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- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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Health Care Guideline:

Prevention and Management of Obesity
(Mature Adolescents and Adults)

Prevention and Diagnosis Algorithm

1. Measure height and weight, and calculate body mass index

2. BMI ≥ 25?
   - yes
     - Assess for major and minor comorbid conditions
   - no

3. Normal weight BMI 18.5-24.9

4. Underweight BMI < 18.5

5. Out of guideline

6. Advise weight maintenance and manage other risk factors

7. Underweight BMI < 18.5

8. Is patient ready to lose weight?
   - yes
     - Assess goals and risk factors, and counsel regarding weight maintenance
   - no

9. Assess goals and risk factors, and counsel regarding weight maintenance

10. Negotiate goals and management strategy to achieve weight loss. Refer to risk-appropriate resources as needed.

   BMI 25-29.9  30-34.9  35-39.9  > 40
   Risk    Low   Moderate  High   Severe
   Nutrition  x    x     x     x
   Physical activity  x    x     x     x
   Behavioral management  x    x     x     x
   Medications  *x +  x     x     x
   Surgery  ?    *x     x

   *May be considered if concomitant obesity-related risk factors or diseases are present
   + May be initiated starting at a BMI of 27 or greater
   ? Currently considered investigational, see Conclusion Grading Worksheet C-Surgery

11. Reassess at 12 weeks

12. Goals achieved?
   - yes
     - Reassess goals and risk factors, and counsel regarding weight maintenance
   - no

13. Reassess goals and risk factors, and counsel regarding weight maintenance

See overview of management recommendations (on following page)

Return to Table of Contents
Overview of Management Recommendations

**Nutrition (balanced healthy eating plan or lower calorie balanced eating plan)**
- Encourage at least five servings of fruits and vegetables per day, whole grains with a fiber intake of 20-35 grams of fiber daily, less than or equal to 30% of calories from fat (7%-10% of calories from saturated fat, less than or equal to 1% from trans fat).
- For weight loss, encourage calorie reduction by evaluating portion sizes and journaling food intake.
- Provide tips for managing eating in social situations, dining out, take-out foods and food label reading.
- Provide referral to a dietitian, nutritionist or structured medically supervised weight loss program if available.
- Consider the use of meal replacements or very low calorie diet (VLCD) under medical supervision to help achieve weight loss in patients who are interested in such programs.

**Physical activity**
- Minimally, all patients should be encouraged to do at least 10 minutes of physical activity above what they are already doing each day and gradually increase the amount of time, followed by an increase in intensity.
- Ideally, all patients should meet the current recommendations of 60 minutes of moderate-intensity activity on most days per week. This can be done in 10-minute increments.
- Patients with chronic activity limitations (e.g., arthritis, respiratory dysfunction, neuropathy, morbid obesity) should be evaluated and managed to establish or enhance patient mobility.
- Small bouts of physical activity, not generally considered exercise, such as taking the stairs, parking farther away, exercising while watching TV, standing rather than sitting and activity breaks from screens (TV, computer, other media) are also important for healthy body weight.

**Behavioral management**
- Identify behaviors that may lead to increased weight gain: for example, stress, emotional eating, boredom and poor sleep.
- Help patients set specific, measurable, time-limited goals to decrease calorie intake and increase physical activity as appropriate.
- Suggest patients weigh themselves at least weekly and record the amount and type of food/beverages consumed and physical activity completed.
- Provide support and encourage patients to also seek support from family, friends and support groups in order to assist them with their eating, activity and weight goals.

**Medication**
- Evaluate for medications that may promote weight gain, and change when appropriate to a more weight-neutral alternative.
- Pharmacotherapy for weight loss should be included only in the context of a comprehensive treatment strategy that includes physical activity and nutritional support.
- Phentermine and orlistat are safe for most patients when carefully monitored by a physician; they may be part of a program for weight management or maintenance, which should include nutrition and physical activity changes when indicated.

**Surgery**
- Bariatric surgery is indicated in carefully selected patients. Patients should be motivated, well-informed in disease management, psychologically stable and accepting of operative risks.
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Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the guideline.

Sayeed Ikramuddin, MD is a speaker and receives funding and grant support from Covidien. He is also a speaker and proctor for Ethicon. None of these specific products is discussed in the guideline.

Bridget Slusarek, NP receives a honoraria from Ethicon and Allergan for speaking on band products. None of these specific products is discussed in the guideline.

No other work group members have potential conflicts of interest to disclose.

Evidence Grading

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document include BMI, BMI assessment for adolescents, BMI percentiles, obesity cultural issues, obesity and musculoskeletal pain, obesity and non-alcoholic fatty liver disease, subcutaneous and cardiovascular disease, obesity, type II diabetes, obesity behavioral management, calories and weight loss, obesity and comorbidities, food pyramid, obesity and genetics, low-fat diets, medication weight gain, physical activity, post-bariatric-surgery management, trans fats, waist circumference, weight-loss drugs, weight loss, depression and weight reduction strategies from January 2009 – June 2010.

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Evidence citations are listed in the document utilizing this format: (Author, YYYY [report class]; Author, YYYY [report class] – in chronological order, most recent date first). A full explanation of ICSI's Evidence Grading System can be found on the ICSI Web site at http://www.icsi.org.

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Reports of New Data Collections</strong></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Randomized, controlled trial</td>
</tr>
<tr>
<td>B</td>
<td>Cohort-study</td>
</tr>
</tbody>
</table>
| C     | Non-randomized trial with concurrent or historical controls  
    | Case-control study  
    | Study of sensitivity and specificity of a diagnostic test  
    | Population-based descriptive study |
| D     | Cross-sectional study  
    | Case series  
    | Case report |
| **Reports that Synthesize or Reflect upon Collections of Primary Reports** | |
| M     | Meta-analysis  
    | Systematic review  
    | Decision analysis  
    | Cost-effectiveness analysis |
| R     | Consensus statement  
    | Consensus report  
    | Narrative review |
| X     | Medical opinion |

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Foreword

Introduction

Obesity is a chronic, multifactorial disease with complex psychological, environmental (social and cultural), genetic, physiologic, metabolic and behavioral causes and consequences. The prevalence of overweight and obese people is increasing worldwide at an alarming rate in both developing and developed countries. Environmental and behavioral changes brought about by economic development, modernization and urbanization have been linked to the rise in global obesity. The health consequences are becoming apparent.

Obesity is a national epidemic in the United States with 72.5 million obese adults (Centers for Disease Control and Prevention, 2010 [D]). In 2007-2008, the prevalence of obesity was 32.4% among men and 35.5% among women (Flegel, 2010 [D]). The prevalence of extreme obesity has also increased. Approximately 6% of U.S. adults now have a BMI of 40 kg/m2 or higher (The Surgeon General’s Vision for a Healthy and Fit Nation, 2010 [NA]). One in every three children (31.7%) is overweight or obese (White House Task Force on Childhood Obesity, 2010 [NA]). More than one quarter of all Americans ages 17-24 are unqualified for military service because they are too heavy (White House Task Force on Childhood Obesity, 2010 [NA]).

For 2006, medical costs associated with obesity were estimated at as much as $147 billion (2008). Obese persons had estimated medical costs that were $1,429 higher than persons of normal weight (Finkelstein, 2009 [M]).

Obesity is the second leading cause of preventable death in the U.S., with only tobacco use use causing more deaths (Mokdad, 2004 [C]). More than 112,000 preventable deaths per year are associated with obesity (Surgeon General’s Vision for a Healthy and Fit Nation, 2010 [NA]).

The prevalence of various medical conditions increases with overweight and obesity for men and women as shown in Tables 1 and 2.

Note: Some studies show significant ethnic variability (Hedley, 2004 [C]; Ogden, 2002 [C]).
Table 1. Prevalence of Medical Conditions by Body Mass Index (BMI) for Men

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>18.5 to 24.9</th>
<th>25 to 29.9</th>
<th>30 to 34.9</th>
<th>&gt; 40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence Ratio (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>2.03</td>
<td>4.93</td>
<td>10.10</td>
<td>10.65</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>8.84</td>
<td>9.60</td>
<td>16.01</td>
<td>13.97</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>23.47</td>
<td>34.16</td>
<td>48.95</td>
<td>64.53</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>2.59</td>
<td>4.55</td>
<td>4.66</td>
<td>10.04</td>
</tr>
</tbody>
</table>

Table 2. Prevalence of Medical Conditions by Body Mass Index (BMI) for Women

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>18.5 to 24.9</th>
<th>25 to 29.9</th>
<th>30 to 34.9</th>
<th>&gt; 40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence Ratio (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>2.38</td>
<td>7.12</td>
<td>7.24</td>
<td>19.89</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>6.87</td>
<td>11.13</td>
<td>12.56</td>
<td>19.22</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>23.26</td>
<td>38.77</td>
<td>47.95</td>
<td>63.16</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>5.22</td>
<td>8.51</td>
<td>9.94</td>
<td>17.19</td>
</tr>
</tbody>
</table>


Scope and Target Population

This guideline addresses the prevention, diagnosis and management of obesity in mature adolescent and adult patients, including behavioral approaches, drug treatment and surgery.

This guideline does not address pregnant women or bodybuilders/weight trainers.

While this guideline does not address the pediatric population, the work group acknowledges the importance of addressing this epidemic and is continuing to gather evidence for future guideline expansion. The work group encourages health care systems to take an active role to educate families and children on body mass index measurements, nutrition, physical activity and lifestyle change.

For more information, the work group recommends the following resources:

- Appendix A of this guideline, "Body Mass Index-for-Age Percentiles."

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Aims

1. Increase percentage of patients who have an annual body mass index (BMI) recorded or measured 
   (Annotation #1)
2. Increase the percentage of patients with an elevated body mass index who have received education and 
   counseling regarding weight loss. (Annotation #10)
3. Improve the outcome of treatment for patients with BMI >= 25. (Annotations #8, 10)
4. Increase community (employers, schools) participation in the prevention and treatment of obesity. 
   (Annotations #10, 13)

Clinical Highlights

- Obesity is a chronic disease that is a multifactorial, growing epidemic with complex political, social, 
  psychological, environmental, economic and metabolic causes and consequences. Obesity affects 
  essentially every organ system in the body. Health consequences increase across the body mass index 
  span, not just for the extremely obese. (Introduction)
- Calculate the body mass index; classify the individual based on the body mass index categories. Educate 
  patients about their body mass index and their associated risks. (Annotation #1; Aim #1)
- Effective weight management strategies are available and include nutrition, physical activity, lifestyle 
  changes, medication and surgery. (Annotation #6; Aim #2)
- A 5%-10% weight loss can reduce a patient's risk of heart disease and diabetes that is clinically significant, 
  and should be encouraged for all patients who are overweight and obese. This amount of weight loss 
  and maintenance should be considered a clinical success and commended. This can be achieved and 
  maintained with a high-intensity medical weight loss program even for the morbidly obese. (Annotation 
  #8; Aim #2)
- The physician should follow the 5 A's (Ask, Advise, Assess, Assist, Arrange). Physician intervention 
  can be effective, the physician can have an important influence, and successful weight management is 
  possible. (Annotation #8; Aim #3)
- Weight management requires a team approach. Be aware of clinical and community resources. The 
  patient needs to have an ongoing therapeutic relationship and follow-up with a health care team. Weight 
  control is a lifelong commitment, and the health care team can assist with setting specific goals with the 
  patient. (Annotations #10, 13; Aim #4)
- Beyond their clinical role, primary care physicians should be aware of their roles as community leaders 
  and public health advocates. (Annotations #10, 13; Aim #4)
Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish a system for using a Patient Readiness Scale. The scale can be used to determine if the patient is ready to talk about weight loss and/or would like information.

2. Establish a system for staff to efficiently calculate body mass index prior to the physician entering the exam room. This action may be considered a vital sign and built into the rooming protocol. A body mass index chart can be placed by each scale in the clinic; if the organization has an electronic medical record, it may have a component for immediate calculation.

3. Develop a tracking system that periodically reviews patient charts to identify patients who are overweight or obese so that clinicians are aware of the need to discuss the issue with the patient.

4. Establish a system for staff and physician training around skills and knowledge in the areas of motivational interviewing; brief, focused advice on nutrition, physical activity and lifestyle changes; and evaluation of evidence of effectiveness of treatment options.

5. Establish a system for continuing education on evidence-based obesity management for providers, nurses and ancillary clinic staff.

6. Remove barriers to referral programs for weight loss by understanding where programs are and what process is required for referrals.

7. Develop medical record systems to track status of patients under the provider's care with the capability to produce a tickler system for patient follow-up by provider/staff.

8. Use tools such as posters and brochures throughout the facility to promote a healthy lifestyle around nutrition and activity while encouraging patient knowledge of his or her body mass index.

9. Develop patient-centered education and self-management programs, which may include self-monitoring, self-management and skills such as journaling.

10. Build systems to track outcomes measures, as well as ongoing process measures. Track the response rate to various treatments/strategies. Improvement rates – the body mass index is stable or has decreased over time.

11. Systems to coordinate care ensure continuity and keep providers informed of progress.
   
   - Develop electronic tracking systems for panel or population management.
   - Educate patients to foster awareness and knowledge of body mass index for self-monitoring and reporting.
   - Structure follow-up visits with patient per guideline recommendations.

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Related ICSI Scientific Documents

Guidelines

- Hypertension Diagnosis and Treatment
- Diagnosis and Management of Type 2 Diabetes Mellitus in Adults
- Lipid Management in Adults
- Major Depression in Adults in Primary Care
- Preventive Services for Adults
- Assessment and Management of Chronic Pain

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Algorithm Annotations

1. Measure Height and Weight, and Calculate Body Mass Index

Key Points:

- Body mass index should be calculated preferably annually for screening and as needed for management.
- Body mass index calculation extends to all age groups. Children and adolescents less than 18 years old should use a body mass index percentile for age to determine a healthy weight status.

1a. Calculate body mass index

Calculate the body mass index at least annually for screening and as needed for management. Classify it based on the body mass index categories (See Table 3). Educate patients about their body mass index and associated risks for them (McTigue, 2003 [M]).

Body Mass Index Calculation

\[
\frac{\text{weight}}{\text{height squared}} = \frac{\text{kg}}{\text{m}^2} \quad \text{or} \quad \frac{(\text{lbs x 703})}{\text{inches}^2}
\]

Table 3: Adult BMI Categories

<table>
<thead>
<tr>
<th>BMI</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5-24.9</td>
<td>Normal weight</td>
</tr>
<tr>
<td>25-29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>30-34.9</td>
<td>Obese – class I</td>
</tr>
<tr>
<td>35-39.9</td>
<td>Obese – class II</td>
</tr>
<tr>
<td>40 or more</td>
<td>Extreme obesity – class III</td>
</tr>
</tbody>
</table>

The clinical significance of an abnormal or rapidly changing body mass index is assessed with the following in mind:

- Body mass index is not a direct measure of adiposity. It is a derived value that correlates well with total body fat and markers of secondary complications, e.g., hypertension and dyslipidemia (Barlow, 2007 [R]).
- An abnormally high body mass index does not address the distribution of body fat: i.e., central vs. peripheral or visceral vs. subcutaneous. Central or visceral fat carry greater risk for morbidity and mortality.
- Waist circumference (as recommended by the National Heart, Lung and Blood Institute: see Annotation #7, "Assess for Major and Minor Comorbid Conditions") provides an additional dimension for assessing visceral adiposity and clinical risk.
- Metabolic assessment is important in the patient at risk, especially if there is a family history of heart disease or type 2 diabetes mellitus.

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Mature adolescents

Management of obesity and treatment options in the mature adolescent is a significant concern due to the serious and potentially life-threatening symptoms and conditions they may face (see Table 4).

For the purpose of this guideline, the physiologically mature adolescent will be considered as having skeletal maturity. The extension of guideline medication and surgical recommendations to this population is physiologically feasible. However, given the complexity of obesity treatment and psychological issues, the use of medication and surgery in physiologically mature adolescents needs to be addressed within provider community practice standards.

Body mass index in children and adolescents is based on a percentile while the child is still growing in height. These percentiles are defined by National Health and Nutrition Examination Survey (NHANES) data.

A body mass index percentile calculation is worthwhile in the growing patient under age 18, because it provides a reference point for future comparison. Subsequent observations establish a relative trajectory for this index of obesity. Although there are no standards for rate of change of body mass index per year, a rapid increase or decrease warrants clinical attention. The separation between 50th and 75th percentiles is approximately two to three body mass index units for adolescent girls across ethnic groups. Adolescent boys have approximately two body mass index units difference between these percentiles. An annual increase of greater than three units suggests excessive gain (Barlow, 1998 [R]).

Overweight is defined as a body mass index greater than 85th percentile, and obesity is defined as body mass index greater than 95th percentile. Extreme obesity is now defined as a body mass index greater than 99th percentile for age.

See Appendix A, "Body Mass Index-for-Age Percentiles."

Table 4: Clinical Conditions Associated with Adolescent Obesity

<table>
<thead>
<tr>
<th>History</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>Gall bladder disease</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>Polycystic ovarian syndrome or HAIRAN syndrome</td>
</tr>
<tr>
<td>Developmental delays</td>
<td>Genetic disorders, e.g., Prader-Willi syndrome, Lawrence Moon-Biedl syndrome</td>
</tr>
<tr>
<td>“Dirty neck”</td>
<td>Insulin resistance, type 2 diabetes mellitus</td>
</tr>
<tr>
<td>Dysfunction in mood, school performance, peer relationships</td>
<td>Depression, anxiety, eating disorders and sexual abuse</td>
</tr>
<tr>
<td>Exercise intolerance</td>
<td>Asthma</td>
</tr>
<tr>
<td>Headache</td>
<td>Pseudotumor cerebri</td>
</tr>
<tr>
<td>Hip/knee pain</td>
<td>Slipped capital femoral epiphysis</td>
</tr>
<tr>
<td>Nocturnal breathing difficulty</td>
<td>Sleep apnea, hypoventilation syndrome</td>
</tr>
<tr>
<td>Poor linear growth</td>
<td>Hypothyroidism, Cushing’s growth hormone deficiency</td>
</tr>
</tbody>
</table>
6. Advise Weight Maintenance and Manage Other Risk Factors

Key Points:

- It is important to address the issue of weight maintenance for those with body mass index in the normal range.

- Weight management includes physical activity, nutrition and behavior management strategies.

Lifetime risk of obesity is high for residents of the United States. Lifetime risk of diabetes is about 32.4% for men and 35.5% for women, and lifetime risk for obesity is higher than this (Flegel, 2010 [D]). Therefore, it is important to address the issue of weight maintenance for those with body mass index in the normal range (18.5 to 24.9). Successful weight management requires a lifestyle approach that integrates physical activity, nutrition, behavioral management and attention to psychosocial needs.

- First, encourage regular physical activity at recommended levels. Regular physical activity is strongly related to maintaining normal weight. In selecting types of physical activity, it is important to consider the age of the patient, musculoskeletal limitations and availability of exercise facilities. For inactive patients, this may include as little as 10 minutes of physical activity a day. Ideally, 30 to 60 minutes of moderate physical activity on most days of the week is recommended (> 150 minutes a week). However, for those who have lost a considerable amount of weight, higher amounts of physical activity may be required for weight maintenance (> 275 minutes a week). Enjoyment and variety of physical activity are also key features for adherence (Jakicic, 2011 [R]; Donnelly, 2009 [R]).

- Second, provide structured lifestyle modification suggestions that include specific nutrition recommendations, educational sessions and frequent contact with health care providers, such as a dietitian. Focus on calorie balancing, using a combination of decreased caloric intake with increased caloric expenditure. Include nutrition education (e.g., interpreting food labels); managing restaurant and social eating situations; making healthy, nutritious food choices; using portion control; and recipe modification.

There is considerable evidence that individuals consuming low-fat, low-calorie diets are successful at maintaining weight loss for 12 months and longer. Data from the National Weight Control Registry demonstrates that successful weight maintainers consume a low-calorie diet containing ~ 40 g fat (24% of calories), 200 g carbohydrate (56% of calories) and 70 g protein (19% of calories). A low-fat diet (25%-30% calories from fat) is considered the conventional therapy for treating obesity (Klein, 2004 [R]). Data is emerging to suggest that patients who are insulin resistant may respond better to a lower carbohydrate diet (< 30% carbohydrate). This may also be linked to genetics (Gardner, 2007 [A]).

