



## **Introduction to Magellan's Adopted Clinical Practice Guidelines for the Treatment of Patients with Obesity**

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## Purpose of this Document

This document is an introduction to Magellan Health Services' (Magellan) adopted clinical practice guideline (CPG) for the treatment of patients with obesity. As with all CPGs, this adopted guideline and this Introduction are intended to augment, not replace, sound clinical judgment. As a matter of good practice, clinically sound exceptions to this practice guideline should be noted in the member's treatment record, documenting the clinical reasoning used in making the exception. Magellan periodically requests clinical files from providers in order to monitor compliance with adopted guidelines. Clear documentation of the rationale for exceptions to the guideline's recommendations should be present in the member's treatment record whenever there is evidence of deviation from the guideline.

Additionally, this guideline does not supersede Food and Drug Administration (FDA) determinations or other actions regarding withdrawal or approval of specific medications or devices, and their uses. It is the responsibility of the treating clinician to remain current on medication/device alerts and warnings that are issued by the FDA and other regulatory and professional bodies, and to incorporate such information in his or her treatment decisions.

## Introduction

The guideline Magellan has adopted to augment providers' clinical decision-making with members with obesity is the ***Position of the American Dietetic Association: Weight Management (2009)***.<sup>1</sup> The position paper published by the American Dietetic Association (ADA) also is endorsed by the American College of Sports Medicine. The following ADA position statement provides the foundation for their recommendations:

Successful weight management to improve overall health for adults requires a lifelong commitment to healthful lifestyle and behaviors emphasizing sustainable and enjoyable eating practices and daily physical activity.<sup>1</sup>

The ADA position presents a framework for the assessment of obesity, principals on the regulation of food intake and goals/recommendations for weight management. It also incorporates current evidence-based information on the following:<sup>1</sup>

- physical activity
- dieting
- behavioral interventions
- pharmacotherapy
- surgery
- developments in weight maintenance.

For additional detailed information on the perioperative management of patients undergoing bariatric surgery, Magellan encourages you to refer to the ***Medical Guidelines for the Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (2008)*** developed by the American Association of Clinical

Endocrinologists, The Obesity Society, and American Society for Metabolic and Bariatric Surgery (AACE/TOS/ASMBS).<sup>2</sup> Since publication of the AACE/TOS/ASMBS guidelines, there have been two noteworthy revisions/updates to their content: (1) a published Erratum in the journal, *Surgery for Obesity and Related Diseases* 6 (2010) 112, to recommendation 68 (R66) stating that “there are no data supporting the need for either low-molecular-weight heparin (LMWH) or unfractionated heparin or sequential compression 3 days before bariatric surgery” and (2) the Updated Position Statement on Sleeve Gastrotomy from the Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery published in *Surgery for Obesity and Related Diseases* 1 (2010) 1-5, where they have summarized more recent findings from clinical trials and no longer consider it an investigational surgery, but now recommend this bariatric procedure for an appropriate high-risk subgroup of patients.<sup>8,9</sup>

In February 2011, the FDA granted approval to Allergan Inc., manufacturers of the Lap-Band Adjustable Gastric Banding<sup>®</sup> (LBAGB) System, to market this laparoscopic surgical procedure to patients who are significantly less obese than specified by the initial set of clinical parameters. The original eligibility criteria required that a patient have a Body Mass Index (BMI) of 40 or a BMI of 35 or higher with at least one severe obesity-related medical condition. Based on the results of a five-year study submitted to the FDA, eligibility criteria for the LBAGB procedure were changed to a BMI of 30 or higher in patients who have at least one obesity-related condition. Findings from this study (n=149) of patients, who had been obese for an average of 17 years, showed that 84 percent of participants lost at least 30 percent of their excess weight and more than 65 percent were no longer considered obese after one year. Also, study findings showed that patients kept the weight off during the second year of the study. According to the manufacturer, a total of 45.6 million Americans currently meet criteria for this surgery because an estimated 26.4 million became eligible with the new criteria.<sup>10, 11, 12, 13, 14</sup>

Clinicians who perform pre-operative mental health evaluations may wish to consult specific articles cited in the AACE/TOS/ASMBS guidelines that provide recommendations regarding the structure and content of these assessments as follows: (1) Behavioral Assessment of Candidates for Bariatric Surgery: A Patient-Oriented Approach by Thomas A. Wadden and David B. Sarwer in *Obesity*, Volume 14, Supplement March 2006<sup>3</sup> and (2) The Boston Interview for Gastric Bypass: Determining the Psychological Suitability of Surgical Candidates by Stephanie Sogg, PhD and DeAnna L. Mori, PhD in *Obesity Surgery*. 2004; 14: 370-380.<sup>4</sup> Since publication of the AACE/TOS/ASMBS guidelines, The Boston Interview for Gastric Bypass has been revised and renamed as The Boston Interview for Bariatric Surgery (BIBS). Further information on the new instrument is available in the article: Revising the Boston Interview: Incorporating new knowledge and experience. *Surgery for Obesity and Related Diseases* 2008; 4:455-63 also by Stephanie Sogg, PhD and DeAnna L. Mori, PhD.<sup>5</sup>

