



**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 provides an introduction to Magellan Healthcare's adopted clinical practice guideline (CPG) for the treatment of patients with obesity. Magellan has adopted the American Dietetic Association's (ADA) ***Position of the American Dietetic Association: Weight Management*** (American Dietetic Association, 2009). This position paper, incorporating developments in pharmacotherapy and areas of psychiatric management of patients with obesity, has expired and the updated paper is in current development. The responsible organization's name has changed to ***Academy of Nutrition and Dietetics*** (Academy of Nutrition and Dietetics, 2015).

As with all of Magellan's Clinical Practice Guidelines (CPGs), this adopted guideline and Magellan's Introduction 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 the U.S. 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 issued by the FDA and other regulatory and professional bodies, and to incorporate such information in his or her treatment decisions.

Executive Summary

(A discussion of changes/new information under each topic in this updated CPG based on a literature review through August, 2015)

Introduction

Obesity is a public health issue associated with multiple comorbidities, e.g., cardiovascular disease and cancer, and with a higher risk of all-cause mortality (Ladabaum et al., 2014). Authors noted that more than two-thirds of adults in the United States are obese or overweight (overweight defined as a body mass index [BMI] of 25.0 to 29.9 and obesity as a BMI of ≥ 30). Obesity and its associated comorbid chronic conditions are linked to psychological concerns, e.g., poor self-esteem, sadness, loneliness, negative self-image (Prost et al., 2015).

For information on a total diet approach to healthy eating, please see *Position of the Academy of Nutrition and Dietetics: Total Diet Approach to Healthy Eating* (Freeland-Graves, et al., 2013).

For information on the management of obesity in the pediatric population, Magellan refers you to *Position of the Academy of Nutrition and Dietetics: Interventions for the Prevention and Treatment of Pediatric Overweight and Obesity* (Hoelscher et al, 2013).

For information on the management of obesity in adults, please see the *2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults* (American College of Cardiology/American Heart Association, and The Obesity Society, 2013) and *Managing Overweight and Obesity in Adults: Systematic Evidence Review from the Obesity Expert Panel, 2013* (National Institutes of Health, 2013).

American Medical Association (AMA) Declares Obesity a Disease

As a pressing public health issue in the United States, obesity is associated with diminished quality of life and decreased life expectancy. Additionally, it increases the risk of cardiovascular disease, diabetes and cancer. In the U.S., more than a third of adults aged 20 years or older were obese in 2011-2012 (Ogden et al., 2014).

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) defined obesity “as a chronic disease characterized by pathophysiological processes that result in increased adipose tissue mass and which can result in increased morbidity and mortality” (Garvey et al., 2014, p. 979). The AACE/ACE *Position Statement on the 2014 Advanced Framework for a new Diagnosis of Obesity as a Chronic Disease* noted that a more medically meaningful and actionable diagnosis of obesity is based not only on body mass index, but also includes the impact of the weight gain on health. Authors noted how obesity “arises from the interaction of susceptibility genes, environment, and behavior with overlapping or additional subsets of gene-environment interactions determining disease severity, health impacts, and complication development” (Garvey et al., 2014, p. 980). In another position paper, American Association of Clinical Endocrinologists’ *Position Statement on Obesity and Obesity Medicine*, authors noted behavioral determinants of obesity, e.g., wellness behavior, diet preferences and physical activity, which are under the control of the individual, while other factors, e.g., availability of fresh food, customs and sociocultural attitudes are environmental factors outside of individual control. Genetic factors also confer risk for obesity (Mechanick et al., 2012).

A recent article discussed the discovery of a single-gene mutation that ceases production of the carboxypeptidase-E (CPE) enzyme causing severe obesity as well as type 2 diabetes (Alsters et al., 2015). Researchers noted the lack of knowledge about the frequency of the CPE gene defect, pointing out that obese people are not usually tested. The authors stated, “as sequencing becomes cheaper and more practical for clinical applications, we are finding more and more genetic causes of obesity like this.” Further, they stated, “more generally, the enhanced understanding of disease mechanisms may highlight new targets for treatment or inform management strategies” (Medscape, 2015, p.2).

Another recent study using single-nucleotide gene editing of human adipocytes found that carriers of the FTO risk allele are more likely to store fat instead of dissipating it as heat (Medscape, 2015). Data from this study by Claussnitzer et al. indicated that the FTO gene acts like a control switch inside the FTO region (Claussnitzer et al., 2015). Researchers indicated that “by manipulating this new pathway, we could switch between energy storage and energy dissipation programs at both the cellular and organism level, providing new hope for a cure against obesity” (Medscape, 2015, p. 2).