- Third, encourage behavior management strategies that may include weekly weight checks, food journals and monitoring daily routine that focuses on a balanced lifestyle. Balance includes eating a nutritionally balanced breakfast soon after awakening and eating balanced meals at regular intervals thereafter; incorporating fun physical activity into the day; and scheduling the week to include rest, play and social interactions along with work, school and family responsibilities.

Specific behavioral strategies to promote behavior change include self-monitoring some aspect of behavior that, in itself, typically results in behavior change; non-food rewards and positive reinforcements; reminders; stimulus control (changing social or environmental cues that trigger eating behavior); stress management, problem solving and helping patients believe they can be successful.
7. Assess for Major and Minor Comorbid Conditions

Key Points:

- It is important to assess for other conditions as treatment decisions and outcomes may be influenced by their presence.

- Waist circumference greater than or equal to 40 inches for males and greater than or equal to 35 inches for females is an additional risk factor for complications related to obesity.

- To rule out depression and eating disorders, brief screenings should be conducted if appropriate.

- Assessment should include a complete medical history including identifying medications that may induce weight gain or interfere with weight loss.

- Screening for sleep disorders should also be done.

Table 5: Comorbid Condition Assessment

<table>
<thead>
<tr>
<th>Comorbid Condition</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25-30</td>
</tr>
</tbody>
</table>
| 0                  | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy |
| 1-2 Minor Comorbid Conditions | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy |
| Major Comorbid Conditions OR 3 Minor Comorbid Conditions | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy | Counsel and educate:  
  • Lifestyle changes  
  • Behavioral management  
  • Medication therapy  
  • Surgical options |

The FDA approves drug therapy only for BMI greater than 27.
Minor Comorbid Conditions

- Cigarette smoking
- Hypertension (BP greater than or equal to 140/90) or current use of antihypertensives
- LDL cholesterol > 130 mg/dL
- HDL cholesterol < 40 mg/dL for men; less than 50 mg/dL for women
- Prediabetes*
- Family history of premature coronary artery disease
- Age ≥ 65 years for males
- Age ≥ 55 years for females or menopausal females

Major Comorbid Conditions

- Waist circumference (males ≥ 40 inches, females ≥ 35 inches)
- Established coronary artery disease
  - History of myocardial infarction
  - History of angioplasty
  - History of CABG
  - History of acute coronary syndrome
- Peripheral vascular disease
- Abdominal aortic aneurysm
- Symptomatic carotid artery disease
- Type 2 diabetes mellitus
- Obstructive sleep apnea

* The term pre-diabetes has been adopted by the American Diabetes Association and others, and refers to those who have a fasting plasma glucose of 100 mg/dL to 125 mg/dL inclusive, as well as those with a two-hour post-75-gram-oral-glucose tolerance test value of greater than or equal to 140 mg/dL to 200 mg/dL or a HbA1C between 6% and 6.5%.

† The clustering of these symptoms has been described as the metabolic syndrome. Several formal definitions exist (deFerranti, 2004 [C]; National Heart, Lung and Blood Institute, 2003 [R]; World Health Organization, 2004 [R]).

Waist Circumferences

While the work group acknowledges the debate on whether or not waist circumference adds information, the work group recommends that clinicians measure waist circumference.

Waist circumference is an additional risk factor for complications related to obesity for males measuring greater than or equal to 40 inches, and females greater than or equal to 35 inches (Yusuf, 2005 [C]; Lean, 1998 [D]). Men with waist circumferences greater than or equal to 40 inches (102 cm) and women with a waist circumference greater than or equal to 35 inches (88 cm) are at increased risk for cardiovascular disease and a range of other conditions such as sleep disorders and diabetes (Lean, 1998 [D]).

There is data that supports systematic and periodic assessment of body mass index and use of this information to assess risk and guide interventions to manage elevated body mass index (Freiberg, 2008 [C]; Klein, 2007 [R]). Body mass index conveys information about obesity, but this information may be supplemented by additional information on waist circumference. Body mass index has been shown to be an accurate predictor of future health states, and elevated body mass index elevates risk of cardiovascular events, cardiovascular death, total mortality, type 2 diabetes, sleep disorders, and myriad other clinical conditions (Balkau, 2007 [D]). Increased waist circumference also predicts many of these disorders (Davidson, 2008 [D]; Balkau, 2007 [D]). There is some evidence that for some patient subgroups, waist circumference that is elevated adds incremental information on future health states (Koster, 2008 [D]; Janssen, 2002 [D]).
Source: National Heart, Lung and Blood Institute.

**Screening for Depression**

The evidence showing the linkage between depression and obesity is mixed (Jorm, 2003 [D]; Roberts, 2003 [B]; Friedman, 1995 [R]; DiPietro, 1992 [B]). Higher rates of depression have been found in severely obese people, especially younger women with poor body image (Dixon, 2003 [C]; Onyike, 2003 [D]). It is difficult to study whether the depression is secondary to the obesity or to existing comorbid conditions (Stunkard, 2003 [R]). Weight loss often leads to improvement of depression scores (Dixon, 2003 [C]).

Depression is identified more often in obese women and teenagers and is less likely to be diagnosed in men (Jorm, 2003 [D]; Stunkard, 2003 [R]; Palinkas, 1996 [C]; Istvan, 1992 [D]). Depression in the elderly is often associated with weight loss, while depression in younger females can be associated with weight gain (DiPietro, 1992 [B]).

In the past, depression has been associated with poor weight loss outcomes (Linde, 2004 [C]). However, this is not necessarily the case. People with depression can do well in weight-loss treatment, and their symptoms can improve (Linde, 2010 [A]).

Bariatric surgery patients with poorly managed depression or anxiety are at greater risk for weight regain within the first five postoperative years (Waters, 1991 [D]). One explanation for this may be found in a line of research investigating biological pathways that link depressive symptomatology to increased adiposity and weight gain (Miller, 2003 [C]). Weight-loss studies have often excluded people with depression (Linde, 2004 [C]). More studies to address this issue are warranted.

Screening for depression can include asking the following questions.

Over the past month, have you been bothered by:

- little interest or pleasure in doing things?
- feeling down, depressed or hopeless?

---

**Measuring-Tape Position for Waist (Abdominal) Circumference in Adults**

To measure waist circumference, locate the upper hip bone and the top of the right iliac crest. Place a measuring tape in a horizontal plane around the abdomen at the level of the iliac crest. Before reading the tape measure, ensure that the tape is snug, but does not compress the skin, and is parallel to the floor. The measurement is made at the end of a normal expiration.
If the patient answers "yes" to either one of the above questions, consider using a questionnaire to further assess whether the patient has sufficient symptoms to warrant a full clinical interview and a diagnosis of clinical major depression. An example of such a questionnaire is the PHQ-9 (Patient Health Questionnaire).

This should not be considered a comprehensive screening for depression, which is beyond the scope of this guideline. See the ICSI Major Depression in Adults in Primary Care guideline for more information.

The work group's opinion is that patients who are clinically depressed should undergo treatment with medication and/or psychotherapy to maximize their ability to lose weight. An antidepressant that does not contribute to weight gain should be chosen. Medications such as bupropion, venlafexine and sertraline have been shown in clinical studies to be associated with the least weight gain over time.

**Screening for an Eating Disorder**

Eating disorders, particularly binge eating disorder, may complicate the treatment of obesity.

Screening for eating disorders can include asking the following questions:

- Do you eat a large amount of food in a short period of time – like eating more food than another person may eat in, say, a two-hour period of time?
- Do you ever feel like you can't stop eating even after you feel full?
- When you overeat, what do you do (e.g., Have you ever tried to "get rid of" the extra calories that you've eaten by doing something like: Take laxatives? Take diuretics [or water pills]? Smoke cigarettes? Take street drugs like cocaine or methamphetamine? Make yourself sick [induce vomiting])?

If the patient answers "yes" to any of the above questions, consider further evaluation or a referral to a dietitian or a behavioral health specialist who specializes in eating disorders or in health psychology and working with bariatric patients.

More comprehensive screening tools include the SCOFF Questionnaire or Eating Attitudes Test (EAT-24).

**Screening for Medication Use That Contributes to Weight Gain**

The assessment of the obese patient should include a complete medication history to identify medications that may induce weight gain or interfere with weight loss. Non-steroidal anti-inflammatory drugs and calcium channel blockers may cause peripheral edema rather than body fat weight gain. HIV protease inhibitors are associated with lipodystrophy (central obesity) that is actually a change in body fat distribution rather than a body fat weight gain. If possible, alternative medications that are weight-neutral or that induce weight loss should be selected (Kushner, 2003b [R]; Vanina, 2002 [R]; Ganguli, 1999 [R]). A common belief exists among women and clinicians that there is an association between the use of combination hormonal contraceptives and weight gain. This belief may prevent some women from starting hormonal contraception or cause early discontinuation of medication. A review of 42 clinical trials – including three randomized, placebo-controlled trials – did not find evidence to support a causal relationship between the use of combination oral contraceptives and weight gain. The authors of the review concluded that current evidence is not sufficient to determine the effect of combination contraceptives on weight, but no large effect is evident (Gallo, 2004 [M]).

Please see Appendix B, "Medications Associated with Weight Gain and Weight Loss," and the ICSI Diagnosis and Management of Type 2 Diabetes Mellitus in Adults guideline for more information.
Screening for a Sleep Disorder

Overweight and obese patients who have not had a sleep study should be encouraged to do so if they show signs of sleep disturbance such as daytime somnolence, snoring, evidence of apnea episodes provided by a partner, or issues with daytime memory and attention.

Screening for sleep disorders such as sleep apnea and night eating syndrome is important. Patients with documented sleep apnea need to be encouraged to be compliant with their treatment plan in order to improve their ability to lose weight. Sleep duration is important for weight loss, as well. Sleep curtailment decreased the proportion of weight lost as fat by a total of 2.4% if patients slept for 5.5 hours compared to 5.4% if the patient slept for 8.5 hours (Nedeltcheva, 2010 [A]).

8. Is Patient Ready to Lose Weight?

Key Points:

• Knowing the patient's readiness to change can help the provider understand a patient's level of motivation and how to tailor communication about weight loss.

• Patients need to set realistic, achievable goals and to be held accountable to practice new behaviors that produce and maintain weight loss.

Introduction to Weight Management/Lifestyle Change

Weight management is a skill. Patients need to set realistic, achievable goals and to be held accountable to practicing the new behaviors that produce and maintain weight loss. Recordkeeping or self-monitoring of progress on specific behaviors is key to successful weight management. Strategies to reduce calorie intake are to incorporate more fruits and vegetables into meals and snacks; make lower-calorie, healthy choices at the grocery store and in social settings; and become more aware of portion sizes consumed. Additionally, portion-controlled, calorie-controlled meal replacements may be used. Every effort needs to be made to incorporate more physical activity on a daily basis.

Patients and physicians must realize that the culture we live in continues to make eating less and being more physically active extremely challenging. It is easy for patients to become overwhelmed by the process if they believe all they need is willpower. It is discouraging if they think they have to quit eating all of their favorite foods and/or do hours of grueling exercise. It is even more challenging if they have a high level of stress in their lives. Providers should be educated that 5%-10% weight loss is clinically successful in reducing health risks (Yancy, 2010 [AJ]).

The ICSI Patient Advisory Council reviewed this guideline and supports the value of the physician initiating the conversation and suggested that patients were more likely to act on the recommendations of their provider. Also, because obesity can be an overwhelming condition for the patient, creating small achievable goals and celebrating those achievements were important for continued success and healthy choices.

The physician should follow the 5 A's (Ask, Advise, Assess, Assist, Arrange). Physician intervention can be effective, the physician can have an important influence, and successful management is possible.

• ASK about, and measure height and weight.

• ADVISE to lose weight. In a clear, strong but sensitive and personalized manner, urge every overweight or obese patient to lose weight.

• ASSESS readiness to lose weight. Ask every overweight or obese patient if he or she is ready to make a weight loss attempt at the time, e.g., within the next 30 days.
• **ASSIST** in weight-loss attempt. Help the patient with a weight-loss plan. Refer to appropriate resources.

• **ARRANGE** follow-up. Schedule follow-up contact, either in person or via telephone.

**ASK**

Implement an office wide system to ensure that for every patient, preferably on an annual basis, weight is measured, body mass index is calculated, and patients are educated about their body mass index and risk status. See Annotation #1, "Measure Height and Weight, and Calculate Body Mass Index."

**ADVISE to lose weight**

Patients who are in the normal weight range should be encouraged to be physically active and eat a healthy diet to help prevent future weight gain. If a patient is overweight or obese, physicians need to communicate this in a direct but sensitive manner and also make the recommendation to consider losing weight. Research suggests that adults who report that their physician advised them to lose weight are more likely to initiate weight loss attempts. Obese patients who reported receiving advice to lose weight have been shown to be almost three times as likely to report trying to lose weight compared to those who did not receive advice. *(Abid, 2005 [M]).* The next important step will be to engage the patient in a discussion regarding his/her current level of motivation for losing weight.

**ASSESS readiness to change/motivation for weight loss**

Although definitive evidence regarding the prognostic significance of an individual's stage of change is not available, assessment of an individual's readiness to make a weight-loss attempt is a key step in encouraging weight loss efforts. There is evidence that moving into and/or staying longer in the "action" stage for weight loss is associated with better weight outcomes. For example, Prochaska and colleagues found that the more clients progressed into the action stage early in weight-loss therapy, the more successful they were in losing weight by the end of treatment *(Prochaska, 1992 [A]).* A study showed that the elapsed time in action or maintenance for multiple weight-loss-related target behaviors is longitudinally related to weight loss over a two-year period *(Logue, 2004 [B]).* However, others have found no association between baseline stage of change for weight loss and short- *(Macqueen, 2002 [C]) and long-term (e.g., three years) weight outcomes *(Jeffery, 1999 [C]).* The only published randomized trial specifically evaluating the efficacy of a primary-case based, transtheoretical model, stage-matched weight loss intervention delivered was associated with weight maintenance, but not weight loss at one year follow-up *(Logue, 2005 [A]).* The authors note that their intervention (e.g., monthly telephone advice) was not intensive enough to produce clinically significant weight losses, which is consistent with a large body of evidence suggesting that intervention intensity and frequency of contact are strongly associated with successful outcomes *(Jeffery, 2000 [R]).* Additional psychological and lifestyle factors clearly have an influence on weight-loss success. For example, research suggests that depression status may adversely affect treatment outcome *(Linde, 2004 [C]) and should be considered when making recommendations for weight loss to patients. It is recommended that physicians assess patient motivation and support, stressful life events, psychiatric status, time availability and constraints, and appropriateness of goals and expectations to help establish the likelihood of lifestyle change in the area of nutrition and physical activity. Assessing readiness to change involves more than simply asking patients, "Are you ready to lose weight?"

One helpful strategy to begin an assessment is to anchor patients' interest and confidence for change on a numerical scale. Ask patients, "On a scale from 0 to 10, with 0 being not important and 10 being very important, how important is it for you to lose weight at this time?" Follow this by asking, "Also, on a scale from 0 to 10, with 0 being not confident and 10 being very confident, how confident are you that you can lose weight at this time?" Physicians can also ask patients, "On a scale from 0 to 10, with 0 being not interested and 10 being very interested, how interested are you in losing weight at this time?"
To obtain further information about patient readiness to change, a Patient Readiness Checklist can be administered. For example, see the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity" (http://www.ama-assn.org/ama/pub/category/10931.html, booklet 3, figure 3.2.). This checklist assesses multiple domains including patient motivation/support for change, stressful life events that may hinder change efforts, psychiatric issues (e.g., depression, binge eating), time availability/constraints, and weight-loss goals/expectations. Figure 3.3 of the AMA guideline is a weight-loss questionnaire that may also be a useful tool.

Another useful tool can be the Patient Activation Measure or PAM. The PAM is a tool designed to assess an individual's knowledge, skill and confidence with respect to managing his or her health. It has been used and studied in several chronic disease management programs. Based on a 13-item scale, each patient is assigned an "activation score" from Level 1 to 4 with 1 being the lowest health activation (patients tend to be overwhelmed and unprepared to play an active role in their own health) to 4 being the highest (patients have adopted many of the behaviors needed to support a healthy lifestyle). Using this measure can help guide a clinician as to where to begin the assessment process. Patients with lower activation need a different approach and more health coaching to get them to a point where they can consider weight management. (Hibbard, 2009[A]; Schmittdiel, 2007 [D]; Hibbard, 2005 [A]; Hibbard, 2004 [C]).

ASSIST in weight-loss attempt

• **Patient not currently interested/motivated for weight loss?** Patients may fit into this category either because they are unaware that their weight status is a problem, or they are not interested in changing (precontemplator), or they are aware of the problem but are just starting to think about changing (contemplator). Providing information about the health risks of obesity and the potential health benefits of weight loss may be most appropriate for those who are not yet interested in changing. For patients who are just beginning to contemplate change, discussion of ambivalence about change and of barriers to change may be helpful strategies. Patient readiness to lose weight should be reassessed at regular intervals.

• **Patient interested/motivated for weight loss?** Patients who are interested and motivated to lose weight likely need information about appropriate nutrition, activity and behavioral recommendations and support in making these lifestyle changes. The sections below describe in detail recommendations for eating, physical activity and behavioral modification. Physicians need to be aware of resources and appropriate referral sources within their clinics and/or local communities for their patients. See the Quality Improvement Support section, "Resources Table," for Web sites and further information about weight management.

ARRANGE follow-up

Although physicians may not necessarily be directly involved in weight-management counseling, it is recommended that a follow-up appointment to evaluate progress be scheduled approximately three months following initiation of a weight-loss program by a patient and progress should be reassessed at appropriate intervals thereafter.

Studies have shown that weekly follow-up for the first three months and gradually decreasing to monthly for the next six months to four years can produce successful weight loss and maintenance (Wing, 2010 [A]). A successful intensive lifestyle intervention program such as the Look AHEAD (Action for Health in Diabetes) program (a study of weight loss and maintenance in diabetic patients) produced 9% weight loss in one year and maintained a 6% weight loss at four years. Institutions wishing to start an intensive lifestyle intervention program for overweight and obese patients should consider modeling it after this successful program (Wadden, 2009 [A]).

See Annotation #13, "Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance."

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9. Assess Goals and Risk Factors, and Counsel Regarding Weight Maintenance

See Annotation #13, "Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance," for additional information.

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- Nutrition recommendations include calorie reduction by evaluating portion size and number of servings recommended in mypyramid.gov.
- The physiological effects of physical activity greatly depend on the frequency, duration and intensity of movement. Ten-minute bouts of exercise to total a goal of 60 minutes a day should be encouraged.
- Pharmacotherapy, when used for six months to one year, along with lifestyle modification including nutrition and physical activity, can produce weight loss in obese adults.
- Bariatric surgery is indicated in carefully selected patients with a body mass index greater than or equal to 40 or 35-39.9 who are at a very high absolute risk for increased morbidity or premature mortality (See Annotation #7, Table 5). Patients are to be motivated, well-informed in disease management, psychologically stable and accepting of operative risks.
- Daily, weekly and short-term goals are important. High-intensity weekly face-to-face meetings produce the best results.

Nutrition

Appropriate nutrition therapy for weight management will be developed collaboratively with the patient. Assessment and education may require a provider with expertise in nutrition therapy. It is important that physicians understand and support the general principles of nutrition recommendations for weight management.

Diet history or eating pattern history. A food/beverage frequency checklist, three-day food/beverage record and weekly food/beverage diary are common tools used to collect information about dietary habits.

