriate interventions and timing of care for their patients and to better stratify obese and overweight patients and optimize healthcare utilization. There is no intent to restrict providers from using their clinical expertise in the care of an individual patient. The guideline's recommendations should facilitate, not replace, clinical judgment.

This guideline has been developed to assist Veterans Health Administration (VHA) and Department of Defense (DoD) facilities to implement processes of care that are evidence-based. The guideline is designed to achieve maximum functionality and independence and improve patient/family quality of life. The recommendations may provide facilities lacking organized weight management care a structured approach to confront the challenges in facing the obesity epidemic and assure that veterans and active duty personnel who can benefit from weight reduction will have access to comparable care, regardless of geographic location. It is also meant to encourage each Veterans Integrated Services Network (VISN) or DoD medical treatment facility (MTF), or other care access sites in developing innovative plans, to remove barriers that prevent patients from gaining prompt access to preventive care and inhibit primary care providers, specialists, and allied health professionals from working together.

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Management of Overweight and Obesity Working Group. VA/DoD clinical practice guideline for screening and management of overweight and obesity. Washington (DC): Department of Veterans Affairs, Department of Defense; 2006. 117 p.

ADAPTATION

The guideline draws, in part, from:

- U.S. Preventive Services Task Force. Screening for Obesity in Adults: Recommendations and Rationale. November 2003. Agency for Health Care Research and Quality, Rockville, MD. (http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.htm).
- National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI). Clinical Guidelines on the identification, evaluation, and treatment of overweight and obesity in Adults. The evidence report. NIH Publication No. 98-4083, 1998.

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GUIDELINE DEVELOPER(S)

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Department of Veterans Affairs - Federal Government Agency [U.S.]
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The Management of Obesity Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Department of Veterans Affairs Web site.

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Screening and management of overweight and obesity guideline summary – update 2006. Washington (DC): Department of Veterans Affairs (U.S.); 2006. 23 p.
- Management of overweight and obesity pocket guide – update 2006. Washington (DC): Department of Veterans Affairs (U.S.); 2006. 2 p.
- Screening and management of overweight and obesity key points card – update 2006. Washington (DC): Department of Veterans Affairs (U.S.); 2006. 2 p.

Electronic copies: Available from the Department of Veterans Affairs Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

In addition, the VHA Web site provides references to related guidelines, performance measures, and other resources.

The following are also available:

- Guideline for Guidelines. Draft. Washington (DC): Veterans Health Administration, Department of Veterans Affairs. Available from the : VHA Web site.
- Guideline development process. Appendix A of the original guideline document
- Putting clinical practice guidelines to work [online tutorial]. Available from the Department of Veterans Affairs Web site.

PATIENT RESOURCES

None available

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