Obesity Treatments

A recent clinical practice guideline for the drug treatment of obesity, *Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline*, recommends that “diet, exercise, and behavioral modification be included in all obesity management approaches for body mass index (BMI) ≥ 25 kg/m² and that other tools such as pharmacotherapy (BMI ≥ 27 kg/m² with comorbidity or BMI over 30 kg/m²) and bariatric surgery (BMI ≥ 35 kg/m² with comorbidity or BMI over 40 kg/m²) be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when this is possible” (Apovian et al., 2015).

Individuals with psychiatric illnesses experience higher risk of obesity than the general population, due in part to the role of psychotropic medications in this population (Ratliff et al., 2012). Authors proposed that weight-producing medication be avoided if possible, and that the monitoring of weight change after beginning the medication is necessary. Authors further indicated that lifestyle or behavioral modification interventions must be the cornerstone for many approaches to obesity treatment. These include methods for gradual lifestyle changes, e.g., modification of diet and physical exercise, changing attitudes by using cognitive techniques, such as cognitive restructuring, and increasing social support by implementing strategies. Other treatments for obesity include weight loss pharmacotherapy, surgery and the use of medical devices; however, before prescribing medicine or recommending surgery, physicians advise healthy eating and increased physical activity. A healthy lifestyle must be maintained for the rest of a patient’s life, even after medical or surgical treatments (Ratliff et al., 2012).

Perioperative Management of Patients Undergoing Bariatric Surgery and Other Bariatric Procedures

The FDA has approved five devices on the market to treat obesity: Lap-Band Gastric Banding System (LAGB) approved in 2001; Realize Gastric Band (2007); Maestro Rechargeable System (2015); ReShape Integrated Dual Balloon System (2015); and ORBERA Intra-gastric Balloon System approved in 2015 (FDA, 2015).

The Realize Gastric Band, a surgically implanted device consisting of a silicone band, tubing and an injection port, helps obese adults with a BMI of at least 40 lose weight. The FDA also approved it for patients with a BMI of at least 35 who had one or more obesity-related medical conditions and had failed nonsurgical weight-loss alternatives. The band limits the amount of food eaten at one time and increases the time it takes for digestion of food (FDA, 2015).

The Maestro Rechargeable System is a first-of-kind device to treat obesity in adults with a body mass index (BMI) of 35 to 45 with one or more obesity-related conditions, e.g., type 2 diabetes. A rechargeable pulse generator (neuroregulator disc), implanted internally, delivers electrical signals to nerve electrodes placed on the trunks of the vagus nerve in the abdomen. Small electrical pulses block transmission of nervous signals in the vagus nerve, suppressing neural communication between the brain and the stomach and promoting weight loss (FDA, 2015).

The ReShape Integrated Dual Balloon System includes two attached balloons filled with saline that occupies space in the stomach to facilitate weight loss in obese adult patients. This temporary system takes up space in the patient’s stomach to help in weight loss. After a period of six months, it is deflated and removed (FDA, 2015).

The ORBERA Intra-gastric Balloon System uses a gastric balloon deposited in the stomach through the mouth and filled with saline, expanding into a spherical shape. This temporary system takes up space in the patient's stomach to help in weight loss. After a period of six months, it is deflated and removed (Medscape, 2015).

Current research focuses on the development of alternative methods of obesity treatment that are less invasive and less costly than surgical procedures. Endoscopic therapies currently being explored include space-occupying devices (intra-gastric balloons), gastric restrictive methods (suturing or stapling) and malabsorptive endoscopic procedures (duodenal-jejunal bypass liners) (Behary and Kumbhari, 2015).

A recent prospective cohort study assessed the frequency of common psychiatric syndromes in bariatric surgery candidates (n=159) using a computerized version of the Patient Health Questionnaire (PHQ) (Alizai et al., 2015). Median age and median BMI of the patients were 42 years and 49, respectively. Authors found that almost 85 percent of the participants screened positive for a mental health disorder and more than 50 percent of participants had three or more mental health disorders. They suggested that obesity results from an intertwined interaction between biological, psychological and social factors. Pain was the most common syndrome found in the study population, followed by anxiety disorders and depressive syndromes. Twenty percent of participants exhibited a binge eating disorder. Authors suggested that the computerized PHQ is a useful instrument for pre-surgical assessment of bariatric patients (Alizai et al., 2015).

Eating Pathology after Bariatric Surgery

A recent review of literature examined several case studies related to the post-operative development of eating disorders in bariatric surgery patients (Marino et al., 2014). Authors noted that it is difficult to distinguish between normal eating and eating pathology after bariatric surgery, which often necessitates changes in eating. Examination of motivation for any changes in eating after the surgery is important. The behavior may result from concerns about weight and shape. Authors discussed some studies suggesting that binge eating behavior may manifest itself after bariatric surgery as "grazing" (continual eating of small amounts of food with feelings of loss of control). Other studies suggested that postoperative patients may develop vomiting, but in a sample where 60 percent of patients reported vomiting after surgery, only 12 percent admitted that it was to influence shape and weight. Authors noted that the development of eating disorders after bariatric surgery seems to be a rare but serious postoperative problem, although eating problems are more common. They emphasize the need for controlled studies investigating the factors contributing to eating pathology after bariatric surgery. Further, authors stress the importance of informing practitioners who work with this population about the potential adverse outcomes of bariatric surgery (Marino et al., 2014).