Nutrition assessment. Evaluate the patient's current food and beverage choices and eating and drinking habits. Assessment may include the following:

- Current intake of food and beverage calories and fat
- Portion sizes and inclusion of all food groups
- Underconsumption or overconsumption of nutrients
- Use of supplements
- Use of meal replacements
- Stage of behavior change for specific behaviors, such as fruit and vegetable consumption
- Symptoms of possible eating disorder – triggers for overeating
- Timing/consistency of meals and snacks

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Nutrition recommendations. Select a meal planning approach that the patient is willing and ready to incorporate into present lifestyle. Dietary guidance should be individualized and tailored to food and beverage preferences; it should allow for flexible approaches to reducing calorie intake (National Heart, Lung and Blood Institute, 2000 [R]). Recommend:

- Achieving weight loss by a reduction in calorie intake. A moderate decrease in calories (500-1,000 kcal per day) can result in a progressive weight loss of 1-2 pounds per week (National Heart, Lung and Blood Institute, 2000 [R]). (See Table 6.)

- A weight-loss eating plan that supplies at least 1,000-1,200 kcal/day for women and 1,200-1,600 kcal/day for men (National Heart, Lung and Blood Institute, 1998 [R]).

Table 6: *Lower-Calorie Meal Plan for Weight Loss (NHLBI, 2000; NHLBI 2002)

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Recommended Intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>500-1,000 kcal/day reduction from usual intake</td>
</tr>
<tr>
<td>Total fat</td>
<td>30% or less of total calories</td>
</tr>
<tr>
<td>Trans fat</td>
<td>Less than or equal to 1% of total calories</td>
</tr>
<tr>
<td>Saturated fat</td>
<td>7%-10% of total calories</td>
</tr>
<tr>
<td>Monounsaturated fat</td>
<td>Up to 15% of total calories</td>
</tr>
<tr>
<td>Protein</td>
<td>15% of total calories</td>
</tr>
<tr>
<td>† Carbohydrates, complex, from variety of vegetables, fruits and whole grains</td>
<td>55% of total calories</td>
</tr>
<tr>
<td>Fiber</td>
<td>Equal to or greater than 25-35 grams</td>
</tr>
</tbody>
</table>

*The macronutrient composition of weight loss diets continues to be controversial and the subject of ongoing research.

† The RDA (recommended daily allowance) for carbohydrates has been established as a minimum of 130 grams per day for adults and children (Institute of Medicine of the National Academies, 2002 [NA]).

- An eating plan that is balanced and consistent with other national dietary guidelines (Esposito, 2003 [AJ]). Encourage at least five servings fruits and vegetables per day. Limit fat intake to 30% of calories from fat, 7%-10% of calories from saturated fat, less than or equal to 1% trans fat. Emphasize whole grains, with a fiber intake of 35 grams or more daily.

- Keep trans fat intake below about 1% of calories. The lower the combined intake of saturated and trans fat and the lower the dietary cholesterol intake, the greater the cardiovascular benefit will be (USDA, 2005 [R]). Many products served in restaurants, including fast food, often contain high levels of trans fat and are exempt from labeling regulations. Reduce the amount of trans fat by limiting foods that contain "partially hydrogenated" vegetable oils that are found in some margarines, shortenings, crackers, candies, baked goods, cookies, snack foods, fried foods, salad dressings and other processed foods.

- All low-calorie diets will produce weight loss in the short term (3 to 12 months) (Bravata, 2003 [M]; Freedman, 2001 [R]; National Heart, Lung and Blood Institute, 1998 [R]). More studies are needed to determine long-term efficacy of weight loss and maintenance of low-carbohydrate (less than 100 grams) diets. Guidelines from the American Diabetes Association state that for short-term weight loss, either a low-carbohydrate or low-fat calorie-restricted diet may be effective. Initiated
with a two-week phase of carbohydrate restriction of 20-25 g daily depending on baseline weight, participants lost weight and were able to increase carbohydrate intake at 5 g increments each week. People who are insulin resistant may respond better to a lower-carbohydrate meal plan (< 30% carbohydrate) (Garder, 2007 [A]).

Low-carbohydrate diets have been found to result in more rapid short-term weight loss than conventional low-calorie diets at three and six months, but the difference was not significant at one year. Over a one-year period, low-carbohydrate diets have been found to result in greater improvements than conventional diets in triglycerides and HDL cholesterol levels but not LDL cholesterol. Long-term safety and effectiveness of low-carbohydrate diets for weight loss and cardiovascular risk factor improvements are not yet known.

- For information on popular diets, see the Resources Table section.
- Weight-loss recommendations that exclude food groups and/or restrict macronutrients substantially below the dietary reference intakes and RDAs can cause nutrient deficiencies and increase health risks (Bonow, 2003 [NA]; Freedman, 2001 [R]). A dietitian can assess food and beverage records using a variety of tools. A quick method is to evaluate portion sizes and number of servings recommended for food groups in the food guide pyramid. There are also food guide pyramid assessment tools available on the USDA Web site that calculate calories and total nutrients from entered food records. See the "Resources Table" section for more information.
- There are reviews of low-cost, moderate-cost and high-cost food plans available at the USDA Web site that evaluate the weekly cost of healthy eating plans. The Web site is http://www.cnpp.usda.gov/USDAFoodPlansCostofFood.htm.
- Another meal planning approach is utilizing meal replacements. This typically involves using frozen meals, formula shakes or bars or prepackaged meals to control portion sizes and simplify food decisions. Drinks and bars are used to replace two meals and one snack per day. Most meal replacements contain 200-400 calories, and additional servings of fruits and vegetables are recommended. Weight maintenance usually involves replacing one meal per day (Delahanty, 2002 [R]; Heymsfield, 2003 [M]; Kushner, 2003a [R]).
- VLCDs (very low calorie diets) should be used only for weight-loss therapy by experienced practitioners with specialized monitoring and use of supplements. (National Heart, Lung and Blood Institute, 2000 [R]). If VLCDs are used, weight loss can be expected in the first six months (~20 kg); however, there is rapid regain between 6 to 12 months if a maintenance program is not included. Weight loss is typically not maintained without ongoing dietary and behavioral support (Paisey 2002 [C]; Torgerson, 1999 [A]).
- Successful weight-loss maintenance is sustained by a combination of lower calorie intake and increased physical activity (Franz, 2007 [M]; Freedman, 2001 [R]; Wing, 2001 [R]; McGuire, 1998 [C]). Analysis of data from the National Weight Control Registry indicates weight-loss maintainers have an average intake of 1,400 kcal/day and get one hour of moderate activity per day, and eat breakfast daily.
- A low-glycemic-index diet is not more effective than traditional low-fat diet for weight loss or weight maintenance in general but may be beneficial for patients with certain risk factors such as insulin resistance (Gardner, 2010 [A]). More studies are needed to determine long-term effect on hunger and satiety, as well as possible genetic predictors of dietary success (Ebbeling, 2005 [A]; Thompson, 2005 [A]).
**Physical Activity**

Physical activity refers to all types and intensities of body movement, including activities of daily living. Exercise, physical fitness and training are terms that suggest elevated intensity, a sense of obligation or sports participation. These terms may have negative connotations for some obese patients. Physical activity is a more inclusive, attainable and acceptable term.

Physical inactivity, or sedentary lifestyle, has been previously identified as an independent risk factor for cardiovascular disease by the American Heart Association (Fletcher, 1992 [R]). Physical inactivity is currently seen as a key contributor to the obesity problem. With approximately 60% of adults in the United States overweight (Flegal, 2002 [D]), it is essential to improve physical activity levels for the prevention and management of obesity.

While physical activity has long been recognized as an important component of a healthy lifestyle and longevity (Paffenbarger, 1986 [B]), the work group recognizes that the literature on physical activity in obesity prevention and management is extensive and the overall results are variable. Some of the confusion arises from inherent individual variability in response to exercise (Skinner, 2001 [C]). There is also significant interstudy variability (e.g., self-reported physical activity compared to measured physical activity). There are variable exercise regimens and research designs that confound comparison of results. This would suggest that selecting physical activity for weight loss is still largely patient preference and compatibility with lifestyle.

Evidence still remains that increasing calorie expenditure by increasing physical activity is necessary for improved weight-loss outcomes and weight maintenance (Esposito, 2003 [A]; Rejeski, 2002 [A]; National Heart, Lung and Blood Institute, 2000 [R]; Miller, 1997 [M]).

Improved outcomes for long-term weight reduction occur when a low-calorie intake is combined with increased physical activity and behavior therapy (Diabetes Prevention Program Research Group, 2002 [A]; Rejeski, 2002 [A]; Freedman, 2001 [R]; Tuomilehto, 2001 [A]; Chao, 2000 [A]; National Heart, Lung and Blood Institute, 2000 [R]; National Heart, Lung and Blood Institute, 1998 [R]; Miller, 1997 [M]).

**Specific Roles for Physical Activity in Obesity**

Physical activity has several potential roles in obesity: prevention, acute weight loss, long-term weight loss and weight maintenance and metabolic fitness with or without weight loss. A brief review of the literature will be done for each potential role.

- **Prevention of obesity**

  There is general consensus that energy expended in physical activity has the potential to affect energy balance and weight regulation. There is some evidence that physical activity can minimize weight gain (Jakicic, 2002 [R]). However, physical activity alone cannot be expected to overcome unhealthy eating habits. Both must be balanced to prevent excessive weight gain. Evidence has shown that it takes > 250 minutes/week to maintain weight after weight loss (Donnelly, 2009 [R]). Individual requirements will likely vary, given age, gender, occupational energy expenditure and habitual caloric intake. The current activity recommendation of 30 to 60 minutes of moderate intensity, five days per week, is a reasonable point of departure for an individualized activity prescription (American College of Sports Medicine, 2001 [R]). However, 200-300 minutes/week of moderate-intensity physical activity is recommended for long-term weight loss (Donnelly, 2009 [R]). Becoming physically active is recognized as an important component of overall behavioral change in obesity. See "Behavioral Management" further in this section.
• **Acute weight loss**

Without some control of caloric intake, studies suggest difficulty losing weight with exercise alone. There is a 2 kg weight loss that is additive to dietary loss when patients exercise more than 150 minutes per week (Jakicic, 2011 [B]). There appear to be gender differences in exercise effect while on ad libitum diets. Men were more likely to lose weight while women only prevented weight gain (Donnelly, 2003 [A]). In the HERITAGE Family Study, men and women of various ages (16-65), two races (black and white), and variable body composition were given 20 weeks of cycle ergometry endurance training, three days per week. All measures of body fat decreased with training, and fat-free mass increased. The magnitude of the changes was judged of limited biological significance. Gender differences in training response were noted (Wilmore, 1999 [C]).

• **Long-term weight maintenance**

The literature shows more support for the role of physical activity in preventing weight regain (Pronk, 1994 [R]; Jeffery, 1984 [C]). A 16-week randomized control trial with a one-year follow-up on 40 obese women found that diet plus lifestyle activity may be a suitable alternative to diet plus structured aerobic activity (Andersen, 1999 [A]). Total weight loss was not improved with aerobic exercise or strength training, but regular exercisers regained significantly less weight at the one-year follow-up (Wadden, 1998 [A]). New evidence shows that weight maintenance is improved with > 250 minutes/week of moderate physical activity after weight loss. However, no evidence from well-designed randomized control trials exists to judge the effectiveness of physical activity for prevention of weight regain after weight loss (Donnelly, 2009 [R]).

Long-term weight maintenance may require as much physical activity as expended during the weight-loss phase. As cited previously, data from the National Weight Control Registry indicates that weight-loss maintainers get one hour or more of moderate activity per day.

• **Metabolic fitness with or without weight loss**

The beneficial effects of physical activity extend beyond weight loss. There is very strong evidence that physical activity is important in the prevention and management of cardiovascular disease (and related risk factors) and type 2 diabetes mellitus. The literature supports a role for physical activity in improving metabolic syndrome with 5% to 10% weight loss (Goldstein, 1992 [R]). Intermittent exercise, two 15-minute brisk walks five days per week, did not result in weight loss but did significantly improve HDL and insulin levels in moderately obese females (Donnelly, 2000 [A]). In men, weight loss induced by increased daily physical activity without caloric restriction reduced abdominal obesity and insulin resistance. Exercise without weight loss reduced abdominal fat and improved cardiovascular fitness but not insulin levels (Ross, 2000 [A]).

Obese men and women with impaired glucose tolerance who received lifestyle intervention and exercise counseling had improved weight loss and significantly reduced progression to diabetes (Tuomilehto, 2001 [A]).

There are studies of physical activity that do not show an independent metabolic effect beyond weight loss. In obese women, aerobic exercise and resistance exercise had no additional affect over diet alone on weight loss, change in regional adiposity nor improvement in insulin or lipid levels (Janssen, 2002 [A]).

**Physical activity prescription**

Over 20 years ago it was suggested that physicians write individualized exercise prescriptions (Gibson, 1983 [R]). The previously introduced National Heart, Lung and Blood Institute and AMA physician guides on obesity management contain sections on physical activity. Please see Appendix C, "Physical Activity Prescription," for an example of a physical activity prescription.
Certain commercially available products such as pedometers and heart rate monitors may be helpful to patients in order to monitor the daily physical activity levels (Stovitz, 2005 [A]).

**Frequency**

In general, three days per week is a minimum frequency to induce physiologic adaptations. Direct improvements in blood pressure or insulin sensitivity require almost daily exercise. Many current activity regimens recommend five or more days per week to reap exercise benefits. From a behavioral perspective, it is better to start with an attainable frequency goal and progress as exercise capacity improves. Having a variety of activities augments greater frequency without onset of boredom or burnout. Enjoyment of physical activity is also a key feature for adherence.

**Duration**

The recommended duration of activity for fitness effects is variable. The traditional cardiovascular fitness guideline was 30 minutes of continuous exercise at 60%-80% of maximal heart rate for three to five days per week. The current American College of Sports Medicine position is 30 minutes of moderate-intensity activity on most days per week (American College of Sports Medicine, 2001 [R]). Multiple short bouts of exercise for 10 minutes duration also achieved cardiovascular improvement and weight loss with better program adherence (Jakićic, 1995 [A]). It has been found that moderate-intensity physical activity between 150 and 200 minutes/week will improve weight loss in conjunction with moderate diet restriction. If this amount of physical activity is used alone without diet restriction, there is only modest weight loss (Donnelly, 2009 [R]).

The Institute of Medicine has recommended 60 minutes a day of total physical activity time to control body weight. Prescribing a weekly energy expenditure of 2,500 kcal (~300 cal/day) improved weight loss for overweight men and women compared to the standard 1,000 kcal/week (~150 cal/day) (Jeffery, 2003 [A]).

**Intensity**

The appropriate intensity of activity is difficult to adjust for individual patients. The obese, physically deconditioned patient will have greater effort and perceived exertion at lower levels of exercise. At-risk, obese patients with cardiovascular disease may warrant a treadmill evaluation to benchmark their current exercise tolerance. Appropriate intensity may be estimated by the patient's ability to talk during activity. Inability to converse suggests a fairly rigorous effort that will be difficult to sustain. Excessive intensity of activity increases the risk of injury and likelihood of lost activity time. It is better to start at a sustainable intensity level and progress as tolerated to continue improvement. Varying the intensity level by adding intermittent hills or stairs will also improve capacity. Slowing the pace to recover breathing and complete the duration of the exercise session is preferable.

Physical activity intensity can be quantified by caloric expenditure per minute or hour. The estimation of calories used depends on weight and intensity of movement. There are extensive reference tables for caloric expenditure by occupation, household activities, recreation and sports (Katch, 1993 [NA]). See Table 7 as an example.
Table 7: Energy Expended in Common Physical Activities

<table>
<thead>
<tr>
<th>Light (less than 3.0 METs or less than 4 kcal/min)</th>
<th>Moderate (3.0-6.0 METs or 4-7 kcal/min)</th>
<th>Hard/Vigorous (greater than 6.0 METs or greater than 7 kcal/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking slowly (strolling) (1-2 mph)</td>
<td>Walking briskly (3-4 mph)</td>
<td>Walking briskly uphill or with a load</td>
</tr>
<tr>
<td>Cycling, stationary (less than 50 W)</td>
<td>Cycling for pleasure or transportation (less than or equal to 10 mph)</td>
<td>Cycling, fast or racing (greater than 10 mph)</td>
</tr>
<tr>
<td>Swimming, slow treading</td>
<td>Swimming, moderate effort</td>
<td>Swimming, fast treading or crawl</td>
</tr>
<tr>
<td>Conditioning exercise, light stretching</td>
<td>Conditioning exercise, general calisthenics</td>
<td>Conditioning exercise, stair ergometer, ski machine</td>
</tr>
<tr>
<td>Golf, power cart</td>
<td>Golf, pulling cart or carrying clubs</td>
<td>——</td>
</tr>
<tr>
<td>Bowling</td>
<td>——</td>
<td>——</td>
</tr>
<tr>
<td>Fishing, sitting</td>
<td>Fishing, standing/casting</td>
<td>Fishing in stream</td>
</tr>
<tr>
<td>Boating, power</td>
<td>Canoeing leisurely (2.0-3.9 mph)</td>
<td>Canoeing rapidly (greater than or equal to 4 mph)</td>
</tr>
<tr>
<td>Home care, carpet sweeping</td>
<td>Home care, general cleaning</td>
<td>Moving furniture</td>
</tr>
<tr>
<td>Mowing lawn, riding mower</td>
<td>Mowing lawn, power mower</td>
<td>Mowing lawn, hand mower</td>
</tr>
<tr>
<td>Home repair, carpentry</td>
<td>Home repair, painting</td>
<td>——</td>
</tr>
</tbody>
</table>


As a rule of thumb, sitting at rest or reading consumes ~ 1 kcal/minute. An average-weight person burns approximately 5 kcal/minute walking, 10 kcal/minute jogging a 10-minute mile and 15 kcal/minute running a 7-minute mile. These same activities done by someone weighing 300 lbs. approximately double the energy expenditures.

Another measure of activity intensity is the metabolic equivalency. The metabolic equivalency is defined as the energy expenditure for sitting quietly at rest. For the average adult this is 1 kcal/kg body weight/hour. A compendium of activities with their metabolic equivalency values can be used to estimate total energy expenditure: (metabolic equivalency value for the activity) x (weight in kgs) x (activity time) (Ainsworth, 2000 [R]; Ainsworth, 1993 [R]).

The recommended daily goal for physical activity ranges from 150 calories (kcal) to 300 calories. An initial level of physical fitness must be established to sustain the duration of activity at moderate levels that is required for weight loss. A pound of body fat contains 3,500 kcal of energy and can sustain 35 miles of walking for the average-weight person. Energy expenditure by physical activity is easily negated by uncontrolled caloric intake. A moderate level of physical activity (5 kcal/min) for 30 minutes expends 150 kcal. This is equivalent to 15 french fries, 15 snack chips or one 12-ounce can of sugared beverage. Physical activity and nutritional recommendations must be coordinated in any weight-management effort.

Although there is consensus on the value of physical activity in obesity management, there is not a standard format for recommending physical activity. The closest examples in the literature are Project PACE (Physician-based Assessment and Counseling for Exercise) (Patrick, 1994 [NA]) and the Activity Pyramid developed by Norstrom at Park Nicollet HealthSource (Park Nicollet Medical Foundation, 1999 [R]).

Office-based assessment of physical activity was pioneered by Project PACE. The one-page questionnaire determines the patient's level of physical activity and readiness to increase activity. The counseling protocols are designed to tailor the message to different patient needs. The program may be administered by physicians, nurses or other health professionals (Patrick, 1994 [NA]).
Written advice to exercise was found to be more effective than just verbal recommendation (Swinburn, 1998 [A]). Yet, activity prescriptions seem more difficult to write than drug prescriptions. Individualized activity prescriptions appear to be very context-dependent. They must take into account individual motivation, self-efficacy, type of activity, available resources, potential physical constraints or possible medical contraindications (CME Resource, 2004 [R]). The "dosages" must be individualized to current patient capacity and then titrated toward improvement (Bhaskarabhatla, 2004 [R]; Ward, 1991 [R]). The time course for expected improvement also varies across patients.

Patient handouts for improving physical activity can be very informative and helpful but often have a target population in mind. Handouts for older patients (Barry, 1993 [R]), "Walking Your Way to Feeling Better" and "Getting Stronger by Using Weights," can be extended to obese patients with similar current activity capacity.

