



Complete Summary

GUIDELINE TITLE

Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians.

BIBLIOGRAPHIC SOURCE(S)

Snow V, Barry P, Fitterman N, Qaseem A, Weiss K. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2005 Apr 5;142(7):525-31. [36 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

Obesity (body mass index [BMI] ≥ 30 kg/m²)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nutrition
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations based on a review of the evidence on pharmacologic and surgical treatments of obesity
- To complement the guidelines on screening for obesity developed by the U.S. Preventive Services Task Force

TARGET POPULATION

Patients with a body mass index (BMI) ≥ 30 kg/m²

Note: The target patient populations vary according to the intervention under consideration, since pharmacologic and surgical trials have used different selection criteria with differing BMIs and comorbid conditions. This guideline does not apply to patients with BMIs below 30 kg/m².

INTERVENTIONS AND PRACTICES CONSIDERED

1. Patient education and counseling
 - Lifestyle and behavioral modifications (i.e., diet and exercise)
 - Individual weight loss goals
 - Possible side effects of medication and surgical options
2. Adjunctive drug therapy
 - Sibutramine
 - Orlistat
 - Phentermine

- Diethylpropion
- Fluoxetine
- Bupropion

Note: Refer to the original guideline document for medications that were considered but not recommended.

3. Surgical options
 - Roux-en-Y gastric bypass (RYGB)
 - Biliopancreatic bypass
 - Laparoscopic adjustable gastric band
 - Vertical band gastroplasty
4. Referral as appropriate for surgery to high volume centers

MAJOR OUTCOMES CONSIDERED

- Weight loss
- Incidence and severity of weight-related comorbidities
- Post-operative mortality
- Adverse events (e.g., surgical complication rates)

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

Note from the National Guideline Clearinghouse (NGC): This guideline is based on the evidence reports and accompanying background papers developed by the Southern California Evidence-Based Practice Center (EPC) (see the "Companion Documents" field).

Search Strategy

EPC staff searched numerous electronic databases electronically, including MEDLINE® and EMBASE, for potentially relevant studies. They scanned the reference lists of recent extensive reviews on sibutramine, orlistat, and bariatric surgery. They also contacted experts in the field.

Inclusion Criteria

The Technical Expert Panel (TEP) suggested that the EPC assessment of pharmacological agents include U.S. Food and Drug Administration (FDA)-approved weight loss medications and other medications for which reports have begun to appear regarding their use as weight loss agents. The FDA-approved weight loss drugs are phentermine, sibutramine, orlistat, diethylpropion, and

mazindol; however, the TEP advised the EPC to ignore mazindol, because it is no longer used. The TEP instructed them to include only studies with treatment durations of 6 months or longer.

To be accepted for analysis, the study had to be a randomized controlled trial (RCT) or controlled clinical trial (CCT). For the analysis of surgical studies, EPC staff broadened these inclusion criteria to encompass cohort studies and case series, since the TEP and a brief scan of the literature suggested that RCTs and CCTs would be few in number. While acknowledging that inferences about efficacy could not be easily made from case series, the EPC staff did judge that such studies provided useful information in the absence of trial data, and, furthermore, would be useful to assess complications and adverse events of surgery. To avoid reviewing potentially numerous case reports, they set a threshold of 10 or more patients for inclusion in the review.

NUMBER OF SOURCE DOCUMENTS

Staff from the Southern California Evidence-Based Practice Center (EPC) screened 1,063 articles. They quality-reviewed 78 medication studies that reported on sertraline (1 article), zonisamide (1 article), orlistat (49), bupropion (5), topiramate (9), and fluoxetine (13). Meta-analysis was performed for all medications except sertraline and zonisamide which are summarized in the text. They quality-reviewed 159 surgery studies reporting on weight loss and considered an additional 8 surgery studies reporting only on complications, for a total of 167 surgery studies. Of these 167 studies, 20 were duplicate publication of an already included study. Of the remaining 147 studies, 89 contributed to the weight loss analysis, 134 contributed to the mortality analysis, and 128 contributed to the complications analysis. Studies could contribute to one or more surgery analyses.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline is based on the evidence reports and accompanying background papers developed by the Southern California Evidence-Based Practice Center (EPC) (see the "Companion Documents" field).

EPC staff abstracted data from the articles onto a specialized form, containing questions about the study design, the number of patients and comorbidities, dosage, adverse events, the types of outcome measures, and the time from intervention until outcome measurement.

Meta-Analysis: Pharmacologic Treatment

Meta-analysis was performed for all medications except sertraline, zonisamide, and fluoxetine, which were summarized narratively. All pooled weight loss values were reported relative to placebo. With one exception, long-term studies of health outcomes were lacking. Significant side effects that varied by drug were reported (see the "Companion Documents" field for detailed information on the meta-analysis).

Meta-Analysis: Surgical Treatment

EPC staff assessed 147 studies. Of these, 89 contributed to the weight loss analysis, 134 contributed to the mortality analysis, and 128 contributed to the complications analysis. The EPC identified 1 large, matched cohort analysis that reported greater weight loss with surgery than with medical treatment in individuals with an average body mass index (BMI) of 40 kg/m² or greater (see the "Companion Documents" field for detailed information on the meta-analysis).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published costs analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the American College of Physicians (ACP) Board of Regents in October 2004.

Recommendations of Others: Recommendations from the U.S. Preventive Services Task Force (USPSTF) were discussed.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation 1: Clinicians should counsel all obese patients (defined as those with a body mass index [BMI] ≥ 30 kg/m²) on lifestyle and behavioral modifications such as appropriate diet and exercise, and the patient's goals for weight loss should be individually determined (these goals may encompass not only weight loss but also other parameters, such as decreasing blood pressure or fasting blood glucose levels).