Dietary Considerations

The U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion provide the administrative leadership for development of the *Dietary Guidelines for Americans – 2015*. The U.S. Department of Agriculture's Center for Nutrition Policy and Promotion provides support to HHS in publishing the updated guidelines. The updated guidelines, currently in the developmental process, encourage Americans to eat a healthful diet that focuses on foods and beverages that help in the achievement of a healthy weight as well as prevent disease (HHS, 2015). The Dietary Guidelines will contain the most up-

to-date, science-based nutrition recommendations, with the goal of preventing disease and promoting healthy and active lifestyles.

(See <http://health.gov/dietaryguidelines/2015/default.asp> for updated information including HHS press releases, fact sheets and other news materials).

The U.S. Department of Health and Human Services produced an *Evidence Report, Managing Overweight and Obesity in Adults: Systematic Evidence Review from the Obesity Expert Panel, 2013*, which includes summary data on studies evaluating dietary interventions (HHS, 2013). The Obesity Expert Panel concluded that several dietary approaches used to create energy deficits are successful in promoting weight loss. The techniques for reducing dietary energy intake included the following:

- An energy intake target less than that required for energy balance, usually 1,200 to 1,500 kcal/day for women and 1,500 to 1,800 kcal/day for men (adjusted for individual's body weight and physical activity level)
- Energy deficit of 500 kcal/day or 750 kcal/day or 30 percent energy deficit prescribed
- Lower calorie intake achieved by restriction or elimination of particular food groups or provision of prescribed foods.

Diets based on a variety of dietary approaches can produce weight loss in obese adults. The Evidence Report provided summary data examining a variety of dietary approaches, e.g., higher protein diet, low-calorie diet with prescribed energy restriction, low-fat, vegan-style diet, low-fat diet, Mediterranean-style diet with prescribed energy restriction. The Obesity Expert Panel found that all prescribed diets that achieved an energy deficit were associated with weight loss with no superiority of one approach over another (HHS, 2013).

According to the Evidence Report, average weight loss is maximal at six months with smaller losses maintained for up to two years while treatment and follow-up tapers. The Obesity Expert Panel suggested future studies to identify strategies to prevent or minimize weight regain after successful dieting. The Obesity Expert Panel emphasized that dietary interventions are a critical part of losing weight and maintaining weight loss. They stressed the need for studies that test the impact of tailoring the choice of dietary interventions to the individual's ability to follow-through and adhere to the intervention over the long term. The Obesity Expert Panel discussed how understanding the physiologic response to weight reduction could help in defining better dietary methods of caloric restriction during weight reduction and maintenance (HHS, 2013).

Behavioral Interventions

In a recent study, authors examined primary (weight loss) and secondary (quality of life) outcomes of behavioral health interventions for adult obesity from recent meta-analyses, systematic reviews and randomized controlled trials (Prost et al., 2015). Behavioral health interventions examined in the studies included motivational interviewing, standard behavioral treatment, acceptance-based treatment, financial incentives, and dietary and lifestyle interventions. Outcomes targeted weight loss and reduced body mass index as well as the promotion of physical activity, self-efficacy and physical activity/energy expenditure. Results showed that behavioral health interventions were associated with positive, though modest, outcomes. In this review, authors sought to identify and evaluate the role of social workers, psychologists and other mental health professionals, but most of the studies were silent about

the professional background and skill sets of the behavioral health interventionists. Prost et al. referred to a lack of coherent psychosocial theories underlining the significance of psychosocial interventions for obesity, suggesting that adding a theory-driven dimension to future investigations of adult obesity may enhance interventions and interdisciplinary research in healthcare settings and communities. Due to the increasing impact of obesity in the lives of Americans, authors emphasized the need for integration of behavioral health intervention techniques into the healthcare professional curriculum to reinforce an integrated healthcare system meeting the needs of adults facing obesity (Prost et al., 2015).