A prototype general Physical Activity Prescription is offered in Appendix C. It represents a composite of key features suggested from the literature (CME Resource, 2004 [R]; Patrick, 1994 [NA]). It has not been evaluated and is intended only as a suggestion for operationalizing the written physical activity prescription. The ICSI Obesity Guideline work group will continue to search for an evidence-based activity prescription format.

An example of a physical activity questionnaire can be found in the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity" at http://www.ama-assn.org/ama/pub/category/10931.html, booklet 5, figure 5.1.

**Behavioral Management**

**Self-monitoring of weight, nutrition and activity**

A key component of successful weight loss and maintenance is regular self-monitoring of energy intake, expenditure and body weight. Participants in weight-loss trials who regularly self-monitor their diet and activity tend to lose more weight compared to those who don't (Boutelle, 1999 [A]; Boutelle, 1998 [D]). Regular monitoring of weight is also a predictor of successful weight control. Evidence from the National Weight Control Registry (NWCR), which was created to compile data on individuals who were successful at losing at least 13.6 kg and maintaining that loss for one year or more, shows that over 75% of these successful weight-loss maintainers report weighing themselves at least once a week (Klem, 1997 [D]).

Patients should be encouraged to keep track of their dietary intake, physical activity level and body weight. Dietary intake and activity should be recorded on a daily basis, and weight should be recorded on a weekly basis. For example, see the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity," http://www.ama-assn.org/ama/pub/category/10931.html, booklet 8, figures 4.2 and 5.7.

**Additional behavioral modification strategies that play a key role in successful weight loss and maintenance include:**

**Stimulus control:** Stimulus control refers to a set of behavioral procedures designed to help people reduce environmental cues associated with eating behavior and inactivity. Individuals should be taught to limit the presence of high-calorie/high-fat foods in the home; to reduce the visibility of unhealthy food choices in the home; to limit where and when they eat; to avoid distractions when eating, such as television watching; and to eat more slowly.

**Cognitive restructuring:** Negative thinking (e.g., perfectionistic thinking, dichotomous/"all-or-none" thinking, pessimistic thinking and self-doubt) often interferes with behavior change efforts. Individuals need to be taught to identify negative thoughts that interfere with their weight-loss efforts and counter them with positive self-statements that promote adherence to healthy eating and activity patterns.
Goal setting: Individuals need to be taught the importance of setting short-term goals for enhancing motivation; setting daily and weekly goals that are reasonable and attainable for eating, physical activity and weight loss should be encouraged.

Problem solving: Teaching problem-solving strategies to deal with barriers to changing eating and physical activity patterns is an important component of weight-loss intervention. Strategies such as defining the problem, brainstorming solutions, selecting a solution, and evaluating the success of the solution are recommended.

Social support: Spouses, family members, friends and co-workers can serve as both barriers and facilitators of successful weight loss. Individuals need to be able to engage their social support systems in ways that facilitate weight loss, eating and physical activity behavior change. Participants may also benefit from learning how to be assertive in social situations involving eating and physical activity so that they can adhere to their behavior change efforts.

Relapse prevention: Restarts are common in behavior change. Patients who relapse should be encouraged to try again when they are ready. In fact, a permanent change may never be achieved.

The relapse prevention model (RPM), originally developed to address cognitive and behavioral factors associated with the relapse process for addictive behaviors (e.g., alcohol abuse) (Marlatt, 1984 [R]), has been shown to be helpful for long-term weight management (Baum 1991 [A]; Perri, 1984 [A]). A key component of relapse prevention model is its distinction between "lapses" and "relapse." Lapses are defined as a "single event, a reemergence of a previous habit, which may or may not lead to the state of relapse," whereas "relapse" refers to a full return to an unhealthy state. An individual's response to a "lapse" is thought to determine the likelihood of relapse. The "abstinence violation effect" is the reaction to a behavioral slip, guilt and perceived loss of control; when this occurs an individual is more likely to experience a full relapse. Alternatively, when framed as a "lapse," people can respond proactively to a slip in behavior, thus avoiding complete relapse. Additional relapse prevention strategies may include helping individuals manage lapses in behavior, identifying high-risk situations for relapse, enhancing skills for coping with these situations and increasing self-efficacy for avoiding relapse (Larimer, 1999 [R]).

Behavior therapy: includes nutrition and physical activity; for the treatment of obesity it has often produced poor long-term results and has led to an increased interest in a drug treatment component.

Follow-up

Weight loss requires frequent follow-up (initially weekly) with planned education/counseling by health care providers to be most effective (i.e., improve adherence) (Rejeski, 2002 [A]; Tuomilehto, 2001 [A]; Chao, 2000 [A]; National Heart, Lung and Blood Institute, 2000 [R]).

Pharmacologic Therapy

Pharmacotherapy, when used for six months to one year, along with lifestyle modification including nutrition and physical activity, produces weight loss in obese adults. Behavioral modification programs including dietary and exercise counseling typically result in a 5% weight loss (Klein, 2002 [R]). The average weight loss with pharmacological agents is 10%-15% of initial weight (Frank, 2004 [D]) or 2-10 kg (4.4 to 22 lbs). However, it is not possible to predict the exact amount of weight an individual may lose. Most of the weight loss with these agents will occur during the first six months of therapy. The amount of weight lost with medications is more likely to be maintained if medications are able to be continued long term. Therefore, medications for obesity are most effective if they are continued indefinitely, unless weight is regained or if significant side effects develop.

Weight-loss drugs should only be used as part of a comprehensive weight-loss regimen that includes a low-calorie diet, increased physical activity and behavior therapy. If a patient has been on a combination regimen that includes nutrition therapy, physical activity and behavior modification and has not lost 1 lb./week, the addition of pharmacotherapy should be considered.
Patients considered for pharmacotherapy should have a body mass index of greater than or equal to 30 or a body mass index of greater than or equal to 27 with concomitant obesity-related risk factors or diseases. The risk factors and diseases that are serious enough to support pharmacotherapy at a body mass index of 27 to 29.9 include hypertension, dyslipidemia, CHD, type 2 diabetes and sleep apnea.

Medication therapy should consist of an initial trial period with a single drug to establish efficacy in a given patient. If a patient does not respond to a drug with reasonable weight loss, the patient should be evaluated to determine adherence with the medication regimen and adjunctive therapies, or to consider the need for a dosage adjustment. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the medication should be discontinued.

Patients who respond to pharmacotherapy should lose at least 2 kg (4.4 lb.) in the first four weeks after initiating therapy. If a patient has not lost 2 kg (4.4 lb.) in the first four weeks, the chance of a long-term response is low and they may be considered non-responders. The amount of weight lost in the first four weeks may be used as a guide to subsequent therapy. Medication can be continued in patients meeting the appropriate response criteria. Consideration should be given to stopping medication in those patients who fail to meet the four-week weight-loss guide. Successful therapy is characterized by weight loss in the first six months of therapy or weight maintenance after the initial weight-loss-phase, and consideration should be given to continued use of medication. Drug therapy may be continued as long as there is a clinical response and there are no serious or unmanageable adverse effects. Patients should be monitored for adverse events as long as they continue on a medication regimen.

**Patient monitoring**

Patient monitoring is important once weight-loss medications have been initiated. A suggested monitoring schedule would include return visits between two and four weeks, then monthly for three months, and then every three months for the first year after starting the medication regimen. The purpose of these visits would be to measure weight, BMI, waist circumference, blood pressure and heart rate to assess any adverse effects, and to conduct laboratory tests and answer questions.

Therapy should be considered successful if, after six months of therapy, a weight loss of greater than or equal to 10% of body weight is achieved and there have been no serious adverse effects from the medication. After six months of drug therapy, the rate of weight loss generally reaches a plateau, and weight maintenance should take priority. To achieve additional weight loss, lifestyle modifications to further decrease caloric intake and increase energy expenditure should be implemented.

To be considered successful weight maintenance, weight regain should be less than 3 kg (6.6 lb.) in two years and there should be a sustained reduction in waist circumference of at least 4 cm (National Heart, Lung and Blood Institute/NIH, 1998 [R]).

Please see Appendix D, "FDA-Approved Medications for the Treatment of Obesity," for more information.

**Phentermine**

Phentermine is an appetite suppressant with stimulant-like properties that is approved for the treatment of obesity. Amphetamines have been used in the past to treat obesity but are not approved and may have dangerous side effects. These latter drugs should not be used to treat obesity.

Primary pulmonary hypertension has been identified in relation to the use of several anorexiant medications, especially when the duration of therapy exceeded three months (McCann, 1997 [M]; Abenhaim, 1996 [C]). These included aminorex and fenfluramine (therefore, the combination medication of phentermine-fenfluramine) (Bray, 2004 [R]). In the case of aminorex, this serious side effect led to the withdrawal of this medication from the market (Apoivian, 1999 [X]).
Cardiac valvular insufficiency is associated with use of fenfluramine (therefore, phentermine-fenfluramine). This led to the removal of phentermine-fenfluramine and its isomer dexfenfluramine from the market (Bray, 2004 [R]). Phentermine, when used in isolation, is not associated with a significant risk of primary pulmonary hypertension or regurgitant valvular heart lesions.

Patients taking phentermine or any other anorexiant should have their blood pressure monitored carefully during treatment due to the possibility of increased blood pressure as a side effect of this medication. However, one study showed no significant differences in blood pressure between placebo-treated patients and patients treated with phentermine (Kim, 2006 [A]).

Due to its anticholenergic effects, phentermine can cause severe constipation and severe dry mouth. Usually however, these side effects are relatively mild and are manageable. Insomnia can also occur but usually resolves if the patient continues to take this medication; it can be minimized by prescribing any afternoon dose to be taken by 3:00 p.m.

Patients who receive long-term therapy with anorexiants (off-label use) should be carefully evaluated for dyspnea, chest pain, syncope and edema. They should be instructed to report any symptoms during therapy and within the first year following cessation of weight-loss drugs. If any of these symptoms emerge and are suspected to be related to drug therapy, the medication should be promptly discontinued.

Efficacy

Phentermine is an anorexiant that is widely available in the United States and is effective in weight loss. In one large meta-analysis study, phentermine was associated with an average of 3.6 kg (7.9 lbs.) additional weight loss at six months as compared to placebo (Pharmacological and Surgical Treatment of Obesity, Shekelle, 2004). Three long-term studies have been done with phentermine, ranging from 14 weeks to 36 weeks and showing an average weight loss of 8.7%-13% body weight compared to 2%-5.1% with placebo (Bray, 2004 [R]).

Orlistat

Orlistat is another FDA approved medication for the treatment of obesity.

The adverse events of orlistat are mainly gastrointestinal. Absorption of the drug is minimal.

| Table 9: Incidence of Adverse Events Commonly Observed During the First Year of Treatment |
|-------------------------------------|-------------|-------------|
| Adverse Event                  | Orlistat    | Placebo    |
| Oily spotting                  | 26.6%       | 1.3%       |
| Flatulence                     | 23.9%       | 1.4%       |
| Fecal urgency                  | 22.1%       | 6.7%       |
| Oily stool                     | 20.0%       | 2.9%       |
| Oily evacuation                | 11.9%       | 0.8%       |
| Increased defecation           | 10.8%       | 4.1%       |
| Fecal incontinence             | 7.7%        | 0.9%       |

Most common adverse reactions were mild and transient, and decreased during the second treatment year. Events usually began within the first three months of therapy. Approximately 50% of all episodes of GI adverse events lasted for less than one week, and most lasted for no more than four weeks. However, adverse GI events may occur in some individuals over a period of six months or longer.

Adherence with a low-fat diet containing less than 30% of calories derived from fat can lessen or avoid the fat-intake-related adverse effects. Since orlistat is useful only if taken with a meal containing some fat, a
dose should be skipped when a meal is fat-free. Cardiac abnormalities have not been reported in association with the use of orlistat.

In May 2010, the FDA approved a revised label for orlistat that included new safety information about cases of severe liver injury that are reported rarely with use of the drug. New warnings about reports of rare liver injury were also added to the label of the over-the-counter version of orlistat.

The new safety information is based on an FDA review that identified 13 total reports of severe liver injury with orlistat: 12 foreign reports and one U.S. report with the over-the-counter version. A cause and effect relationship of severe liver injury with orlistat use has not been definitively established because of the following factors:

- One U.S. case with Alli and 12 foreign cases with Xenical reported between 1999 and 2009 out of an estimated 40 million people who have used one of the two products.
- Some patients in the reported cases also used other drugs or had other conditions that may have contributed to the development of severe liver injury.
- Severe liver injury can occur in people not taking drugs and without a distinct cause.

The primary intent of the FDA in requiring the addition of the information about reported cases of liver injury to the label of orlistat is to educate the public about the signs and symptoms of liver injury and the need to see a physician promptly should they occur.

**Efficacy**

Patients taking orlistat as part of a program of nutritional and physical activity changes can expect a weight loss of 3.9 to 10.6 kg after one year of treatment and 4.6 to 7.6 kg after two years of treatment. A weight loss of at least 5% of initial body weight at one year is reported by 30% to 73% (vs. 13% to 45% of patients taking placebo); a weight loss of at least 10% of initial body weight at one year is reported by 10% to 41% (vs. 4% to 21% of patients taking placebo) (Torgeson, 2004 [A]; Rissanen, 2003 [M]; Hauptman, 2000 [A]; Rossner, 2000 [A]; Sjostrom, 1998 [A]).

**Drug interactions**

The potential for drug-drug interactions should be assessed before initiating therapy with weight-loss agents.

Phentermine is contraindicated for use with MAO inhibitors, and it should not be started within 14 days of discontinued MAOI. Phentermine should be used with caution with SSRIs or stimulant medications.

Orlistat has also been shown to reduce serum concentrations of fat-soluble vitamins (vitamins A, D, E and K). Although most patients' plasma levels remained within normal ranges during clinical trials, a daily multivitamin supplement containing fat-soluble vitamins at bedtime is recommended. Caution should also be exercised with concomitant use of orlistat and other lipophilic drugs, as their overall bioavailability may be compromised.

With orlistat, patients should have their cyclosporine levels monitored more frequently. Increased monitoring should also apply to patients taking other medications with a narrow therapeutic index, such as warfarin, that could be affected by fat malabsorption.

**Summary**

- As an adjunct to intensive nutritional and lifestyle changes, both phentermine and orlistat are associated with greater weight loss than placebo.
When on orlistat, gastrointestinal side effects are common, but the frequency and severity decrease over time (typically after one week) and can be reduced by careful attention to dietary fat content.

Medical opinion is currently shifting toward the need for chronic pharmacological therapy in obesity, as it is a chronic disease. However, with the current paucity of weight-loss medications available, this remains a clinical challenge.

The long-term safety of phentermine and other anorexiants, as well as orlistat, is unknown. Therefore, more studies need to be done on the safety and efficacy of weight-loss medications used for the long-term treatment of obesity.

**Sibutramine: no longer on market**

Sibutramine was approved by the FDA in November 1997 for weight loss and maintenance of weight loss in patients with a body mass index greater than or equal to 30 kg/m² or for patients with a body mass index greater than or equal to 27 kg/m² who had other cardiovascular risk factors.

In October 2010, the FDA recommended against continued prescribing and use of sibutramine because of potential unnecessary cardiovascular risks to patients with known cardiovascular disease. The FDA requested the manufacturer of sibutramine voluntarily stop marketing the drug in the United States based on data from the Sibutramine Cardiovascular Outcomes (SCOUT) trial. The manufacturer has complied with that request (James, 2010 [A]).

The SCOUT trial was a randomized, double-blind, placebo-controlled multicenter trial conducted over 60 months in Europe, Latin America and Australia. This trial was conducted as part of a postmarket requirement for European approval in 1999 because of previously known concerns regarding increases in blood pressure and heart rate observed in other clinical trial data.

The study population consisted of over 10,000 men and women aged greater than or equal to 55 years with a body mass index between 27 kg/m² and 45 kg/m² or between 25 kg/m² and 27 kg/m² with an increased waist circumference. To be included in the study, patients were required to have a history of cardiovascular disease defined as coronary artery disease, stroke, occlusive peripheral arterial disease and/or type 2 diabetes mellitus with at least one other cardiovascular risk factor. Patients underwent a six-week lead-in period on sibutramine 10 mg and were then randomized to either sibutramine 10 mg daily or placebo. Titration to sibutramine 15 mg daily was allowed. Mean duration of exposure to sibutramine or placebo was 3.5 years.

Study results indicated a 16 % increase in the relative risk of the primary outcome event which was a composite of non-fatal myocardial infarction, non-fatal stroke, resuscitation after cardiac arrest, and cardiovascular death in the sibutramine group compared to placebo [Hazard Ratio (HR) = 1.16; 95% CI, 1.03-1.31; p=0.02]. There was no difference between treatment groups regarding cardiovascular death or all-cause mortality. The primary outcome was the result of differences in non-fatal myocardial infarction (HR = 1.28, 95% CI, 1.04-1.57, p = 0.02) and non-fatal stroke (HR = 1.36, 95% CI, 1.04-1.77, p = 0.03).

The FDA’s most recent recommendation is based on data gathered from the SCOUT trial which suggest that the small benefit of weight loss, without evidence of other potential health benefits related to weight loss, are outweighed by even a small risk of an adverse cardiovascular outcome caused by the drug (James, 2010 [A]).

**Non-Prescription and alternative medicine**

Numerous products, touted as weight-loss preparations, are available to patients without a prescription. These products contain a wide range of ingredients either alone or in combination.

Alternative therapy agents have become attractive options for the treatment of obesity. Herbal and dietary supplements are thought to be natural products and perceived to be safer than prescription medications. Also, patients do not perceive a need to seek professional assistance with these products. Obese patients...
with limited financial resources may find this to be a cheaper solution. Other patients choose alternative therapies after previous failed attempts at weight loss with more conventional treatments.

No long-term data (longer than one year) is available for any of these herbal agents. While there has been a growing popularity and interest in herbal therapies, there is no adequate data to support their use for weight loss. The short- and long-term adverse effects of these agents are largely unknown. Since many herbal products are not standardized, the content of the ingredients can vary substantially from the label and among lots of the same product (Gurley, 2000 [D]). Patients who use non-prescription or herbal preparations should be cautioned about adverse effects, drug interactions and the potential impurities of herbal products (Miller 1998 [R]; Winslow, 1998 [R]). The combination of these agents with 500-calorie diets is not safe and should be discouraged.

**Safety and adverse effects**

In these patients who were on sibutramine, there was an increased risk of vascular disease from the drug after a mean of 3.5 years of exposure (James, 2010 [A]).

The safe and effective use of any weight-loss drug beyond two years has not been established.

Providers considering pharmacotherapy should obtain complete medication histories on their patients including the use of other prescription, non-prescription or herbal preparations for weight loss before recommending or prescribing prescription weight-loss medications.

Adverse side effects from the use of weight-loss drugs have been observed in patients. Dose-related minor effects may occur soon after beginning therapy. These effects are often mild and spontaneously resolve over time. Initial adverse effects can be avoided or minimized by:

- adjusting dosage and administration schedules,
- identifying patients at high risk for adverse effects and selecting drug therapy accordingly, and
- providing patient education and monitoring for adverse effects at the beginning of therapy or when making dosage adjustments

Infrequent, but potentially serious, effects can also occur much later in the course of therapy.

The practice of combination drug therapy for obesity may increase the frequency of adverse events. There is also a lack of safety data on the use of combination therapy. Until data is available, it may be prudent to use weight-loss medications as single agents. Using the lowest possible effective dose may also reduce the chance of an adverse event.

None of the weight-loss drugs is approved for use in pregnant or lactating women, and the safe use of these drugs in pregnant or lactating women has still not been determined.