For information on the management of obesity in the pediatric population, Magellan encourages you to refer to: ***Prevention and Treatment of Pediatric Obesity: An Endocrine Society Clinical Practice Guideline Based on Expert Opinion (2008)***. In addition, Magellan directs you to the most recently published recommendations for healthy eating and requirements for a nutritionally adequate diet published by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services: ***Dietary Guidelines for Americans – 2010***.<sup>15,16</sup>

## Additional Recommendations Based on Recent Literature Review

The Position of the ADA is based on a literature review through 2008. Magellan conducted a further review of the clinical literature on assessment and treatment through June 2011. Key relevant recommendations from this more recent literature review are summarized here. Magellan encourages providers to be familiar with this information, as well as the information in the position statement.

### Weight-Loss Diets with Different Macronutrient Compositions

A large study (n=811) published in February 2009 by Sacks et. al., compared the efficacy of reduced-calorie diets featuring different macronutrient profiles.<sup>6,7</sup> Patients were randomly assigned to one of four diets:

- (1) low-fat, average-protein – 20 percent fat, 15 percent protein and 65 percent carbohydrates
- (2) low-fat, high-protein – 20 percent fat, 25 percent protein, and 55 percent carbohydrates
- (3) high-fat, average-protein – 40 percent fat, 15 percent protein and 45 percent carbohydrates
- (4) high-fat, high-protein – 40 percent fat, 25 percent protein and 35 percent carbohydrates.

Study participants were between 30 and 70 years of age and had a body mass index of 25 to 40 kg/m<sup>2</sup>. Individuals with diabetes, unstable cardiovascular disease, or who were judged to have poor motivation on screening interviews were excluded from participation. Researchers maintained blinding of participants by the use of similar foods for each diet and reduced each participant's caloric consumption by approximately 750 calories per day. Participants attended three group sessions for diet counseling per month during the first six months of the trial and then every two weeks from six months to two years. Individual counseling sessions were held every eight weeks. The goal for physical activity was 90 minutes per week for all participants.<sup>6,7</sup>

The main outcome of the study was the change in body weight at two years, waist circumference, satisfaction with diet and laboratory markers of cardiovascular risk. Study results showed that weight loss at two years was similar in *all* four diet groups. Mean weight loss among participants in the 25 percent and 15 percent protein groups was 3.6 and 3.0 kg, respectively. The mean weight loss among subjects in both the low-fat and high-fat groups was 3.3 kg. The level of carbohydrate in the diet did not significantly affect weight loss. Additionally, waist circumference decreased by approximately 4 cm in all study groups. Most weight loss occurred in the first six months of the trial. After 12 months, all groups, on average, slowly regained weight. At two years, 14 percent to 15 percent of participants in each diet group had lost at least 10 percent of their baseline body weight. Laboratory findings showed that low-fat diets were associated with greater reductions in LDL cholesterol levels, whereas the lowest-carbohydrate diet promoted higher HDL cholesterol levels. All diets reduced fasting serum insulin levels, and blood pressure decreased modestly with all diet interventions. Also important to note is that craving, fullness, hunger and diet-satisfaction were similar at six months and two years among the diets, and that attendance at group sessions strongly predicted weight loss at two years.<sup>6,7</sup>

Sacks and the study team concluded that diets that are successful in causing weight loss can emphasize a range of fat, protein and carbohydrate compositions that have beneficial effects on risk factors for cardiovascular disease and diabetes. These diets also can be tailored to individual patients on the basis of their personal and cultural preferences, and may impact the chances of long-term success.<sup>5,6</sup>

## Behavioral Interventions

The adopted guideline discusses the value of cognitive behavioral therapy (CBT) combined with a healthful diet and physical activity in achieving weight loss goals by providing individuals with a set of skills in handling barriers to achieving successful outcomes. The guideline also states that overcoming these barriers may be “a difficult endeavor in a fast-paced environment that encourages overconsumption of energy-dense, palatable, low-cost food and promotes energy saving devices. A healthy lifestyle requires significant planning, proficiency in making appropriate choices, estimating portion sizes, diligence in monitoring energy intake and activity, all of which take time to develop and maintain. As such, strategies for simplifying and making this process more practical by providing structure and reducing time spent in meal planning and decision making may be useful for some people (ADA, pp. 338-339)”.<sup>1</sup>