In a study reviewing the evidence on the efficacy of lifestyle interventions for obesity in patients with severe mental illness, Ratliff et al. discussed behavioral changes necessary for weight reduction (Ratliff et al., 2012). Authors discussed behavioral interventions as the cornerstone for many approaches to obesity treatment, indicating that “the key elements of behavioral approaches are: giving participants a set of structured methods for gradual lifestyle change in order to modify diet and physical activity, utilizing cognitive techniques to change attitude, and implementing strategies that increase social support” (Ratliff et al., p. 132). They suggested that one of the most important techniques taught is self-monitoring. Authors reviewed published studies of weight control in psychiatric populations, e.g., patients with schizophrenia or schizoaffective disorder with conventional antipsychotic weight gain. The results of these studies showed that “individual or group lifestyle interventions are more effective in reducing or attenuating antipsychotic-induced weight gain than ‘usual care,’” suggesting that “a combination of individual and group instruction may provide enhanced results” (Ratliff et al., p. 138). Authors emphasized monitoring weight change after starting patients on psychotropic medications and incorporating behavioral strategies for weight control into routine office visits. Further, they suggested that psychiatrists should have a scale (weight) in their offices to weigh patients often, calculate BMI, and discuss weight issues with patients, stressing the importance of patients learning self-monitoring techniques (Ratliff et al., 2012).

A recent study investigated treatment beliefs and preferences for psychological weight loss therapies in overweight individuals (n=80) trying to manage their weight (Moffitt et al., 2015). Authors indicated that little research has investigated treatment beliefs and preferences for psychological therapies, specifically for weight management. They discussed previous findings that consideration of treatment preferences (satisfying three psychological needs: competence, autonomy and relatedness) results in decreased attrition from therapy and improved outcomes, attributed to increased motivation. In this study, overweight adults (n=80) who were trying to manage their weight, read therapy descriptions of cognitive behavioral therapy (CBT), behavioral therapy (BT), cognitive therapy (CT), and acceptance and commitment therapy (ACT). They then ranked the treatments in order of preference, explaining the reasons for their preferences. CBT and BT delivered face-to-face or technologically were the preferred options. The primary reason provided for those who preferred CBT was comprehensiveness, whereas the primary reason for those who preferred BT was practicality. Authors noted that an all-inclusive treatment approach teaching practical behavioral strategies was preferred over a treatment approach targeting internal processes. Authors suggested more research to “ascertain the stability of treatment beliefs and the efficacy of modifying the treatment context to meet individual needs” (Moffitt et al, p. 584).

Weight Loss Pharmacotherapy

In a recent *Position Statement on Anti-Obesity Medications* by the American Society of Bariatric Physicians, whose name is changing to Obesity Medicine Association (American Society of Bariatric Physicians, 2015), authors discussed obesity as a chronic disease with a high risk of relapse when treatment is discontinued, advising that treatment should be appropriate for chronic use. They stated that pharmacotherapy for patients with obesity should be part of a comprehensive obesity management program, which includes a thorough medical evaluation and lifestyle change support. Authors suggested that anti-obesity medications added to a properly supervised intensive behavioral program improves the odds of achieving a 5-10 percent weight loss. This weight loss reduces the health risks of obesity according to the National Institutes of Health (NIH, 2015).

The American Society of Bariatric Physicians considers that defining overweight and obesity according to BMI alone is too narrow and suggests expanding the definition to include the presence of commonly used measures of excess body fat. Further, they believe “there should be no absolute contra-indications for the use of pharmacotherapy for obesity based on BMI, body-fat percentage, or waist circumference” and that “because overweight and obesity are chronic medical conditions, there should be no time limitation on the use of any existing pharmacotherapy for obesity” (ASBP, 2015). The FDA recommends monitoring of patients who receive long-term pharmacotherapy during the first twelve weeks of therapy for both efficacy and side effects. Continued monitoring is required in order to ensure optimum treatment of the patient.

The *JAMA Patient Page* specifies that unless a patient loses at least 5 percent of his or her starting weight after taking a full dose of medication for three months, the medication should stop, with the doctor deciding upon other types of treatment (Jin, 2015). It further states that obesity medications not be used by women who plan to become pregnant or who are pregnant. It notes that like other medications taken for chronic conditions, gradual weight gain may occur after discontinuation of the drug.

The FDA has approved these medications for the chronic management of obesity (Bragg et al., 2015):

- *Orlistat (Xenical)* – The FDA approved this medication in 1999 for the treatment of chronic obesity in conjunction with a reduced caloric diet. Orlistat (marketed as Alli) was approved for over the counter use for weight loss in overweight adults in 2007. Orlistat is associated with significant improvements in cardiovascular risk factors and in slowing the progression to diabetes in patients with one risk factor. Adverse effects of orlistat include significant GI events, which decrease with chronic use and reduction of fat intake.
- *Lorcaserin hydrochloride (Belviq)* – The FDA approved Belviq, a serotonin 2C receptor agonist, as an addition to a reduced calorie diet and exercise, to treat adults with a BMI of 30 or more, or adults with a BMI of 27 or greater and who have at least one weight-related condition, on June 27, 2012. Belviq should not be used during pregnancy and may cause side effects, e.g., serotonin syndrome, when taken with medicines that activate serotonin receptors. On June 18, 2013, Belviq became available to certain patients by prescription.
- *Phentermine/Topiramate (Qsymia)* – On July 17, 2012 the FDA approved Qsymia (formerly known as Qnexa) for chronic weight management and as an addition to a reduced-calorie

diet and exercise. Qsymia should not be used during pregnancy as it may cause harm to a fetus and it should not be used to treat patients with glaucoma or hyperthyroidism as it can increase heart rate. The FDA has required the manufacturer to have a risk evaluation and mitigation strategy (REMS) to explain the need to avoid becoming pregnant while taking Qsymia. This medication is a controlled substance; phentermine, one of its ingredients, has the potential for abuse.