**Surgery for Obesity**

**Introduction**

Bariatric surgery is a tool that can produce substantial weight loss in patients who are morbidly obese. It is therefore critical to understand that it is an important part of the treatment paradigm, not just a "last resort" therapy for obesity. The proper clinical role of various bariatric surgery procedures is not yet completely understood for several reasons. First, only a limited number of large randomized clinical trials with long-term follow-up (7-10 years or more) have been reported. Second, there are many bariatric procedures, and innovation in the field has been rapid, so that matching a given surgical candidate with the optimal surgical procedure is challenging. Please see Table 10, "Overview of Bariatric Procedures" and Appendix E, "Overview of Bariatric Procedures" for more information.
Patient selection

Bariatric surgery is not without risk. Just because a patient has a body mass index greater than 40 does not mean when he or she is a candidate for bariatric surgery. Bariatric procedures are associated with significant complications. It is critical, therefore, that bariatric surgery be applied to the most appropriate group of patients possible. Unfortunately there is very little practical psychological data to guide procedural choice. In terms of comorbid illness and weight, however, there is data that suggests potential advantages of one procedure over another. The current indications, for bariatric surgery include:

- Body mass index greater than 40
- Body mass index greater than 35 with significant comorbid illness including diabetes, hypertension, dyslipidemia, sleep apnea, cardiovascular disease, gastroesophageal reflux disease not amenable to medical management, pseudotumor cerebri
- Patients who have successfully lost weight with behavioral and medical therapy are the best candidates for bariatric surgery (Wadden, 2009 [A])
- Age greater than 18
- Other indications include need for significant weight loss in order to facilitate renal transplantation, donor nephrectomy, or joint replacement
- Medical management to (a) exclude untreated endocrinopathies, (b) stabilize medical problems including hypertension and type 2 diabetes, and (c) demonstrate patient compliance, including preoperative weight loss
- Psychologic stability as determined by an evaluation by an experienced practitioner in the field of bariatric patient evaluation

Shared decision-making

Surgery of any sort is a significant decision for any patient. The informed consent process, while providing a simple framework for explaining the procedure, risks and benefits, doesn't provide a deeper understanding of the patient values, lifestyle changes, or implications for the future. Shared decision-making between the provider and the patient for bariatric surgery can include some decision support tools to guide the patient as he or she considers this surgery. One resource for evaluating the patient's readiness for shared decision-making is the Ottawa Personal Decision Aid. A decision aid specifically for guiding the patient and family through the pros and cons of surgery and to support the discussion with the provider can be found here: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID.

Bariatric surgery for patients with BMI of 30-40

Bariatric surgery is sometimes indicated for patients with BMI of 30-40 who have other comorbidities such as severe GERD or ventral hernia.

More research is needed to clarify which patients would benefit and which procedures are optimal for bariatric surgery. [Conclusion Grade III: See Conclusion Grading Worksheet A – Annotation #10 (Bariatric Surgery for Patients with BMI 30 <= 35)]

One randomized study from O'Brien (O'Brien, 2006 [A]) and colleagues demonstrated that in the patient population with a body mass index between 30 and 35 undergoing adjustable banding compared to lifestyle modification, there are substantial improvements over two years in both weight loss and improvement of the metabolic syndrome in the surgical group compared to those who are medically managed.

In a slightly heavier cohort of patients, BMI 30 to 40, dramatic improvements were seen in patients with mild (less than two-year history) diabetes. Clearly there are indications that may suggest a role for use of...
bariatric surgery in patients with obesity who may not meet traditional criteria (Dixon, 2008 [A]). Laparoscopic adjustable gastric (lap banding) has been approved by the FDA for these patients.

**Review of bariatric procedures**

The most common bariatric procedures performed in the United States include the Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, the sleeve gastrectomy, and the duodenal switch (SRC). At this juncture, there is little justification for primary bariatric surgery to be done in an open fashion except in the setting of a reoperative abdomen (Nguyen, 2001 [A]). Functionally speaking procedures are divided into either a restrictive or a malabsorptive category. The restrictive operations include laparoscopic adjustable banding for which there are two types of bands available on the market, and the vertical sleeve gastrectomy. The malabsorptive group includes the gastric bypass and the duodenal switch operation. The latter group involves varying components of restriction and malabsorption. Table 10, "Overview of Bariatric Procedures," provides selected information about the advantages and limitations of various bariatric procedures. Additional information on each procedure can also be found in Appendix E, "Overview of Bariatric Procedures." See Appendix I, "Band Assessment Protocol," for band adjustment scheduling.

**Impact on mortality**

Long-term data suggests that bariatric surgery in properly selected patients may reduce overall mortality over a 15-year period compared to conservative medical management. The Swedish obesity study (SOS) demonstrated less percentage chance of mortality for those who underwent surgery. 6.3% in the control group died as compared with 5.0% in the surgery group (Sjostrom, 2007 [B]). Another study by Christou and colleagues reported the mortality rate in the bariatric surgery cohort to be 0.68% compared with 6.17% in controls (Christou, 2004 [B]). Another study by Adams did note a small increase in suicide rate and accidental death in patients who have undergone gastric bypass operation. Rates of accidental death and suicide were 0.11% in the surgical group and 0.064% in the control group (Adams, 2007 [B]).

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Table 10. Overview of Bariatric Procedures

<table>
<thead>
<tr>
<th></th>
<th>Adjustable Band</th>
<th>Sleeve Gastrectomy</th>
<th>Gastric Bypass</th>
<th>Duodenal Switch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanism</strong></td>
<td>Restrictive</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Malabsorptive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Both</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Estimated weight loss</strong></td>
<td>45.1% at 1 year</td>
<td>45% at 1 yr</td>
<td>49% at 14 yrs</td>
<td>75% at 12 yrs</td>
</tr>
<tr>
<td><strong>Readmission rate</strong></td>
<td>1%</td>
<td>5%</td>
<td>6%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td>0.02</td>
<td>0.2</td>
<td>0.2%</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>All procedures: unstable psychological conditions, endocrine disorders, and pregnancy</td>
<td>Esophageal dysmotility, inflammatory bowel disease</td>
<td>Hx of gastric cancer, need for NSAID, bile duct pathology, inflammatory bowel disease</td>
<td>Vegetarians, inflammatory bowel disease</td>
</tr>
</tbody>
</table>
| **Effect comorbid illness** | Diabetes | ++ | ++ | +++ | ++++
|               | Hypertension | ++ | ++ | +++ | ++++
|               | Sleep Apnea | ++ | ++ | ++ | +++
|               | GERD | + | — | +++ | — |
| **Failure rate** | 20%-35% | - | 9%-18% | - |
| **Complications and Side Effects** | All procedures: hair loss, excess skin, nausea, vomiting and dehydration | Slippage, erosion, concentric dilation, port-related problems | Leak, stricture, bowel obstruction | Malnutrition, leak, stricture, bowel obstruction |
|               |             | Leaking, marginal ulcer, bowel obstruction | Nutritional, leak, stricture, bowel obstruction | Malnutrition, leak, stricture, bowel obstruction |
|               |             | Intestinal hernia | Nutritional, leak, stricture, bowel obstruction | Malnutrition, leak, stricture, bowel obstruction |
| **Common Nutritional Deficiencies** | N/A Except in the presence of complications | Iron, B12, Thiamine | Vitamins A, D, E, K |
| **Anatomical workups** | UGI including motility | No | H-pylori, EGD if hx of ulcer |
| **Preoperative workup** | Three months to document compliance | Psychological | Nutritional, mandatory weight-loss, sleep study |
| **Medical follow-up** | Band assessment protocol (See Appendix J) | 1, 3, 6 and 12 months, then annually | 1, 3, 6 and 12 months, then annually | 1, 3, 6 and 12 months, then annually |
| **Radiology** | Annual UGI | | | |
| **Follow-up labs** (See Appendix J) | Three months after surgery, then annually | + | + | + | + |

** If bariatric patient presents in emergency department do not provide glucose-containing IV fluids***
- At five years patients with BMI > 35
- % EWL = (current weight – IBW / initial weight – IBW) x 100
- + - ++++ Relative effectiveness, less to greater
- — No effect

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Preoperative workup of the bariatric surgical patient

As mentioned, once it has been determined that a patient has met the preoperative requirements and has undergone the necessary weight loss, it is important to prepare patients and screen them for surgery. For patients undergoing laparoscopic adjustable banding it is helpful, though not mandatory, to obtain a preoperative upper-GI study. Though not specific, the presence of esophageal anatomic abnormality may preclude a band. The presence of preoperative dysphagia or atypical gastroesophageal reflux disease may warrant workup including pH probe studies and manometry. All patients who are obese, regardless of intended procedure, should undergo careful nutritional screening including vitamin status and an albumin level. For those patients undergoing malabsorptive procedures, a vitamin B panel should be checked to include thiamine, riboflavin, folic acid and cyanocobalamin (B12). For patients planning Roux-en-Y gastric bypass, careful history of ulcers or family history of gastric cancer would suggest the need for preoperative upper endoscopy. Whether such patients should have biopsy and screening for H. Pylori is unknown. Please see Appendix J, "Sample Weight Loss Surgery Preoperative Laboratory – SUR and Checkout Orders."

Medical Emergencies Following Bariatric Surgery

![Algorithm Diagram]

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Postoperative nutritional follow-up

Please see Appendix H, "Nutritional Supplement Recommendations," for more information. Also, please see Appendix K, "Sample Post-Bariatric-Surgery Patient Diet," for more information.

The final phase introduces the lifelong way of eating for patients. Patients should focus on eating protein first as they add solid foods back into their diet. Tougher foods like fruits, vegetables and whole grains should be introduced more slowly. These foods, unless chewed well, have a tendency to plug the outlet from the stomach pouch. Patients should be advised to introduce new foods at separate times to assess for tolerance.

To maintain success with weight management, patients need to do the following:

- Drink fluids 30 minutes before and/or 30 minutes after meals, not during the meal.
- Eat lean sources of protein first, followed by fruits, vegetables and whole grains.
- Aim for a minimum of 50 to 60 grams of protein per day.
- Avoid high-fat or high-sugar foods.
- Drink at least six to eight cups of non-calorie fluids daily (choose water most often).
- Drink two glasses skim or 1% milk daily in addition to water (between meals).
- Limit fluids with calories to skim or 1% milk (two cups daily).
- Eat three meals a day.
- Take multivitamins and supplements daily.

**Protein.** The newly formed anatomy of the stomach reduces availability of rennin, pepsin and hydrochloric acid, consequently limiting protein digestion. These alterations in anatomy, coupled with a significantly reduced intake of food, make it difficult to meet the requirements for protein and prevent catabolism immediately following surgery. Protein supplements should be considered, especially in the early postoperative phase, to prevent excess loss of lean tissue (Moize, 2003 [D]).

Counseling patients on adequate protein intake is pertinent both before and after surgery. Many patients cannot tolerate high-protein foods, which may jeopardize their ability to take in recommended amounts. These intolerances may be long term, particularly with red meat (Avinoah, 1992 [D]; Kushner, 2000 [D]). Supplements are often used until adequate protein intake through solid foods can be maintained, usually about six months after surgery (Detel, 2002 [R]; Moize, 2003 [D]).

**Gastric bypass nutritional deficiencies.** Because gastric bypass surgery excludes critical portions of the gastrointestinal tract, including the fundus, duodenum and upper portion of the jejunum, nutrient deficiencies are predictable and should be proactively treated. Patients should be advised to take a multivitamin or prenatal vitamin in addition to the nutrients discussed below.

**Calcium and vitamin D.** Calcium deficiency is difficult to detect because a normal blood calcium level can be maintained despite poor intake. Several factors affect calcium intake following surgery, including reduced dairy intake as a result of decreased stomach capacity or as a result of lactose intolerance, food dislikes and patient adherence with the meal plan. Since the primary absorption pathway for calcium has been removed with gastric bypass, supplementation is vital to bone health (Elliot, 2003 [R]). Calcium citrate with added vitamin D would be the preferable source, since it does not rely on stomach acidity for absorption (Elliot, 2003 [R]; Kushner, 2000 [D]). Fifty-eight percent of people have vitamin D deficiency when they present (Gemmel, 2009 [B]). The American Association of Clinical Endocrinologists Guideline recommends 400-800 IU of vitamin D per day (Mechanick, 2008 [R]).
Iron. Iron deficiency post gastric bypass occurs in 33% to 50% of patients (Deitel, 2002 [R]). Deficiency may be due to several factors, including possible food intolerance (patients may not be taking in sufficient heme iron), bypassed absorption site (duodenum and upper jejunum) and reduced stomach acidity. Iron should be supplemented to prevent deficiency (Elliot, 2003 [R]; Avinoah, 1992 [D]), with special attention to premenopausal women (Klein, 2002 [R]). In addition, the iron may need to be administered either by intravenous or intramuscular methods due to absorption change. Ferritin levels may need to be monitored annually as the levels can decline for up to seven years post bypass (Buchwald, 2004 [M]). After six weeks of oral repletion, iron infusions can be instituted. Provide sodium ferric gluconate (125 mg in 100 cc of normal saline) and infuse for over one hour once per week in six doses for a total of six infusions. Follow-up with patient includes checking CBC and ferritin in two to three months.

B vitamins

B12

B12 deficiency occurs in greater than 30% of patients with gastric bypass (Kushner, 2000 [D]), and the American Gastroenterological Association reports it may reach greater than 50% if supplemental B12 is not used (Klein, 2002 [D]). Of note, most multivitamins do not have enough B12 to return post-gastric bypass patients to their normal plasma levels (Buchwald, 2004 [M]). Vitamin B12 has a complex method of absorption, which is greatly impaired by gastric bypass surgery. Additionally, patients may have difficulty tolerating foods rich in B12 (meat, eggs and milk) and consume very little, if any, of these. Supplemental B12 greater than the recommended daily intake has been found to maintain normal plasma cobalamin levels (Elliot, 2003 [R]; Kushner, 2000 [D]).

Thiamine

Thiamine deficiency can occur as a result of bypass of the jejunum, where thiamine is primarily absorbed, or as a result of impaired nutritional intake from recurrent emesis. Neurologic symptoms one to three months after surgery are the predominant indication for thiamine deficiency. Parenteral supplementation with thiamine (100 mg/d) should be initiated in patients with active neurologic symptoms. After a 7-14 day course, an oral preparation (10 mg/d) can be used until neurologic symptoms resolve (Mechanick, 2008 [R]).

Duodenal switch nutritional deficiencies

Further considerations exist for the duodenal switch patients due to fat malabsorption, particularly for vitamins A, D, E, K. Water miscible preparations exist as a combination and patients can take these. Additional supplementation is warranted when levels dip. Additionally, hypoalbuminemia can be observed in duodenal switch patients manifested by postoperative edema. Therapy is to institute pancrelipase 1-3 tablets/meal for six weeks until prealbumin and albumin have normalized.

Medications

It is important to individually evaluate every post-procedure bariatric patient on an ongoing basis to determine whether or not chronic medications should be continued. In addition, certain medications require dosing adjustments due to their method of absorption or narrow therapeutic window. Changes in a patient's weight may require dose modifications to avoid toxicity and increased side effects.

Extended-release medications may be problematic in some patients since the mechanism by which delayed absorption occurs might be affected. Drugs with narrow therapeutic windows should be monitored especially closely. For example, warfarin dosing may need to be monitored due to alterations in dietary intake post-procedure or due to any possible changes in absorption. Until more research is done in this area, there are no standard rules for adjustments of medications following bariatric surgery. Patients taking any medications should be closely monitored for both toxicity and increased side effects. Also drugs with weight requirements for dosing should be reevaluated frequently as patients experience weight loss. Since many drugs are monitored for a therapeutic outcome, the dose can be titrated to this outcome (Buchwald, 2004 [M]).
Surgery for adolescents

Bariatric surgery in adolescents is highly controversial and must be carried out on a case-by-case basis for patients in a high-volume center (O’Brien, 2010 [A]).

Failed bariatric surgery

Bariatric surgery can fail. At 10 years it is estimated that 23% of patients with a BMI less than 50 fail bariatric surgery. Also at 10 years, it is estimated that 58% of patients with a BMI greater than 50 fail bariatric surgery. Failed bariatric surgery is when the patient will achieve less than 25% of excess weight lost (Christou, 2006 [B]). Besides beginning BMI, we have no good indicator for prediction of weight-loss.

13. Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance

Key Points

- Follow-up and long-term management of weight loss are crucial.
- The primary care physician also may serve as a community leader and a public health advocate.

Patients need regular follow-up for obesity, which is a lifelong problem in most cases. Regular follow-up conveys the message that the condition is important to the patient, and it affords the opportunity for monitoring body mass index, as well as evaluation and management of any of the common complications that are often associated with obesity.

Intensive intervention with weekly contact for the first three months and then continued support out to four years such as the Look AHEAD program is the most successful at creating and maintaining the 5%-10% weight loss needed to reduce clinically significant health risks (Wadden, 2009 [A]).

Patients on pharmacotherapy for obesity need ongoing evaluation for blood pressure, adequacy of nutrition, and surveillance for specific nutrient deficiencies such as low levels of fat-soluble vitamins in those on orlistat.

Patients who have had bariatric surgery may also need procedure-specific follow-up.

Ongoing reinforcement of important behavior strategies may include provision of new information on obesity management, control of local food environment, strategies to cope with restaurant eating, strategies to limit perimeal snacking and high-calorie beverages, and strategies for achieving regular physical activity.

See Annotation #6, "Advise Weight Maintenance and Manage Other Risk Factors."

The primary care physician also may serve as community leader and public health advocate. Such advocacy may occur in a variety of forms and settings:

Schools: Priorities for school activities that limit risk of obesity include control of the food environment, enhancement of regular physical activity including lifelong forms of physical activity as a regular part of the school curriculum, and education of students on advantages and practical approaches for healthy eating and regular physical activity.

Work sites: Advocate for healthy food choices at worksites, including both healthy food choices in cafeterias and healthy food choices in vending machines. Especially consider limiting availability of sweetened carbonated beverages and high-calorie, high-fat snacks in vending machines.
Other community settings: There are opportunities for political advocacy and community health education that emphasize the importance of healthy lifestyle. Issues such as availability of sidewalks, pedestrian access to commercial establishments, and availability of public affordable exercise facilities of different sorts are among the issues that may be relevant.
This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
  - Measurement Specifications
- Implementation Recommendations
- Resources
- Resources Table
Aims and Measures

1. Increase percentage of patients who have an annual body mass index (BMI) measurement recorded or measured. *(Annotation #1)*

   Measure for accomplishing this aim:
   a. Percentage of patients age 18-74 years who have a screening body mass index measurement during the last 12 months. *(2009 HEDIS Measure)*

2. Increase the percentage of patients with an elevated body mass index who have received education and counseling regarding weight loss. *(Annotation #10)*

   Measure for accomplishing this aim:
   a. Percentage of patients with elevated body mass index (BMI ≥ 25) who receive education and counseling for weight-loss strategies that include nutrition, physical activity, lifestyle changes, medication therapy and/or surgery:
      • BMI 25-30: Lifestyle changes and behavioral management.
      • BMI 30-35: Lifestyle changes, behavioral management and medication therapy.
      • BMI 35-40: Lifestyle changes, behavioral management and medication therapy.
      • BMI 40+: Lifestyle changes, behavioral management, medication therapy and surgical options.

3. Improve the outcome of treatment for patients with BMI ≥ 25. *(Annotations #8, 10)*

   Measures for accomplishing this aim:
   a. Percentage of patients with initial body mass index equal to or greater than 25 who have no change in body mass index or have a reduction in body mass index over a 12-month period.
   b. Percentage of patients with BMI ≥ 25 who have 30 minutes of physical activity five times per week.
   c. Percentage of patients with documentation that they set an individualized goal along with target date for reduction in body mass index.
   d. Percentage of patients with documentation that reach their goal body mass index by the set target date.

4. Increase community (employers, schools) participation involvement in the prevention and treatment of obesity. *(Annotations #10, 13)*

   Measures for accomplishing this aim:
   a. Number of employers or schools that offer or support weight-management programs.
   b. Number of employers or schools that offer healthy food choices.
   c. Number of employers or schools that facilitate/support physical activity to degree possible at work site or community sites.

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Measurement Specifications

Measurement #1a
Percentage of patients age 18-74 years who have a screening body mass index measurement during the last 12 months. *(HEDIS Measure 2010)*

Notes
This is a HEDIS measure by National Committee for Quality Assurance (NCQA).