Recommendation 2: Pharmacologic therapy can be offered to obese patients who have failed to achieve their weight loss goals through diet and exercise alone. However, there needs to be a doctor–patient discussion of the drugs' side effects, the lack of long-term safety data, and the temporary nature of the weight loss achieved with medications before initiating therapy.

Recommendation 3: For obese patients who choose to use adjunctive drug therapy, options include sibutramine, orlistat, phentermine, diethylpropion, fluoxetine, and bupropion. The choice of agent will depend on the side effects profile of each drug and the patient's tolerance of those side effects.

Recommendation 4: Surgery should be considered as a treatment option for patients with a BMI of 40 kg/m² or greater who instituted but failed an adequate exercise and diet program (with or without adjunctive drug therapy) and who present with obesity-related comorbid conditions, such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidemia, and obstructive sleep apnea. A doctor–patient discussion of surgical options should include the long-term side effects, such as possible need for reoperation, gall bladder disease, and malabsorption.

Recommendation 5: Patients should be referred to high-volume centers with surgeons experienced in bariatric surgery.

CLINICAL ALGORITHM(S)

A clinical algorithm for managing obesity is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by data from randomized controlled trials and meta-analyses. See the evidence report and accompanying background papers listed in the "Availability of Companion Documents" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate pharmacologic and surgical management of obesity in primary care

POTENTIAL HARMS

Side Effects of Medications

- *Sibutramine*: Modest increase in heart rate and blood pressure, nervousness, insomnia
- *Phentermine*: Cardiovascular, gastrointestinal
- *Diethylpropion*: Palpitations, tachycardia, insomnia, gastrointestinal
- *Orlistat*: Diarrhea, flatulence, bloating, abdominal pain, dyspepsia
- *Bupropion*: Paresthesia, insomnia, central nervous system effects
- *Fluoxetine*: Agitation, nervousness, gastrointestinal

Surgery

- Mortality
- Surgical complications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The existing literature is almost bereft of data regarding either pharmaceutical or surgical treatment of adolescent and pediatric patients. To the extent that existing data on adults are judged to be inapplicable to adolescents or children, new studies will need to be performed.
- Pharmacological treatment: Publication bias may exist despite a comprehensive search and despite the lack of statistical evidence for the existence of bias. Evidence of heterogeneity was observed for all meta-analyses.
- Surgical treatment: Only a few controlled trials were available for analysis. Heterogeneity was seen among studies, and publication bias is possible.
- This guideline is not intended to be used by commercial weight loss centers or for direct-to-consumer marketing by manufacturers.
- Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient 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)

Snow V, Barry P, Fitterman N, Qaseem A, Weiss K. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2005 Apr 5;142(7):525-31. [36 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Apr 5

GUIDELINE DEVELOPER(S)

American College of Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Physicians

GUIDELINE COMMITTEE

Clinical Efficacy Assessment Subcommittee (CEAS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Potential Financial Conflicts of Interest: Employment: P. Barry (Merck Institute of Aging and Health); Stock ownership: P. Barry (Merck & Co., Inc.); Grants received: P. Barry (Merck Co. Foundation)

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Annals of Internal Medicine Web site](#).

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Shekelle PG, Morton SC, Maglione M, Suttorp M, Tu W, Li Z, Maggard M, Mojica WA, Shugarman L, Solomon V. Pharmacological and surgical treatment of obesity. Summary, Evidence Report/Technology Assessment No. 103. (Prepared by the Southern California–RAND Evidence-based Practice Center, under Contract No. 290-02-0003.) AHRQ Publication No. 04-E028-1. Rockville, MD: Agency for Healthcare Research and Quality. July 2004. Electronic copies: Available from the [Agency for Healthcare Research and Quality \(AHRQ\) Web site](#).
- Shekelle PG, Morton SC, Maglione MA, Suttorp M, Tu W, Li Z, Maggard M, Mojica WA, Shugarman L, Solomon V, Jungvig L, Newberry SJ, Mead D, Rhodes S. Pharmacological and Surgical Treatment of Obesity. Evidence Report/Technology Assessment No. 103. (Prepared by the Southern California-RAND Evidence-Based Practice Center, Santa Monica, CA, under contract Number 290-02-0003.) AHRQ Publication No. 04-E028-2. Rockville, MD: Agency for Healthcare Research and Quality. July 2004. Electronic copies: Available from the [Health Services/Technology Assessment Text \(HSTAT\) Web site](#).
- Li Z, Maglione M, Tu W, Mojica W, Arterburn D, Shugarman LR, Hilton L, Suttorp M, Solomon V, Shekelle PG, Morton SC. Meta-analysis: pharmacologic

treatment of obesity. Ann Intern Med. 2005 Apr 5;142(7):532-46. Electronic copies: Available from the [Annals of Internal Medicine Web site](#).

- Maggard MA, Shugarman LR, Suttorp M, Maglione M, Sugarman HJ, Livingston EH, Nguyen NT, Li Z, Mojica WA, Hilton L, Rhodes S, Morton SC, Shekelle PG. Meta-analysis: surgical treatment of obesity. Ann Intern Med. 2005 Apr 5;142(7):547-59. Electronic copies: Available from the [Annals of Internal Medicine Web site](#)

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

PATIENT RESOURCES

The following is available:

- Summaries for patients. Treating obesity with drugs and surgery: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2005 Apr 5; 142(7):I-55

Electronic copies: Available from the [Annals of Internal Medicine Web site](#).

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on April 14, 2005. The information was verified by the guideline developer on June 3, 2005. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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