- *Naltrexone/Bupropion (Contrave)* – The FDA approved Contrave on September 10, 2014 as a treatment for chronic weight management in addition to a reduced-calorie diet and physical activity (FDA, 2014). Approval of this drug is for use in adults with a BMI of 30 or more or adults with a BMI of 27 or greater who also have at least one weight-related condition (e.g., high blood pressure). Contrave has a boxed warning alerting patients and healthcare professionals to the increased risk of suicidal thoughts and behaviors. Because it can cause seizures, it should not be used in patients with seizure disorders. Additionally, patients with uncontrolled high blood pressure should not use Contrave as it can also raise blood pressure and heart rate. Other products that contain bupropion should not be taken along with Contrave. Patients who have eating disorders and those using opioids should not take Contrave.
- *Liraglutide (Saxenda)* – Saxenda was approved by the FDA on December 23, 2014 as a treatment option for chronic weight management in addition to a reduced-calorie diet and physical activity (FDA, 2014). It was approved for adults with a BMI of 30 or more or adults with a BMI of 27 or more and one weight-related condition such as hypertension. A glucagon-like peptide-1 (GLP-1) receptor agonist, it should not be used in combination with other drugs belonging to this class, including Victoza, a treatment for type 2 diabetes. The safety and efficacy of Saxenda for the treatment of diabetes is not established. This drug has a boxed warning cautioning it is unknown whether Saxenda causes thyroid C-cell tumors, and it should not be used in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia. The FDA approved Saxenda with the requirement that a REMS inform doctors about the serious risks associated with this medication.

Exercise/Improved Fitness and Weight Loss

In a recent analysis of data from the National Health and Nutrition Examination Survey (NHANES) from a more than 20 year period from 1988 to 2010 (based on a series of cross-sectional surveys), researchers found a sharp drop in leisure-time physical activity as well as an increase in average BMI (Ladabaum et al., 2014). The proportion of adult women and adult men who reported no leisure-time physical activity increased from 19.1 percent to 51.7 percent and from 11.4 percent to 43.5 percent in women and men, respectively. In both women and men, average BMI increased by 0.37 percent, and average waist circumference increased by 0.37 percent and 0.27 percent in women and men, respectively. While the obesity rate among Americans continued to rise, there was no evidence that average daily caloric intake increased significantly or substantial changes occurred in the intake of daily fat, carbohydrate and protein during the study period. Among women and men reporting no leisure-time physical activity, the associated changes in adjusted BMIs were 8.3 percent and 1.7 percent higher, respectively, than in individuals with leisure-time activity. Researchers concluded that “physical activity can protect against weight gain and attenuates the increased mortality risk associated with obesity” although “an ideal level of physical activity does not by itself ensure a normal weight” (Ladabaum et al., p 725).

Investigative Treatments for Obesity

Technological advancements, e.g., cognitive conditioning for weight reduction, are being developed to assist in controlling and modifying behavior (Kumar et al., 2015). Examples may include the following: a spoon that vibrates if it detects a person is eating too quickly; a fork that measures how long a person eats and vibrates to facilitate cognitive conditioning. These technologies provide feedback on eating habits and allow online viewing of the results and trends. These technologies, currently lacking FDA approval for use in weight loss, represent a “promising, not to mention important, area for future research” (Kumar et al., p. 183).

In an overview of obesity and deep brain stimulation (DBS), authors cited studies identifying three potential neural targets that may be associated with excessive food consumption: the lateral hypothalamus, the ventromedial hypothalamus and the nucleus accumbens (Kumar et al., 2015). Authors noted three neural targets considered for placement of electrodes for DBS in obesity treatment. Three human trials are currently investigating the safety and efficacy of DBS as a treatment option for treatment-refractory obesity.

Introduction

Obesity is a public health issue associated with multiple comorbidities, e.g., cardiovascular disease and cancer, and with a higher risk of all-cause mortality (Ladabaum et al., 2014). Authors noted that more than two-thirds of adults in the United States are considered obese or overweight (overweight defined as a BMI of 25.0 to 29.9 and obesity as a BMI of ≥ 30). Obesity and its associated comorbid chronic conditions are linked to psychological concerns, e.g., poor self-esteem, sadness, loneliness, negative self-image (Prost et al., 2015).

The adopted guideline published by the ADA 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” (American Dietetic Association, p. 330).