Full specifications for this measure can be obtained from NCQA at [http://www.ncqa.org](http://www.ncqa.org).

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Measurement #2a

Percentage of patients with elevated body mass index (BMI \( \geq 25 \)) who receive education and counseling for weight-loss strategies that include nutrition, physical activity, lifestyle changes, medication therapy and/or surgery:

- BMI 25-30: Lifestyle changes and behavioral management.
- BMI 30-35: Lifestyle changes, behavioral management and medication therapy.
- BMI 35-40: Lifestyle changes, behavioral management and medication therapy.
- BMI 40+: Lifestyle changes, behavioral management, medication therapy and surgical options.

Population Definition

Patients, mature adolescents and adults, with an elevated body mass index (BMI \( \geq 25 \)).

Data of Interest

Number of patients who receive education and counseling for weight-loss strategies appropriate to their BMI

\[ \text{Numerator:} \quad \text{Number of patients with an elevated body mass index (BMI} \geq 25 \text{) who receive education and counseling for weight loss appropriate to their BMI, including nutrition, physical activity, lifestyle changes, medication therapy and/or surgery.} \]

- BMI 25-30: Lifestyle changes and behavioral management.
- BMI 30-35: Lifestyle changes, behavioral management and medication therapy.
- BMI 35-40: Lifestyle changes, behavioral management and medication therapy.
- BMI 40+: Lifestyle changes, behavioral management, medication therapy and surgical options.

\[ \text{Denominator:} \quad \text{Number of patients with an elevated body mass index (BMI} \geq 25 \text{).} \]

Method/Source of Data Collection:

No electronic medical record:

Select 20 patients with BMI \( \geq 25 \) seen in your practice 12 months earlier from the measurement date. If the body mass index is not documented, use the following calculation: weight (lbs.) \( \times 703 \) divided by height (inches) squared.

Or refer to a body mass index chart or wheel.

Review selected medical records to determine if one or more of the weight-management strategies have been documented appropriate to patient's BMI at any time during a 12-month period.

Electronic medical record available:

Query data for patients seen in your practice with BMI \( \geq 25 \), 12 months earlier from the measurement date. Review medical records to determine if one or more of the weight-management strategies have been documented appropriate to patient's BMI at any time during a 12-month period.
Time Frame Pertaining to Data Collection

The suggested time period is monthly. Each month review patients seen 12 months earlier and whether weight-management strategies appropriate to their BMI were discussed with them at any time over a 12 month period.

Notes

This is a process measure, and improvement is noted as increase in the rate.
Measurement #3a

Percentage of patients with initial body mass index equal to or greater than 25 who have no change in body mass index or have a reduction in body mass index over a 12-month period.

Population Definition

Patients, mature adolescents and adults, with an elevated body mass index (BMI > = 25).

Data of Interest

\[
\frac{\text{# of patients who have no change in BMI or have a reduction in BMI in the last 12 months}}{\text{# of patients with BMI > = 25}}
\]

Numerator/Denominator Definitions

Numerator: Number of patients with an elevated body mass index (BMI > = 25) who have no change in BMI or have a reduction in BMI over a 12-month period.

Denominator: Number of patients with an elevated body mass index (BMI > = 25).

Method/Source of Data Collection

No electronic medical record

Select 20 patients with BMI > = 25 seen within your practice 12 months earlier from the measurement date. If the body mass index is not documented, use the following calculation: weight (lbs.) x 703 divided by height (inches) squared, or refer to a body mass index chart or wheel.

Review selected medical records to determine whether patients had no change in their initial BMI or had a reduction in BMI over a 12-month period.

Electronic medical record available

Query data for patients seen in your practice with BMI > = 25 12 months earlier from the measurement date.

Review medical records to determine whether patients had no change in their initial BMI or had a reduction in BMI over a 12-month period.

Time Frame Pertaining to Data Collection

The suggested time period is monthly. Each month review patients seen 12 months earlier and whether they had a change in their BMI or BMI remained stable over a 12-month period.

Notes

This is an outcome measure, and improvement is noted as increase in the rate.
Measurement #3b

Percentage of patients with BMI $\geq 25$ who have 30 minutes of physical activity five times per week.

Population Definition

Patients, mature adolescents and adults, with an elevated body mass index (BMI $\geq 25$).

Data of Interest

| # of patients who have 30 minutes of physical activity five times per week | # of patients with BMI $\geq 25$ |

Numerator/Denominator Definitions

Numerator: Number of patients with an elevated body mass index (BMI $\geq 25$) who have 30 minutes of physical activity five times per week.

Denominator: Number of patients with an elevated body mass index (BMI $\geq 25$).

Method/Source of Data Collection

No electronic medical record

Select 20 patients with BMI $\geq 25$ seen within the last month in your practice. If the body mass index is not documented, use the following calculation: weight (lbs.) x 703 divided by height (inches) squared, or refer to a body mass index chart or wheel.

Review selected medical records to determine whether patients are having 30 minutes of physical activity five times per week.

Electronic medical record available

Query data for patients seen in the last month with BMI $\geq 25$.

Review medical records to determine whether patients are having 30 minutes of physical activity five times per week.

Time Frame Pertaining to Data Collection

The suggested time period is monthly.

Notes

This is an outcome measure, and improvement is noted as increase in the rate.

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Measurement #3c

Percentage of patients with BMI ≥ 25 who set an individualized goal along with target date for reduction in body mass index.

Population Definition

Patients, mature adolescents and adults, with an elevated body mass index (BMI ≥ 25).

Data of Interest

\[
\frac{\text{# of patients who set an individualized goal along with target date for reduction in BMI}}{\text{# of patients with BMI ≥ 25}}
\]

Numerator/Denominator Definitions

Numerator: Number of patients with BMI ≥ 25 who set an individualized goal along with target date for reduction in BMI.

Denominator: Number of patients with an elevated body mass index (BMI ≥ 25).

Method/Source of Data Collection

No electronic medical record

Select 20 patients with BMI ≥ 25 seen in your practice 12 months earlier from the measurement date. If the body mass index is not documented, use the following calculation: weight (lbs.) x 703 divided by height (inches) squared, or refer to a body mass index chart or wheel.

Review selected medical records to determine whether patients set an individualized goal along with target date for reduction in BMI at the time of finding out their BMI ≥ 25, 12 months earlier.

Electronic medical record available

Query data for patients seen in your practice with BMI ≥ 25, 12 months earlier from the measurement date.

Review medical records to determine whether patients set an individualized goal along with target date for reduction in BMI at the time of finding out their BMI ≥ 25, 12 months earlier.

Time Frame Pertaining to Data Collection

The suggested time period is monthly. Each month review patients seen 12 months earlier and whether they set an individualized goal along with target date for reduction in BMI at the time of finding out their BMI ≥ 25, 12 months earlier.

Notes

This is an outcome measure, and improvement is noted as increase in the rate.

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**Measurement #3d**

Percentage of patients with BMI \( \geq 25 \) who reach their goal BMI by the set target date.

**Population Definition**

Patients, mature adolescents and adults, with an elevated body mass index (BMI \( \geq 25 \)).

**Data of Interest**

\[
\frac{\text{# of patients who reach their goal BMI by the set target date}}{\text{# of patients with BMI } \geq 25}
\]

**Numerator/Denominator Definitions**

Numerator: Number of patients with BMI \( \geq 25 \) who reach their goal BMI by set target date.

Denominator: Number of patients with an elevated body mass index (BMI \( \geq 25 \)).

**Method/Source of Data Collection**

**No electronic medical record**

Select 20 patients with BMI \( \geq 25 \) seen in your practice 12 months earlier from the measurement date. If the body mass index is not documented, use the following calculation: weight (lbs.) \times 703 divided by height (inches) squared, or refer to a body mass index chart or wheel.

Review selected medical records to determine the number of patients who reached their goal BMI by set target date over a 12-month period.

**Electronic medical record available**

Query data for patients seen in your practice with BMI \( \geq 25 \), 12 months earlier from the measurement date. Review medical records to determine the number of patients who reached their goal BMI by set target date over a 12-month period.

**Time Frame Pertaining to Data Collection**

The suggested time period is monthly. Each month review patients seen 12 months earlier and whether they reached their goal BMI by set target date over a 12-month period.

**Notes**

This is an outcome measure, and improvement is noted as increase in the rate.

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Measurements #4a, b, c

4a: Number of employers or schools that offer or support weight-management programs.
4b: Number of employers or schools that offer healthy food choices.
4c: Number of employers or schools that facilitate/support physical activity to degree possible at work or community sites.

Method/Source of Data Collection

Data for these measures can be collected through surveying schools and employers in the community to determine if they offer weight-management programs, healthy food choices or facilitate opportunities for physical activity. Once the information has been gathered, a community resources list can be developed.

Notes

Community resources list should be available to community organizations and medical groups as a resource to refer patients to for support with weight-management strategies.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish a system for using a Patient Readiness Scale. The scale can be used to determine if the patient is ready to talk about weight loss and/or would like information.

2. Establish a system for staff to efficiently calculate body mass index prior to the physician entering the exam room. This action may be considered a vital sign and built into the rooming protocol. A body mass index chart can be placed by each scale in the clinic; if the organization has an electronic medical record, it may have a component for immediate calculation.

3. Develop a tracking system that periodically reviews patient charts to identify patients who are overweight or obese so that clinicians are aware of the need to discuss the issue with the patient.

4. Establish a system for staff and physician training around skills and knowledge in the areas of motivational interviewing; brief, focused advice on nutrition, physical activity and lifestyle changes; and evaluation of evidence of effectiveness of treatment options.

5. Establish a system for continuing education on evidence-based obesity management for providers, nurses and ancillary clinic staff.

6. Remove barriers to referral programs for weight loss by understanding where programs are and what process is required for referrals.

7. Develop medical record systems to track status of patients under the provider’s care with the capability to produce a tickler system for patient follow-up by provider/staff.

8. Use tools such as posters and brochures throughout the facility to promote a healthy lifestyle around nutrition and activity while encouraging patient knowledge of his or her body mass index.

9. Develop patient-centered education and self-management programs, which may include self-monitoring, self-management and skills such as journaling.

10. Build systems to track outcomes measures, as well as ongoing process measures. Track the response rate to various treatments/strategies. Improvement rates – the body mass index is stable or has decreased over time.

11. Systems to coordinate care ensure continuity and keep providers informed of progress.

- Develop electronic tracking systems for panel or population management.
- Educate patients to foster awareness and knowledge of body mass index for self-monitoring and reporting.
- Structure follow-up visits with patient per guideline recommendations.

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Resources

Criteria for Selecting Resources

The following resources were selected by the guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are only available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

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<th>Title/Description</th>
<th>Audience</th>
<th>Web sites/Order Information</th>
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<tbody>
<tr>
<td>America On the Move</td>
<td>America On the Move (AOM): Challenges you, your family and your community to take small steps and make small changes to a healthier way of life. Get involved!</td>
<td>Patients and Families</td>
<td><a href="http://www.americaonthemove.org">http://www.americaonthemove.org</a></td>
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<tr>
<td>American Dietetic Association</td>
<td>American Dietetic Association: Provides information on nutrition and current research</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://www.eatright.org">http://www.eatright.org</a></td>
</tr>
<tr>
<td>Calorie King</td>
<td>Calorie King: Provides a review of the most popular diets</td>
<td>Patients and Families</td>
<td><a href="http://www.calorieking.com">http://www.calorieking.com</a></td>
</tr>
<tr>
<td>Centers for Disease Control (CDC)</td>
<td>Overweight and Obesity: an overview. Includes a body mass index calculator.</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://www.cdc.gov/ncdphp/dnpa/obesity/contributing_factors.htm">http://www.cdc.gov/ncdphp/dnpa/obesity/contributing_factors.htm</a></td>
</tr>
<tr>
<td>Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign</td>
<td>NAT (Nutritional Assessment Tools for Good Health): Provides a free Web-based program that allows one to perform a nutritional analysis of one's diet</td>
<td>Patients and Families</td>
<td><a href="http://www.nat.uiuc.edu">http://www.nat.uiuc.edu</a></td>
</tr>
<tr>
<td>Department of Health and Human Services</td>
<td>President's Council on Physical Fitness and Sports: Online pamphlet providing information on physical fitness fundamentals</td>
<td>Patients and Families</td>
<td><a href="http://www.health.gov/paguidelines/factsheetprof.aspx">http://www.health.gov/paguidelines/factsheetprof.aspx</a></td>
</tr>
<tr>
<td>Dole Company</td>
<td>Dole Super Kids: Provides basic nutrition education for kids and classroom ideas for teachers</td>
<td>Patients and Families</td>
<td><a href="http://www.dole5aday.com">http://www.dole5aday.com</a></td>
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### Resources Table

* Author/Organization       | Title/Description                                                                 | Audience                  | Web sites/Order Information                                      |
---                         | ----------------------------------------------------------------------------------|---------------------------|-------------------------------------------------------------------|
|                           |                                                                                    | Health Care Professionals |                                                                   |
* Institute for Clinical    | Prevention and Management of Obesity Guideline Pilot Summary:                     | Health Care Professionals | http://www.icsi.org                                                  |
| Systems Improvement        | Affiliated Community Medical Centers and St. Mary's/Duluth Clinic Health          |                           |                                                                   |
|                           | System participated in a guideline pilot from mid-2005 to early 2006. This      |                           |                                                                   |
|                           | summary will tell their story and provide information around strategies           |                           |                                                                   |
|                           | for implementation, measurement/outcomes and overall improvement in processes.    |                           |                                                                   |
| and Education - PNC       |                                                                                    |                           |                                                                   |
| and Education - PNC       |                                                                                    |                           |                                                                   |
| and Education - PNC       |                                                                                    |                           |                                                                   |
Institute for Research      | Simple Strategies for Weight Management: Nutrition pamphlet                        | Patients and Families     | http://www.healthsource.org or 800-372-7776                        |
| and Education - PNC       |                                                                                    |                           |                                                                   |
Krames - Health and Safety  | Understanding Bariatric Surgery: Your Surgical Options for Weight Loss; Surgery | Patients and Families     | Call 1-800-333-3032                                                 |
| Education                 | pamphlet                                                                          |                           |                                                                   |
|                           |                                                                                    | Health Care Professionals |                                                                   |
Mayo Clinic                 | Mayo Clinic: Provides a wide variety of information on nutrition, programs and    | Patients and Families     | http://www.mayoclinic.com                                            |
|                           | a food pyramid placing fruits and vegetables at the bottom vs. carbohydrates.    |                           | Book                                                              |
|                           | The Mayo Clinic Diet: Eat Well, Enjoy Life, Lose Weight                           |                           |                                                                   |
National Heart, Lung        | Aim for a Healthy Weight: provides key recommendations from the National Heart,  | Patients and Families     | http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm |
| and Blood Institute       | Lung and Blood Institute national guidelines, how to get started and links to    |                           |                                                                   |
|                           | other publications.                                                              |                           |                                                                   |

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### Resources Table

**Prevention and Management of Obesity (Mature Adolescents and Adults)**

Fifth Edition/April 2011

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<tbody>
<tr>
<td>OptumHealth</td>
<td><strong>Health A to Z:</strong> Provides information on nutrition and fitness, as well as self-assessment tools.</td>
<td>Patients and Families</td>
<td><a href="http://www.healthatoz.com">http://www.healthatoz.com</a></td>
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<tr>
<td>Paths to Healthy Weight</td>
<td>At Paths to Healthy Weight, the Health Care Innovations Exchange presents new approaches for helping communities and clinicians prevent overweight and obesity, in a joint effort of the Agency for Healthcare Research and Quality and the Health Resources and Services Administrations.</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://www.innovations.ahrq.gov/healthyweight.aspx">http://www.innovations.ahrq.gov/healthyweight.aspx</a></td>
</tr>
<tr>
<td>Shape Up America</td>
<td><strong>Shape Up America:</strong> Provides information on an interactive personalized weight-loss program with links to a support center, recipes and fitness information.</td>
<td>Patients and Families</td>
<td><a href="http://www.shapeup.org">http://www.shapeup.org</a></td>
</tr>
<tr>
<td>The Discovery Health Channel</td>
<td><strong>Discovery Health:</strong> Provides information on nutrition, fitness and weight management.</td>
<td>Patients and Families</td>
<td><a href="http://www.health.discovery.com">http://www.health.discovery.com</a></td>
</tr>
<tr>
<td>U.S. Department of Agriculture</td>
<td><strong>My Pyramid:</strong> Use the pyramid as an interactive nutrition education tool. Create a personalized dietary and activity guide to achieve a healthy lifestyle.</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://www.mypyramid.gov">http://www.mypyramid.gov</a></td>
</tr>
<tr>
<td>We Can (Ways to Enhance Children's Activity and Nutrition)</td>
<td><strong>We Can:</strong> National Heart, Lung and Blood Institutes national movement designed to give parents, caregivers and entire communities a way to help children 8-13 stay at a healthy weight.</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://wecan.nhlbi.nih.gov">http://wecan.nhlbi.nih.gov</a></td>
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The subdivisions of this section are:

- Conclusion Grading Worksheet Summary
  - Conclusion Grading Worksheets
- References
- Appendices
Conclusion Grading Worksheet Summary

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

**Grade I:** The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

**Grade II:** The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

**Grade III:** The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

**Grade Not Assignable:** There is no evidence available that directly supports or refutes the conclusion.

The symbols +, –, ø, and N/A found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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**Work Group’s Conclusion:**
- Studies have consistently found that patients with preoperative body mass index between 30 and 35 kg/m² have good weight-loss results.
- Additionally, studies have consistently found improvements of comorbidities.
- One randomized controlled trial (80 participants) found comparable results for surgical and behavioral/pharmacotherapy at six months follow-up, but at later follow-ups the non-surgical group regained weight while the surgical group continued to lose weight.
- Findings from case series are consistent with randomized controlled trial findings.