Acknowledging previous clinical studies and the documented success of Internet-delivered weight loss programs, the research team of Burke et al. (2011) conducted a randomized clinical trial comparing the newer technology of personal digital assistants (PDA), with or without tailored email feedback (PDA+ FB, PDA groups) for self-monitoring against the use of more traditional paper records/diaries (PR). This study (n=210) of healthy adults with a mean BMI 34.01 kg/m<sup>2</sup> demonstrated that participants in each of the three groups achieved a significant weight loss. A higher proportion of those using the PDA+FB (63 percent) achieved  $\geq 5$  percent weight loss compared to the PDA group (49 percent) and the PR group (46 percent). Additionally, median percent self-monitoring adherence over six months was higher in the PDA groups (PDA+ FB 90 percent, PDA, 80 percent) than in the PR group (55 percent). Investigators also reported that waist circumference decreased more in the PDA groups. While these initial findings were positive, researchers noted that the male representation in the study population was only 15.2 percent despite recruitment efforts and acknowledged that longer-term outcomes remain to be determined.<sup>17</sup>

## Weight Loss Pharmacotherapy

At the present time, phentermine and diethylpropion (noradrenergic agents), benzphetamine and phendimetrazine (sympathomimetic drugs) and orlistat (a gastrointestinal and pancreatic lipase inhibitor) are FDA-approved drugs and available in the U.S. for the treatment of obesity. Since publication of the guideline, the FDA has made a number of decisions affecting weight-loss drugs on the market and in the pipeline for approval:

- Sibutramine (Meridia) – A serotonin and adrenergic reuptake inhibitor voluntarily recalled by the manufacturer and no longer marketed in the U.S. due to increased risk of heart attack and stroke.
- Lorcaserin (Lorqess) – FDA voted against approval for this anti-obesity drug of the 5-HT<sub>2C</sub> agonist class requiring further study of drug safety due to concerns about drug-induced valvular heart disease and tumors in the brain and breast .
- Phentermine/Topiramate (Qnexa) – FDA held approval pending further evidence of safety for this combination low-dose noradrenergic and anti-epileptic agent due to concerns about adverse effects associated with its use – i.e., cognitive disorders, metabolic acidosis, increased heart rate and birth defects suggesting possible teratogenicity.

- Naltrexone/Bupropion (Contrave) – FDA voted against approval for this combination sustained-release opioid receptor antagonist and antidepressant of the aminoketone class. The agency noted that it would not make a final determination until the manufacturer conducted a new clinical trial specifically evaluating the drug’s cardiovascular risks.<sup>18, 19</sup>

### Obtaining Copies of the American Dietetic Association (ADA) Position Paper

Copies of the adopted *Position of the American Dietetic Association: Weight Management. (2009)* may be obtained through the American Dietetic Association at: <http://www.eatright.org/About/Content.aspx?id=8382> and by obtaining this article as published in the *Journal of the American Dietetic Association*, 2009; 109:330-346 (doi: 10.1016/j.jada.2008.11.041).

### Obtaining Copies of Referenced Guidelines and Resources

Copies of the referenced guideline, *Medical Guidelines for the Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient. (2008)* may be acquired through the American Association of Clinical Endocrinologists, The Obesity Society and American Society for Metabolic and Bariatric Surgery at: <http://www.aace.com/pub/guidelines> by obtaining this article as published in *Endocrine Practice* 2008 Jul-Aug; 14 Suppl 1:1-83.

Copies of the referenced guideline, *Prevention and Treatment of Pediatric Obesity: An Endocrine Society Clinical Practice Guideline Based on Expert Opinion (2008)* may be acquired through The Endocrine Society at: <http://www.endo-society.org/guidelines/Current-Clinical-Practice-Guidelines.cfm> by obtaining this article as published in the *Journal of Clinical Endocrinology & Metabolism*, December 2008, 93 (12).

Copies of the referenced *Dietary Guidelines for Americans 2010* may be acquired through U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services at: <http://www.dietaryguidelines.gov>.

More detailed information on the structure and content of mental health evaluations may be found in the following articles:

- Behavioral Assessment of Candidates for Bariatric Surgery: A Patient-Oriented Approach by Thomas A. Wadden and David B. Sarwer in *Obesity*, Volume 14, Supplement March 2006.
- The Boston Interview for Gastric Bypass: Determining the Psychological Suitability of Surgical Candidates by Stephanie Sogg, PhD and DeAnna L. Mori, PhD in *Obesity Surgery*. 2004; 14: 370-380.
- Revising the Boston Interview: Incorporating new knowledge and experience. *Surgery for Obesity and Related Diseases* 2008; 4:455-63 also by Stephanie Sogg, PhD and DeAnna L. Mori, PhD.

## Provider Feedback

Magellan welcomes feedback on our clinical practice guidelines. We take all suggestions and recommendations into consideration in our ongoing review of the guidelines. Submit your comments to:

Clinical Operations Coordinator  
Re: CPG  
Magellan Health Services  
6950 Columbia Gateway Dr.  
Columbia, Maryland 21046  
CPG@MagellanHealth.com

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