The ADA position presents a framework for the assessment of obesity, including principles on the regulation of food intake and goals/recommendations for weight management. It also incorporates current evidence-based information supporting a multidisciplinary approach to interventions related to the following:

- Physical activity
- Regulation of food intake
- Behavioral interventions
- Pharmacotherapy
- Surgery
- Developments in weight maintenance.

The Position of the ADA on weight management is based on a literature review through 2008. Magellan conducted a further review of the clinical literature on assessment and treatment of

obesity through August 2015. Summarized in the paragraphs below are key relevant recommendations from this more recent literature review. Magellan encourages providers to be familiar with this information, as well as the information in the position statement.

Magellan refers you to its eating disorders guideline, ***Introduction to Magellan's Adopted Clinical Practice Guideline for the Assessment and Treatment of Patients with Eating Disorders***, for additional information and references related to obesity/eating disorders prevention programs promoting healthy weight management. Also, please refer to Magellan's ***Clinical Practice Guideline for Patients with Attention Deficit/Hyperactivity Disorder*** (ADHD) which refers to studies demonstrating significant association between the number of self-reported childhood ADHD symptoms and the risk for obesity in adulthood.

We extensively address weight gain for patients on psychotropic drugs in Magellan's CPGs. The ***Introduction to the Magellan's Clinical Practice Guideline for the Treatment of Bipolar Disorder*** addresses the use of second-generation antipsychotics (SGAs) for the treatment of mania and mixed bipolar episodes and notes the effect of these SGAs on weight gain. The guideline advises clinicians to assess and monitor weight and waists of patients on these medications, e.g., olanzapine, risperidone, ziprasidone, aripiprazole, quetiapine, asenapine. The ***Introduction to Magellan's Adopted Clinical Practice Guidelines for the Treatment of Schizophrenia*** discusses weight gain along with metabolic disturbances related to the use of SGAs and reports studies suggesting that clozapine and olanzapine are among the most weight gain-producing antipsychotics. The ***Introduction to Magellan's Adopted Clinical Practice Guideline for the Assessment and Treatment of Patients with Major Depressive Disorder*** cautions that when compared with other strategies for antidepressant non-responders, augmentation with a second-generation antipsychotic carries the risk of weight gain.

The monograph entitled ***Appropriate Use of Psychotropic Drugs in Children and Adolescents: A Clinical Monograph*** discusses the broadened use of psychotropic medication in children and adolescents today. The guideline reports studies showing children and adolescents have greater benefits, i.e., reduction in mania, with SGAs than traditional mood stabilizers, i.e., lithium and antiepileptics. However, SGAs were associated with greater weight gain than mood stabilizers and SGAs caused greater weight gain in youth than in adults. The guideline addresses the use of SGAs, risperidone and aripiprazole to treat repetitive behaviors manifested in autistic spectrum disorders (ASDs), and notes that because marked weight gain and risk of extrapyramidal symptoms are significant in these agents, they are most often reserved for cases of severe impairment or risk of injury.

For information on a total diet approach to healthy eating, see ***Position of the Academy of Nutrition and Dietetics: Total Diet Approach to Healthy Eating*** (Freeland-Graves et al., 2013).

For information on the management of obesity in the pediatric population, Magellan refers you to ***Prevention and Treatment of Pediatric Obesity: An Endocrine Society Clinical Practice Guideline Based on Expert Opinion (2008)*** and to ***Position of the Academy of Nutrition and Dietetics: Interventions for the Prevention and Treatment of Pediatric Overweight and Obesity*** (Hoelscher et al., 2013).

For information on the management of obesity in adults, see **2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults** (American College of Cardiology/American Heart Association, and The Obesity Society, 2013) and **Managing Overweight and Obesity in Adults: Systematic evidence Review from the Obesity Expert Panel, 2013** (National Institutes of Health, 2013).

American Medical Association (AMA) Declares Obesity a Disease

On June 18, 2013, the American Medical Association officially designated obesity a chronic medical disease state that requires medical treatment and prevention (Frellik, 2013). Obesity is associated with conditions such as heart disease, stroke, sleep apnea, type 2 diabetes mellitus and certain types of cancer (Holes-Lewis et al., 2013). It both significantly decreases the quality of life and reduces life expectancy. According to the National Health and Nutrition Examination Survey (NHNES), 35.7 percent of adults in the United States were obese in 2009-2010. In 2011-2012, 34.9 percent of adults aged 20 years or older were obese (Ogden et al., 2014). Women aged 60 and older were more likely to be obese than younger women, whereas among men there was no significant difference in obesity prevalence by age (National Center for Health Statistics, 2012). The Centers for Disease Control and Prevention (CDC) defines obesity in adults as body mass index (BMI) greater than or equal to 30.