**Conclusion Grade: III**

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<thead>
<tr>
<th>Author/Year</th>
<th>Design Type</th>
<th>Class Quality</th>
<th>Population Studied/Sample Size</th>
<th>Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)</th>
<th>Authors' Conclusions/Work Group’s Comments (italicized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michaelson et al, 2008</td>
<td>Case series</td>
<td>D -</td>
<td>118 patients (108 women and 10 men) with BMI between 30 and 35, mean BMI of 33.2 kg/m² and mean excess body weight of 22.7 kg followed for 6 months after surgery</td>
<td>Primary outcome was mean weight loss at 6 months post laparoscopic adjustable gastric banding surgery. Mean (SD) weight loss at 6 months was 15.0 kg (7.2), mean excess body weight lost was 63.7% (36.6). Secondary outcomes were reported improvement or resolution of comorbidities including sleep apnea, diabetes mellitus, insulin resistance, hypertension, hyperlipidemia, reflux, joint pain, low back pain, incontinence, asthma, depression, polycystic ovarian syndrome.</td>
<td>The authors conclude that the lap band is an effective tool for weight loss and improvement of obesity-related comorbidities in an obese population not currently considered candidates for surgical intervention. There were 8 complications – 2 port revisions for slipped ports, 2 port replacements for leaks, and 4 slipped bands that were repositioned laparoscopically. [This is a meeting abstract, so there are no details of study design, data collection, loss to follow-up, or study limitations.]</td>
</tr>
<tr>
<td>Kakoudlidis et al, 2008</td>
<td>Case series</td>
<td>D -</td>
<td>23 patients (21 women and 2 men) with BMI between 30-35 kg/m² who underwent sleeve gastrectomy and were followed for 6 months. At baseline, median BMI was 33.8 kg/m².</td>
<td>Primary outcome was excess body weight lost at 6 months. Median excess BMI lost (%) was: 1 month: 37.3 3 month: 66.8 6 month: 100 On average, the patients lost 100% of the excess BMI (excess BMI defined as body mass in excess of 25 kg/m²) and BMI at 6 months had decreased to 25 kg/m². Most comorbidities resolved at 6 months as well (diabetes mellitus, hypertension, dyslipidemia, osteoarthritis, infertility, sleep apnea, GERD).</td>
<td>The authors conclude that sleeve gastrectomy results in promising early weight loss and quality-of-life improvements. [There are some serious limitations with this study. 1) 79 patients underwent surgery, but only 23 were followed for 6 months. It’s possible and likely that those who were not followed up for 6 months were non-compliant patients and potentially had less favorable outcomes, which suggests that the results presented in the paper are biased away from the null. 2) The authors claim that there were quality-of-life improvements, but they only report quality-of-life measures at follow-up, not at baseline, so there is no comparison. While this study provides some information regarding surgical interventions for class I obesity (BMI 30-35 kg/m²), the important aspects of comparing surgical and non-surgical groups are not covered.]</td>
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<tr>
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<td>Cohen et al, 2006</td>
<td>Case series</td>
<td>D Ø</td>
<td>37 patients (30 women and 7 men) with BMI between 32 and 35 kg/m² were enrolled. Mean BMI was 32.5 kg/m². Patients were followed between 6 and 48 months post laparoscopic roux-en-Y gastric bypass surgery.</td>
<td>Primary outcome was mean excess weight lost. At 6 months follow-up the mean excess weight lost was 44% (excess weight defined using Metropolitan Life Foundation height and weight tables). 33 patients were followed for 12 months and lost 71.6% of excess weight, 9 patients were followed for 48 months and lost 81% of excess weight. 36 of 37 patients had total remission of their comorbidities (diabetes, hypertension, dyslipidemia, GERD and sleep apnea).</td>
<td>The authors conclude that gastric bypass surgery in the selected patients was associated with no morbidity or mortality. They also report that the short-term weight loss was slightly better than that observed in patients with BMI &gt; 35 kg/m². The authors acknowledge limitations related to selection bias and study design limitations.</td>
</tr>
<tr>
<td>Parikh et al, 2006</td>
<td>Case series</td>
<td>D Ø</td>
<td>93 patients (76 women and 17 men) with BMI between 30-35 kg/m² who underwent adjustable gastric bandings surgery (LAP-BAND) and followed for up to 3 years. Mean BMI preoperative was 32.7 kg/m².</td>
<td>The primary outcome was excess weight lost (excess weight defined as weight in excess of ideal weight based on Metropolitan Life height and weight tables). 72 patients were followed for one year, percent excess weight lost was 58% and mean (SD) BMI at 1 year was 27 kg/m² (2). 70 patients were followed for 2 years with 57% excess weight lost and mean BMI at 2 years was 27 kg/m² (3). At 3 years postoperative, 67 patients were retained and had 54% excess weight lost, mean BMI of 27 kg/m² (3).</td>
<td>In this series of low BMI patients who underwent LAP-BAND surgical interventions, there was good weight loss, minimal complications, and comorbidities were partially or wholly resolved. The discussion section of the paper mentions that the advantages of bariatric surgery over other interventions include good compliance and weight loss is maintained, thus ensuring resolution of comorbidities compared to behavioral interventions and pharmacotherapy, which both have poor compliance and relatively modest weight losses.</td>
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<tr>
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<tr>
<td>O’Brien et al, 2006</td>
<td>Randomized controlled trial</td>
<td>A</td>
<td>+</td>
<td>80 adults with BMI between 30-35 kg/m² randomly assigned to either program of very low calories diets, pharmacotherapy, and lifestyle change for 24 months (non-surgical group) or to placement of a laparoscopic gastric band (LAP-BAND) and followed for 24 months.</td>
<td>Primary outcomes measured were weight change and excess weight lost (excess weight defined as weight in excess of BMI of 25 kg/m²). Adjusted for age, sex and baseline weight, mixed effect models were run to estimate changes in weight, BMI and excess weight lost at 6, 12 and 24 months follow-up. At 6 months follow-up there were no statistically significant differences between treatment groups with regard to weight change or excess weight lost (p=0.99 and 0.98 respectively). At 12 months follow-up there were statistically significant differences between treatment groups – the surgical group lost 76.3 kg and non-surgical group lost 85.3 kg (p &lt;0.0001), the surgical group lost 78.6% and the non-surgical group lost 41.1% of excess weight (p &lt;0.0001). At 24 months follow-up, the surgical group had lost 74.5 kg and the non-surgical group lost 89.5 kg (p &lt;0.0001), and the surgical group had 21.8% excess weight lost (p &lt;0.0001). Secondary outcomes included resolution of comorbidities and changes in quality of life. At 2 years follow-up, the resolution of metabolic syndrome between the two groups differed significantly: at baseline metabolic syndrome was present in 15% of each group and at 24 month follow-up present in 2.7% in surgical group and 24% in the medical group (p = 0.006). There were no baseline differences in quality of life scores from SF-36. At 24 months follow-up, both groups had statistically significant improvements in quality of life on all 8 domains of the SF-36.</td>
</tr>
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<tr>
<td>Angrisani et al, 2004</td>
<td>Case series</td>
<td>Ø</td>
<td>210 patients (34 males, 176 females) with BMI ≤ 35 kg/m² were included in this retrospective study using data collected from 27 Italian surgical team sites. Mean BMI preoperative was 33.9 kg/m² and mean excess weight was 29.6 kg.</td>
<td>Primary outcomes in this study were change in BMI and excess weight lost. At 6 months follow-up, mean (SD) BMI was 31.1 kg/m² (2.15) and mean (SD) excess weight lost was 28.1% (20.7). At later follow-ups, patients were lost to follow-up. At 12 months, 182 patients had a mean (SD) BMI of 29.7 kg/m² (2.19) and mean (SD) excess weight lost of 52.5% (13.2). At 36 months follow-up, 119 patients had a mean BMI 28.7 kg/m² (3.8) and mean excess weight lost of 61.3% (14.7). At 48 months follow-up, 75 patients had a mean BMI of 27.9 kg/m² (3.2) and mean excess weight loss of 68.8% (15.3). And at 60 months follow-up, 75 patients had mean BMI of 28.2 kg/m² (0.9) and mean excess weight loss of 71.9% (10.7).</td>
<td>In this study of the LAP-BAND, all but one patient achieved normal weight and most experienced resolution of all their comorbidities. The authors suggest that low BMI (30-35 kg/m²) patients are good candidates because they have more underlying comorbid conditions that apparent and they pose fewer risks and have fewer surgical complications. They further suggest that indications of this procedure should be carefully evaluated by internist and surgeon in each individual case. [This study has a fair amount of loss-to-follow-up but is among those with the longest follow-up time. They do not report what standard they are using to define excess weight.]</td>
</tr>
<tr>
<td>Nadler et al, 2008</td>
<td>Case series</td>
<td>+</td>
<td>53 adolescents (54 female and 19 male) aged 13 to 17 years who have undergone laparoscopic adjustable gastric banding. Mean preoperative weight was 298 lb with mean BMI of 48 kg/m².</td>
<td>At 6 months follow-up, 53 patients had a mean (SD) weight of 247 lb (53), mean (SD) BMI of 39.8 kg/m² (7.0), and excess weight loss of 35.1% (16.2). At 1 year follow-up, 47 patients had mean weight of 214 lb (59), mean BMI of 34.3 kg/m² (23.0), and excess weight loss of 56.7% (23.0). At 2 years follow-up, 16 patients had a mean weight of 204 lb (41), mean BMI of 32.1 kg/m² (6.4), and mean excess weight loss of 60.9% (26.5). At 1 year of follow-up, 70% of comorbid conditions were resolved (among 21 patients with comorbid conditions preoperatively). No patients experienced intraoperative complications. 27 patients experienced non-surgical complications including hair loss, iron deficiency, band slip, and vitamin D deficiency. Two patients required post-operative band removal because of slippage.</td>
<td>The authors advocate the use of laparoscopic gastric banding in morbidly obese pediatric populations.</td>
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<tr>
<td>Author/Year</td>
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<td>Class</td>
<td>Quality</td>
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<tr>
<td>Pinheiro et al, 2007</td>
<td>Case series</td>
<td>D</td>
<td>-</td>
<td>13 patients with BMI between 30-35 kg/m² with low quality of life results and without serious comorbidity underwent gastric sleeve gastrectomy procedure.</td>
<td>Excess weight loss was 30% at 6 months, 45% at 12 months (4 patients), 56% at 24 months (3 patients). BMI was under 27 kg/m² in all patients. At 12 months, patients presented with higher scores in labor and self-esteem compared to previous questionnaires.</td>
</tr>
<tr>
<td>Dixon et al, 2008</td>
<td>RCT</td>
<td>A</td>
<td>+</td>
<td>60 obese patients (BMI &gt;30 and &lt;40, mean BMI 37 kg/m) with type 2 diabetes diagnosed within last 2 years. Patients were randomized to conventional diabetes therapy with a focus on lifestyle change or laparoscopic adjustable gastric banding with conventional diabetes care.</td>
<td>The primary outcome of this study was remission of type 2 diabetes. The secondary outcomes were weight and components of the metabolic syndrome. Of the 60 patients enrolled, 55 completed the 2-year follow-up. Remission of diabetes was achieved by 22 in the surgical group and 4 in the conventional-therapy-alone group. The surgical group lost a mean (SD) of 20.7% (8.6%) and 1.7% (5.2%) of weight, respectively, at 2 years. At baseline, the metabolic syndrome was present in 97% of each treatment group. At 2 years follow-up, 70% of surgically treated and 13% of conventionally treatment patients did not meet NCEP criteria for metabolic syndrome.</td>
</tr>
</tbody>
</table>
References


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Brolin RE, Cody RP. Weight loss outcome of revisional bariatric operations varies according to the primary procedure. *Ann Surg* 2008;248:227-32. (Class D)


Catalano MF, Rudic G, Anderson AJ, Chua TY. Weight gain after bariatric surgery as a result of a large gastric stoma: endotherapy with sodium morrhuate may prevent the need for surgical revision. *Gastrointest Endosc* 2007;66:240-45. (Class D)


Christou NV, Look D, MacLean LD. Weight gain after short- and long-limb gastric bypass in patients followed for longer than 10 years. *Ann Surg* 2006;244:734-40. (Class B)


CME Resource. What healthcare professionals should know about exercise. *CME Resource* December 2004. (Class R)


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Appendix A – Body Mass Index-for-Age Percentiles

2 to 20 years: Girls

Body mass index-for-age percentiles

<table>
<thead>
<tr>
<th>Name</th>
<th>Record #</th>
</tr>
</thead>
</table>

*To Calculate BMI: Weight (kg) ÷ Stature (cm) = Stature (cm) x 10,000
or Weight (lb) ÷ Stature (in) = Stature (in) x 703

Published May 30, 2000 (modified 10/16/00).

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
http://www.cdc.gov/growthcharts

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2 to 20 years: Boys
Body mass index-for-age percentiles

<table>
<thead>
<tr>
<th>Date</th>
<th>Age</th>
<th>Weight</th>
<th>Stature</th>
<th>BMI*</th>
<th>Comments</th>
</tr>
</thead>
</table>

*To Calculate BMI: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
or Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703

Published May 30, 2000 (modified 10/16/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).
http://www.cdc.gov/growthcharts

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## Appendix B – Medications Associated with Weight Gain and Weight Loss

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Mechanism of Action or Pharmaceutical Class</th>
<th>Medication</th>
<th>Weight Neutral</th>
<th>Related to Weight Gain</th>
<th>Related to Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antidepressants</strong></td>
<td>(Masand, 2000 [R]; Sussman, 2001[M])</td>
<td>Norepinephrine and Dopamine RI</td>
<td>Bupropion</td>
<td></td>
<td>X (especially when combined with naltrexone)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Venlafaxine</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SSRI</td>
<td>Fluoxetine</td>
<td>X</td>
<td>X (initially but may gain over time)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sertraline</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Tricyclics</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Monamine oxidase inhibitors</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multiple</td>
<td>Mirtazapine</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypoglycemics</strong></td>
<td>(The Diabetes Control and Complications Trial Research Group; 1993 [A]; Purnell, 1998 [A]; Williams, 1999 [B])</td>
<td>GLP-1 analogs</td>
<td>Exenatide</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Liraglutide</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Biguanides</td>
<td>Metformin</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Amylin analog</td>
<td>Pramlitide</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Alpha-Glucosidase inhibitors</td>
<td>Acrbose</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Miglitol</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Insulin secretagogues – meglitinides</td>
<td>Nateglinide</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repaglinide</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Insulin secretagogues – sulfonylureas</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Thiazolidine-diones</td>
<td>Pioglitazone</td>
<td>Weight neutral if used with metformin</td>
<td>X (when used alone or in combination with sulfonylurea)</td>
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<tr>
<td></td>
<td></td>
<td>Insulin</td>
<td>Sitagliptin Saxagliptin</td>
<td>X</td>
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<tr>
<td></td>
<td></td>
<td>DPP-4 inhibitors</td>
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<tr>
<td></td>
<td></td>
<td>Anticonvulsants</td>
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<tr>
<td></td>
<td></td>
<td>Opioid Antagonist</td>
<td>Naltrexone II</td>
<td>X</td>
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</tr>
<tr>
<td><strong>Mood Stabilizer</strong></td>
<td></td>
<td>Lithium II</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Antihypertensives</strong></td>
<td></td>
<td>Antihypertensives</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Antipsychotics</strong></td>
<td>(consider empiric use of metformin to minimize weight gain)</td>
<td>Antipsychotics</td>
<td>Risperidone</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Aronne, 2003 [R])</td>
<td></td>
<td>Sertindole</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Olanzapine</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clozapine</td>
<td>X (small increase)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Ziprasidone</td>
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<td></td>
</tr>
</tbody>
</table>

Sources: (Aronne, 2009 [R]; Astrup, 2009 [A]; Moyers, 2005 [R])
Appendix C – Physical Activity Prescription

Name _____________________
Date ___________
Follow-up interval _______

Health Status for Physical Activity:
Current Diagnoses (see contraindications):
1. ____________________
2. ____________________
3. ____________________

Current Medications:
1. ____________________
2. ____________________
3. ____________________

Assessment:
_____ OK for a self-monitored activity program
_____ OK for a supervised activity program (referral)
_____ Needs exercise tolerance testing (referral)

Activity Planner:  Season(s) of Year _____________

Indoors - Alone
1. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

2. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

Indoors - with Others
1. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

2. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

Outdoors – Alone
1. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

2. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

Outdoors – with Others
1. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

2. Activity __________________________
   Resources
   a. ________________________________
   b. ________________________________
   c. ________________________________

Patient should identify at least two possible activities under each circumstance to achieve variety.

For each selected activity, identify key resources needed to make it happen. Resources include both physical (e.g., equipment, coach, time) and psychological (e.g., social support, goals).

Goals are to adjust activity plans for seasons and weather, minimize boredom, develop social support and personalize activity selection, given resources.

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Dimensions for Physical Activity Improvement:
Frequency – recommended number of days per week to perform selected activities.
1. Cardiovascular – Start at 3x/week and advance to most days per week.
2. Strength – Start at 2-3 x/week and advance to every other day for a given muscle group.
3. Flexibility – Start at every other day and advance to most days per week; especially stretch after aerobic or resistance activities during the cool-down phase.

Duration – recommended amount of time or total work per activity session. Frequency and duration are more important for total caloric expenditure and weight management. They should be increased before intensity.

Intensity – recommended speed of movement (walking pace) or amount of weight to be lifted for each repetition. Increasing intensity creates continued improvement after physiologic adaptation to a given frequency and duration of activity. Intensity can be monitored with the Borg Perceived Exertion Scale. Typical target intensity on the Borg 6-20 scale is: 10-12 Fairly Light to 13-14 Somewhat Hard.

Also, the “talk test” indicates need to decrease intensity if difficulty in talking during aerobic activity.

**Activity Prescription:** Record prescribed activity and amount of time for each day of the week.

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<table>
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<tr>
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<tr>
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<tr>
<td>(Activity)</td>
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<tr>
<td>Outdoors: (Activity)</td>
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<td>(Activity)</td>
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Week 2

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<tr>
<td>(Activity)</td>
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</tr>
<tr>
<td>Outdoors: (Activity)</td>
<td></td>
<td></td>
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<tr>
<td>(Activity)</td>
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</tr>
</tbody>
</table>
```

Work up to _____ minutes for (activity) in ____ weeks. Work up to _____ lbs. for (activity) in ____ weeks.

I agree to this activity prescription and to keep an activity log on my calendar from ______ to ______.

Patient’s Signature _________________________ Provider’s Signature _________________________

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Appendix D – FDA-Approved Medications for the Treatment of Obesity

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Mechanism of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzphetamine</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Diethylpropion</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Phendimetrazine</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Phentermine</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Phentermine resin complex</td>
<td>Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.</td>
</tr>
<tr>
<td>Orlistat</td>
<td>Reversible inhibitor of lipases; exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with gastric and pancreatic lipases and a subsequent reduction in triglyceride hydrolysis and absorption of dietary fat, including cholesterol.</td>
</tr>
</tbody>
</table>

*Orlistat 60, TN Alli, available for over-the-counter use.

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Restrictive procedures (adjustable band)

Figure 1: Adjustable Band

The most common restrictive procedure that is performed today is the adjustable band. At present there are two types available in the United States, the Lap Band™ and the Realize Band™. In principle both devices function as circumferential balloons that are placed just below the level of the gastroesophageal junction and then secured in a way to prevent migration. The band balloons are connected to a port (similar to a chemotherapy port) that is secured to the anterior abdominal wall fascia below the skin, providing access for saline placement. In most cases patients will have an overnight stay and beginning six weeks postoperatively fluid will be introduced into the band either in the office setting or under direct radiologic guidance. Initially adjustment protocols were designed to produce a maximal amount of restriction, lending some advantage to the radiologic adjustment model. However, the actual mechanism may also be related to the direct pressure placed externally. Some studies show no actual delay in the progression of food from the pouch into the remainder of the stomach (Burton, 2011 [C]). The bands differ slightly in terms of the pressure generated on the stomach in relation to the same amount of fluid in the band. There are no good control studies to suggest differences in outcomes of weight loss between the two groups (Cunneen, 2008 [M]). The weight-loss from banding is typically 45% to 55% of excess weight. Unlike other bariatric operations, the weight loss is far more gradual and in many cases will reach the nadir between two and three years following surgery.

Complications following adjustable banding and suggestions for management

Laparoscopic adjustable banding carries the best safety profile of any operation performed in the short term. The mortality rate is 0.05% (Longitudinal Assessment of Bariatric Surgery [LABS] Consortium, The, 2009 [B]). Despite this, appropriate preoperative workup including deep venous thrombosis (DVT) prophylaxis has been shown to be a benefit (Scholten, 2002 [B]). Four types of technical complications exist following banding; these include slippage, concentric dilatation, erosion, and port-related problems. In aggregate, this results in a substantial need postoperatively for re-operation. In most cases including erosion, the patients will present with subacute symptoms. However, acute gastric distention, necrosis and perforation can occur. Access of the patient and the primary care physician to the original team or an experienced team that is receptive to managing complications is imperative to minimize the long-term sequelae of these complications. There is a great deal of variability in how complications are managed.
Slippage is defined by passage of stomach, usually fundus and body, underneath the band and above the band. In almost all cases the slippage occurs anteriorly. The classic presentation is obstruction usually preceded by an episode of vomiting. Diagnostically, this can be suggested by a change in the angle of the band on plain x-ray. Usually the band is oriented at a 45° angle from the left down to the right. In slippage, the band takes a more horizontal orientation. The mainstay of therapy is fluid removal from the band, and observation. If symptoms are immediately improved and the slippage is small, fluid may be reintroduced after a period of four weeks with careful dietary counseling. In case of large slippage or persistent obstruction, emergent surgery is performed. The stomach should be decompressed and the band either replaced, repositioned or removed, with conversion to alternative procedure if weight loss has been inadequate.

**Impact on comorbid illness**

Despite being one of the more recently introduced procedures, some of the best data (randomized) exists for laparoscopic adjustable banding. Dixon, et al. reported two studies looking at weight loss and improvement of patients with type 2 diabetes (Dixon, 2008 [A]). The effect of the laparoscopic adjustable band was demonstrably superior to medical management alone.

**Vertical sleeve gastrectomy**

This is a relatively new procedure that has gained considerable growth over the last five to six years. In principle this operation involves removal of the greater curvature of the stomach including the fundus while preserving the antrum. Unlike the laparoscopic adjustable band, this restrictive procedure does not require adjustments. It does, however, involve construction of a long staple line. This increases the potential for leakage. Additionally, there is uncertainty about the best way to construct the sleeve in terms of size of the sleeve caliber. This results in variations in both weight loss and complications. At present, use of the sleeve gastrectomy is not covered by CMS. It remains, however, an intriguing procedure to use in select circumstances. In patients with inflammatory bowel disease (IBD) this may have advantages over the gastric bypass. The laparoscopic adjustable band includes IBD as a contraindication for surgery. The relative lack of malabsorption, the lack of need for adjustments, and the potential for converting this to a more robust operation such as the gastric bypass and the duodenal switch remain promising. The initial draw for the sleeve gastrectomy was in patients considered high risk secondary to cardiopulmonary disease or extremes of obesity. Many authors have found that preoperative liquid diets can easily and more safely substitute as a first step in the treatment of this patient population (Still, 2007 [B]).

**Complications of the sleeve gastrectomy**

These are similar to those found in the Roux-en-Y gastric bypass. Complications include leakage, stricture and significant issues with nausea and vomiting.

**Figure 2: Roux-en-Y gastric bypass**

Illustrated by Farha Ikramuddin
The gastric bypass represents the gold standard bariatric surgical operation. It produces a durable weight loss, is the most intensively studied, and has the most predictable set of complications. It is, therefore, reasonable that operations be compared to this in terms of superiority or inferiority. The gastric bypass was first used as an operation to treat ulcer disease. Observations that it produced massive weight loss in obese patients prompted its use as a primary operation to treat obesity. Currently, the operation is performed laparoscopically.

There are a number of technical complications that can follow the gastric bypass. A high index of suspicion should be maintained in patients, and prompt bariatric surgical input should be obtained (Podnos, 2003 [C]).

- Leaks (3%) occur early within the first week.
- Internal bleeding (1%) occurs within the first week and can be in the GI tract.
- Anastomotic stenosis (2%-20%) occurs most often by three-four weeks.
- Internal hernia formation (1%-5%) occurs most often beyond six months.
- Wound infections can occur in up to 6.6% of patients.
- Anastomotic marginal ulceration can be as high as 15%, but the true incidence is likely unknown. Recalcitrant ulcers raise the concern of gastrogastric fistula formation that can be seen even following a divided gastric bypass.

Severe life-threatening complications appear to be influenced by gender and by weight and age. Overall mortality of the gastric bypass is 0.5% (Schauer, 2000 [D]). Livingston, et al. found that patients older than 55 years had a threefold higher mortality from surgery than younger patients, although the complication rate (5.8%) was the same in both groups (Livingston, 2002 [C]). The risk for severe life-threatening adverse outcomes in women increased from 4% for a 200 lb. female patient to 7.5% for a 600 lb. patient. In males, the risk increased from 7% for a 200 lb. male to 13% for a 600 lb. patient (Livingston, 2002 [C]).

The waist-to-hip ratio may also correlate with the difficulty of surgery, as it may correlate to increased visceral fat stores and may contribute to possible respiratory difficulty (Schwartz, 2003 [C]).

The incidence of serious respiratory complications varies from 0% to 4.5% in both laparoscopic and open procedures (Podnos, 2003 [C]).

Dealing with the excluded limb following the gastric bypass can be a significant issue. Usually concern is warranted to evaluate the excluded stomach in patients with unexplained pain or the presence of a mass. In some cases it becomes useful to access the stomach to perform an ERCP in order to remove common duct stones. The stomach can be accessed using interventional radiologic techniques, laparoscopy or conventional surgery.

Pregnancy after the bypass operation is possible. Fertility can be increased following the bypass in some patients. Patients should wait until weight loss has ceased prior to conceiving, which usually occurs at 18 months after surgery. Patients should undergo a thorough nutritional evaluation prior to and during pregnancy (Wittgrove, 1998 [D]).

**Post-gastric-bypass hypoglycemia**

This is a rare condition associated with low blood sugar following the ingestion of concentrated sweets. It begins usually after maximal weight loss has been achieved and patients’ beginning to resume higher quantity of food intake. It is characterized by symptoms of neuroglycopenia, which include dizziness, syncope, confusion, blurred or double vision, or even seizure activity (Bantle, 2007 [D]). It is a variant of the dumping syndrome. There are two phases. The earlier phase is associated with initial ingestion of concentrated carbohydrates – symptoms include nausea, abdominal pain, palpitations, and the urge to lie down. These are mediated by a number of intestinal peptides such as vip and neurotensin. Workup should...
include determination that fasting hypoglycemia due to insulinoma is present. Phase two is associated with increased insulin secretion and hypoglycemia in some patients. In patients who have neuroglycopenia e.g., associated neurologic change further workup is indicated. Please see Appendix F, "Meal Tolerance Test Orders: HIGH CHO Meals," and Appendix G, "Meal Tolerance: Low CHO Meals."

**Figure 3: Duodenal switch**

The duodenal switch procedure is a combination of the sleeve gastrectomy and a long intestinal bypass. The common channel, which is the length of the bowel exposed to both food and bilio-pancreatic fluid, is between 50 and 150 cm. The pylorus and most proximal portion of the duodenum are left intact. This allows for improved food processing by the stomach and thus little if any dumping syndrome. The small segment of duodenum, 1-4 cm, is quite resistant to the development of marginal ulceration, a common problem associated with the gastric bypass. The presence of a large sleeve facilitates more food intake over time than the gastric bypass. DS patients tend to suffer from diarrhea in comparison to patients with the gastric bypass, who have constipation.

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Appendix F – Meal Tolerance Test Orders: High CHO Orders

Patient name: _____________________

Diagnosis: Symptomatic Hypoglycemia

Patient should be fasting for at least 8 hours prior to testing.

<table>
<thead>
<tr>
<th>Time Intervals</th>
<th>Chart Time</th>
<th>Action</th>
<th>Document BP/HR/Symptoms</th>
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<tbody>
<tr>
<td>Baseline (Pre-meal)</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>0 min,**</td>
<td></td>
<td>Ask patient to eat HIGH CHO meal within 10 minutes.</td>
<td></td>
</tr>
<tr>
<td>+ 15 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 30 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 45 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 60 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 90 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 120 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 180 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>+ 240 min.</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
</tbody>
</table>

* Blood samples for plasma glucose (2ml blood in grey-top tube) and serum insulin (3 ml in red-top tube).

** Time zero starts when patient is eating meal. Patient must eat the entire meal.

Record amount eaten: _________________________________________________________

High CHO meal: 8 oz. orange juice, 6 oz Yoplait fat-free fruit-flavored yogurt, 1 slice bread or toast with 1 tsp. margarine and 2 tsp. jam. For patients who are lactose intolerant, ¾ cup applesauce can be substituted for the yogurt.

If patient becomes confused, check finger prick blood glucose; if < 45 mg/dL, treat with 3 glucose tablets and note in record. Continue drawing blood samples according to schedule.

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Appendix G – Meal Tolerance: Low CHO Meals

Patient name: _____________________
Diagnosis: Symptomatic Hypoglycemia
Patient should be fasting for at least 8 hours prior to testing.

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>Chart Time</th>
<th>Action</th>
<th>Document BP/HR/Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (Pre-meal)</td>
<td></td>
<td>Obtain blood samples*</td>
<td></td>
</tr>
<tr>
<td>0 min.**</td>
<td>Ask patient to eat LOW CHO meal within 10 minutes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 15 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 30 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 45 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 60 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 90 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 120 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 180 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 240 min.</td>
<td>Obtain blood samples*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Blood samples for plasma glucose (2ml blood in grey-top tube) and serum insulin (3 ml in red-top tube).

** Time zero starts when patient is eating meal. Patient must eat the entire meal and within 10 minutes.

Record amount eaten: ____________________________________________________________

**Low CHO meal:** decaffeinated black coffee or tea, 1 scrambled egg, 2 oz sausage patties, 1 slice (1.0 oz) cheese. No sugar or cream with coffee.

If patient becomes confused, check finger prick blood glucose: if < 45 mg/dL, treat with 3 glucose tablets and note in record. Continue drawing blood samples according to schedule.

At each blood draw: document symptoms, check pulse and blood pressure.

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## Appendix H – Nutritional Supplement Recommendations

<table>
<thead>
<tr>
<th>Supplement</th>
<th>Amount recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin containing thiamine and 400 mcg folic acid</td>
<td>1-2 each day</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>IM: Either mcg weekly, 1,000 mcg monthly or 3,000 mcg every six months or Sublingual: 350 mcg per day</td>
</tr>
<tr>
<td>Iron (ferrous sulfate, fumarate or gluconate)</td>
<td>150-300 mg per day (for menstruating women)</td>
</tr>
<tr>
<td>Calcium citrate + Vitamin D</td>
<td>400-800 mg twice daily (to achieve total dose of 1,200-2,000 mg per day)</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>5,000 to 10,000 units per day</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>600-50,000 units per day</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>400 International units per day</td>
</tr>
</tbody>
</table>
Appendix I – Band Assessment Protocol

Band Adjustments

Clinic Assessment

Follow-up Schedule

Upper GI—preop

Operation - 0 or 1 day hospital stay

Clinic visit to assess wound 1-4 weeks after surgery

1st Band Adjustment 2 months after surgery

2nd Band Adjustment 3 months after surgery

then every 1-2 months until the end of year one

then every 6 months for the rest of life Annual Laboratory Data

Upper GI—every year and as needed

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Appendix J – Sample Weight-Loss Surgery Preoperative Laboratory – SUR and Checkout Orders

Prevention and Management of Obesity (Mature Adolescents and Adults)
Fifth Edition/April 2011

UNIVERSITY OF MINNESOTA MEDICAL CENTER, FAIRVIEW
Weight Loss Surgery Pre-Operative Laboratory - SUR and Checkout Orders
☐ No Orders  ☐ Check Results in __________

Ordering Physician: Please LEGIBLY print FIRST and LAST NAME if different than label.

DR. __________

If resident/fellow, list attending physician for billing purposes.

DR. __________

DIAGNOSIS / DIAGNOSIS CODES (ICD-9) - OUTPATIENTS ONLY:
Check at least one of the following diagnoses:
☐ 278.01 Morbid Obesity  ☐ 401.9 Hypertension
☐ 250.01 Type 1 Diabetes  ☐ 260.00 Type 2 Diabetes
☐ 272.4 Dyslipidemia  ☐ 327.23 Obstructive Sleep Apnea
☐ Other __________

*Tests ordered on Medicare outpatients must follow HIPAA rules regarding medical necessity and HIPAA approval guidelines and must include diagnosis, symptoms or the reasons for testing as indicated in the medical report. **A wellness test does not carry under Medicare guidelines for payment. A signed Advance Beneficiary Notice must be included.

<table>
<thead>
<tr>
<th>Code</th>
<th>CHEMISTRY/HMATOLOGY</th>
<th>Call Vol</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLIPR</td>
<td>Lipid: Chol, Trig, HLD wireless to measured LDL, when Trig &gt;400*</td>
<td>G0 1-2</td>
</tr>
<tr>
<td>X</td>
<td>C00MP</td>
<td>G0 0-1</td>
</tr>
<tr>
<td></td>
<td>Comprehensive Metabolic Panel: Na, K, Cl, CO2, CR, BUN, GLO, Ca, Alk. Phos, ALT, AST, SALT, TP</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>CBC</td>
<td>P 0 3-1</td>
</tr>
<tr>
<td>X</td>
<td>CI</td>
<td>HH 1-24</td>
</tr>
<tr>
<td>X</td>
<td>FERTN</td>
<td>RR 0 4-1</td>
</tr>
<tr>
<td>X</td>
<td>FOLIC</td>
<td>RG 0 9-2</td>
</tr>
<tr>
<td>X</td>
<td>HCY</td>
<td>RH 1-2-3</td>
</tr>
<tr>
<td>X</td>
<td>Mg</td>
<td>GG 2 3-1</td>
</tr>
<tr>
<td>X</td>
<td>PHOS</td>
<td>GG 0 3-1</td>
</tr>
<tr>
<td>X</td>
<td>PTH</td>
<td>P 0 4</td>
</tr>
<tr>
<td>X</td>
<td>VIT &amp; A</td>
<td>RF 3-6-2</td>
</tr>
<tr>
<td>X</td>
<td>VIT &amp; B12</td>
<td>RF 1 6-6</td>
</tr>
<tr>
<td>X</td>
<td>Vitamins: B complex</td>
<td>GS 3</td>
</tr>
<tr>
<td>X</td>
<td>Vitamin A2</td>
<td>PF 3-6-2</td>
</tr>
<tr>
<td>X</td>
<td>Vitamin B12</td>
<td>RG 3 8-1</td>
</tr>
<tr>
<td>X</td>
<td>Vitamin D3 (25 &amp; 100)</td>
<td>RG 3 6-1</td>
</tr>
<tr>
<td>X</td>
<td>ZNC</td>
<td>DB 1 8-4</td>
</tr>
</tbody>
</table>

ADDITIONAL LAB TESTS

If history of diabetes or borderline diabetes before surgery, check tests below.

<table>
<thead>
<tr>
<th>Code</th>
<th>CHEMISTRY</th>
<th>Call Vol</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLY</td>
<td>Glycated Hemoglobin (A1c)*</td>
<td>P 0 5-2</td>
</tr>
<tr>
<td>UR  1</td>
<td>Albumin, Random, Quant.</td>
<td></td>
</tr>
</tbody>
</table>

UMMC, Fairview SLEEP CENTER
705 23rd Ave, E, St. Paul, MN 55105
Ph: 612-273-3300 Fax: 612-273-4790

Reason for order (Diagnosis and/or ICD-9): BMI = _____ [please fill in]
- OSA preliminary 327.23
- OSA known diagnosis 327.22
- Other __________

Please obtain lab results from your primary care provider.
Fax results to 612-924-1173 to the attention of Dr. Andrade, Dr. Buchwald, Dr. Kramuddin, Dr. Kellogg, Dr. Lasie, Kristin Kopacz PA or Donna Schneider CNP.

Section of Gastrointestinal Surgery, Department of Surgery
420 Delaware Street SE, MMC 206, Minneapolis, MN 55405

Requesting Provider Signature Date Time

WEIGHT LOSS SURGERY PRE-OPEARATIVE CHECKOUT ORDERS AND LAB REQUEST FORM

www.icsi.org
Institute for Clinical Systems Improvement
Appendix K – Sample Post-Bariatric-Surgery Patient Diet

Step 1: Clear Liquid Diet: 2 days

- Water or Sugar free clear liquid drinks
- Sugar free Jell-O
- Vegetable, chicken, or beef broth (regular or low-sodium)
- Diluted Juice (50:50) (Rec. Apple, white grape, or white cranberry juices)

Step 2: Full Liquid Diet: 2 Weeks

- Skim, 1%, no sugar added soy, or lactose free milk (no more than 2 cups per day)
- Healthy Choice, Healthy Request Campbell’s or other low fat strained cream soups
- Thinned light yogurt, sugar free puddings, and unsweetened applesauce
- Other protein rich, low-sugar liquid drinks (at least 15 grams of protein per 6-8 ounces)

Step 3: Pureed Diet: 1 week

- Smooth, light yogurt (no lumps or food particles present)
- Hot cereal made with milk, protein powder or non-fat dry milk powder
- Canned tuna, chicken, or salmon, blended
- Blenderized tender meats and cottage cheese
- Thinned instant mashed potatoes (made with dry milk powder or protein powder)
- Blenderized fruits and vegetables (avoid skins, peels, and membranes)

Step 4: Soft Solids: 6-8 weeks

- Tender, moist meats
- Canned/cooked vegetables (fresh vegetables as tolerated- skins, peels, membranes not tolerated well in the beginning)
- Baked Fish (non-breadcrided and without bones)
- Low fat or fat free refried beans
- Tuna, chicken, crab, or egg salad (made with fat free or light mayonnaise), blended
- Banana, seedless melons, or canned fruit in its own juice
- Advance textures as tolerated (try 1 new food every other day)

Step 5: Regular Bariatric Diet

Avoid foods with skins, peels, membranes, and seeds for the 1st 3 months after surgery

- Skinless, boneless moist chicken and turkey breasts
- Pork loin, pork tenderloin
- Lean ground meats
- Lean and extra lean cuts of beef and turkey (sirloin, round, flank, 93%-96% hamburger)
- Cottage cheese or part skim ricotta cheese
- Cooked or canned vegetables
- Fresh, frozen, or canned fruit in own juice
- Cooked cereals, potatoes, whole grain crackers, etc
Original Work Group Members

<table>
<thead>
<tr>
<th>Member</th>
<th>Organization</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teri Barker Connor, RN</td>
<td>Park Nicollet Health Services</td>
<td>Health Education</td>
</tr>
<tr>
<td>Lynne Hemann, PA</td>
<td>Olmsted Medical Center</td>
<td>Health Education</td>
</tr>
<tr>
<td>Sayeed Ikramuddin, MD</td>
<td>Surgery Consultant</td>
<td></td>
</tr>
<tr>
<td>Kathy Johnson, PharmD</td>
<td>U of MN Physicians</td>
<td></td>
</tr>
<tr>
<td>Patrick O'Connor, MD</td>
<td>St. Mary's/Duluth Clinic</td>
<td></td>
</tr>
<tr>
<td>Nancy Greer, PhD</td>
<td>Kathryn Nelson, MD</td>
<td></td>
</tr>
<tr>
<td>Pam Pietruszewski</td>
<td>Julie Roberts, MS, RD</td>
<td></td>
</tr>
<tr>
<td>Beth Green, MBA, RRT</td>
<td>Pharmacists</td>
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<tr>
<td>HealthPartners</td>
<td>Paula Roe</td>
<td>Employer Representative</td>
</tr>
<tr>
<td>George Biltz, MD</td>
<td>Pharmacy</td>
<td>Wells Fargo</td>
</tr>
<tr>
<td>HealthPartners</td>
<td>Nancy Sherwood, PhD</td>
<td>Psychology</td>
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<tr>
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<td>ICSI</td>
<td>HealthPartners Research</td>
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<tr>
<td>David Hanekom, MD</td>
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<td>Michael Hanekom, MD</td>
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<td>ICSI</td>
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</tr>
</tbody>
</table>

Document History

- **Statewide Health Improvement Program selected ICSI Obesity guideline for implementation.**
ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Document Development and Revision Process

The development process is based on a number of long-proven approaches. ICSI staff first conducts a literature search to identify pertinent clinical trials, meta-analysis, systematic reviews, regulatory statements and other professional guidelines. The literature is reviewed and graded based on the ICSI Evidence Grading System.

ICSI facilitators identify gaps between current and optimal practices. The work group uses this information to develop or revise the clinical flow and algorithm, drafting of annotations and identification of the literature citations. ICSI staff reviews existing regulatory and standard measures and drafts outcome and process measures for work group consideration. The work group gives consideration to the importance of changing systems and physician behavior so that outcomes such as health status, patient and provider satisfaction, and cost/utilization are maximized.

Medical groups, who are members of ICSI, review each guideline as part of the revision process. The medical groups provide feedback on new literature, identify areas needing clarification, offer recommended changes, outline successful implementation strategies and list barriers to implementation. A summary of the feedback from all medical groups is provided to the guideline work group for use in the revision of the guideline.

Implementation Recommendations and Measures

Each guideline includes implementation strategies related to key clinical recommendations. In addition, ICSI offers guideline-derived measures. Assisted by measurement consultants on the guideline development work group, ICSI's measures flow from each guideline's clinical recommendations and implementation strategies. Most regulatory and publicly reported measures are included but, more importantly, measures are recommended to assist medical groups with implementation; thus, both process and outcomes measures are offered.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Prevention and Management of Obesity (Mature Adolescents and Adults) and thank them for their suggestions to improve the recommendations that physicians initiate the discussion with patients on weight loss and weight maintenance strategies.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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