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) defined obesity “as a chronic disease characterized by pathophysiological processes that result in increased adipose tissue mass and which can result in increased morbidity and mortality” (Garvey et al., 2014, p. 979). The AACE/ACE *Position Statement on the 2014 Advanced Framework for a new Diagnosis of Obesity as a Chronic Disease* noted that a more medically meaningful and actionable diagnosis of obesity is based not only on body mass index, but also includes the impact of the weight gain on health. Authors noted how obesity “arises from the interaction of susceptibility genes, environment, and behavior with overlapping or additional subsets of gene-environment interactions determining disease severity, health impacts, and complication development” (Garvey et al., 2014, p. 980). In another position paper, American Association of Clinical Endocrinologists’ *Position Statement on Obesity and Obesity Medicine*, authors noted behavioral determinants of obesity, e.g., wellness behavior, diet preferences and physical activity, which are under the control of the individual, while other factors, e.g., availability of fresh food, customs and sociocultural attitudes are environmental factors outside of individual control. Genetic factors also confer risk for obesity (Mechanick et al., 2012).

A recent article discussed the discovery of a single-gene mutation that ceases production of the carboxypeptidase-E (CPE) enzyme causing severe obesity as well as type 2 diabetes (Alsters et al., 2015). Researchers noted the lack of knowledge about the frequency of the CPE gene defect, pointing out that obese people are not usually tested. The authors stated, “as sequencing becomes cheaper and more practical for clinical applications, we are finding more and more genetic causes of obesity like this.” Further, they stated, “more generally, the enhanced understanding of disease mechanisms may highlight new targets for treatment or inform management strategies” (Medscape, 2015, p.2).

Another recent study using single-nucleotide gene editing of human adipocytes found that carriers of the FTO risk allele are more likely to store fat instead of dissipating it as heat

(Medscape, 2015). Data from this study by Claussnitzer et al. indicated that the FTO gene acts like a control switch inside the FTO region (Claussnitzer et al., 2015). Researchers indicated that “by manipulating this new pathway, we could switch between energy storage and energy dissipation programs at both the cellular and organism level, providing new hope for a cure against obesity” (Medscape, 2015, p. 2).

The NHNES shows that almost 17 percent of children and adolescents were obese in 2009-2010, with the prevalence of obesity higher among adolescents than among preschool-aged children and higher among boys than among girls. The U.S. Task Force on Childhood Obesity reviewed programs and policies related to child nutrition and physical activity, developing a national action plan to solve the challenge of childhood obesity. The CDC defines obesity in children as a BMI greater than or equal to the age- and sex-specific 95th percentiles of the 2000 CDC BMI-for-age growth charts (Ogden, 2012).

Obesity Treatments

A recent clinical practice guideline for the drug treatment of obesity, ***Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline***, recommends that “diet, exercise, and behavioral modification be included in all obesity management approaches for body mass index (BMI) ≥ 25 kg/m² and that other tools such as pharmacotherapy (BMI ≥ 27 kg/m² with comorbidity or BMI over 30 kg/m²) and bariatric surgery (BMI ≥ 35 kg/m² with comorbidity or BMI over 40 kg/m²) be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when this is possible” (Apovian et al., 2015).

Individuals with psychiatric illnesses are more at risk of obesity than the general population, due in part to the role of psychotropic medications in this population (Ratliff et al., 2012). They proposed that weight-producing medication be avoided if possible, and that the monitoring of weight change after beginning the medication is necessary. Authors further indicated that lifestyle or behavioral modification interventions are the cornerstone for many approaches to obesity treatment. These include methods for gradual lifestyle changes, e.g., modification of diet and physical exercise, changing attitudes by using cognitive techniques, such as cognitive restructuring, and increasing social support by implementing strategies. Other treatments for obesity include weight loss pharmacotherapy, surgery and the use of medical devices; however, before prescribing medicine or recommending surgery, physicians advise healthy eating and increased physical activity. A healthy lifestyle must be maintained for the rest of a patient’s life, even after medical or surgical treatments (Ratliff et al., 2012).

Perioperative Management of Patients Undergoing Bariatric Surgery and Other Bariatric Procedures

For detailed information on the perioperative management of patients undergoing bariatric surgery, Magellan encourages you to refer to the ***Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient - 2013 Update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery*** (Mechanick et al., 2013). This update of the earlier published *Medical Guidelines for the Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient*

(Mechanick et al., 2008) reevaluates recommendations reflecting recent additions to the evidence base regarding bariatric surgery. After publication of the 2008 guidelines, noteworthy revisions/updates included a published Erratum stating that “there are no data supporting the need for either low-molecular-weight heparin (LMWH) or unfractionated heparin or sequential compression three days before bariatric surgery” (Mechanick et al., 2010). The 2013 updated AACE/TOS/ASMBS guidelines include 74 recommendations that replace 164 recommendations in the 2008 guidelines. Some of the recommendations include:

- Reclassification of sleeve gastrectomy from an investigational surgical option to an effective surgical option - benefits comparable to other procedures, e.g., laparoscopic adjustable gastric band (LAGB), Roux-en-Y gastric bypass (RYGB), in terms of weight loss, rate of complications and resolution of obesity-related
- Expansion of surgical eligibility to patients with mild to moderate obesity (BMI of 30-34.9 kg/m²) with diabetes or metabolic syndrome – insufficient evidence for recommending a bariatric surgical procedure for glycemic control alone
- Psychosocial-behavioral evaluation assessing environmental, familial and behavioral factors before bariatric surgery
- Evaluation of patients’ ability to incorporate changes before and after bariatric surgery, i.e., nutritional and behavioral
- Emergence of the term metabolic surgery to describe surgical procedures to treat type 2 diabetes as well as to reduce cardiometabolic risk factors
- Assessment of copper levels after bariatric surgery, and provision of copper supplements (and other vitamins and minerals) as needed for patients with conditions such as anemia and impaired wound healing
- Avoidance of pregnancy preoperatively and for 12 to 18 months postoperatively
- Longitudinal Assessment of Bariatric Surgery (LABS) data showing that history of thrombophilia (deep vein thrombosis [DVT]) and pulmonary embolism (PE), or obstructive sleep apnea, may predict adverse outcomes from RYBG
- Use of a mandatory team approach to perioperative care with attention to metabolic and nutritional issues
- Enrollment of patients in programs facilitating impulse control and improving mood as perioperative behavioral strategies to improve adherence with lifestyle modification
- Discussion with patients about risks and benefits, choices of surgeon and medical institution, need for follow-up and obtaining informed consent from patient
- Determination that other bariatric procedures including gastric plication, electrical neuromodulation, and endoscopic sleeves remain investigational.

The latest revision (2012) of the American Society for Metabolic and Bariatric Surgery’s ***Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure*** considered randomized controlled trials and matched-cohort, prospective and case-control studies demonstrating durable weight loss, long-term patient satisfaction, improved medical comorbidities and significant improvements after sleeve gastrectomy (ASMBS, 2012). The updated position statements also recognized sleeve gastrectomy as a “first stage procedure in high risk patients as part of a planned staged approach.” (ASMBS, p. e24).

The FDA has approved five devices on the market to treat obesity: Lap-Band Gastric Banding System (LAGB) approved in 2001, Realize Gastric Band (2007), Maestro Rechargeable System

(2015), ReShape Integrated Dual Balloon System (2015) and ORBERA IntraGastric Balloon System approved in 2015 (FDA, 2015).

In February 2011, the FDA granted approval to Allergan Inc., manufacturers of the Lap-Band Adjustable Gastric Banding® (LBAGB) System, to market this laparoscopic surgical procedure to patients who are significantly less obese than specified by the initial set of clinical parameters (FDA Market Approval Letter, 2011). The original eligibility criteria required that a patient have a 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 (FDA, 2011). 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. Study findings also showed that patients kept the weight off during the second year of the study.

The Realize Gastric Band, a surgically implanted device consisting of a silicone band, tubing, and an injection port, helps obese adults with a BMI of at least 40 lose weight. The FDA also approved it for patients with a BMI of at least 35 who had one or more obesity-related medical conditions and had failed nonsurgical weight-loss alternatives. The band limits the amount of food eaten at one time and increases the time it takes for digestion of food (FDA, 2015).

The Maestro Rechargeable System is a first-of-kind device to treat obesity in adults with a body mass index (BMI) of 35 to 45 with one or more obesity-related conditions, e.g., type 2 diabetes. A rechargeable pulse generator (neuroregulator disc), implanted internally, delivers electrical signals to nerve electrodes placed on the trunks of the vagus nerve in the abdomen. Small electrical pulses block transmission of nervous signals in the vagus nerve, suppressing neural communication between the brain and the stomach and promoting weight loss (FDA, 2015).

The ReShape Integrated Dual Balloon System includes two attached balloons filled with saline that occupies space in the stomach to facilitate weight loss in obese adult patients. This temporary system takes up space in the patient's stomach to help in weight loss. After a period of six months, it is deflated and removed (FDA, 2015).

The ORBERA IntraGastric Balloon System uses a gastric balloon deposited in the stomach through the mouth and filled with saline, expanding into a spherical shape. This temporary system takes up space in the patient's stomach to help in weight loss. After a period of six months, it is deflated and removed (Medscape, 2015).

Current research focuses on the development of alternative methods of obesity treatment that are less invasive and less costly than surgical procedures. Endoscopic therapies currently being explored include space-occupying devices (intraGastric balloons), gastric restrictive methods (suturing or stapling) and malabsorptive endoscopic procedures (duodenal-jejunal bypass liners) (Behary and Kumbhari, 2015).

Clinicians who perform pre-operative mental health evaluations may consult specific articles cited in the AACE/TOS/ASMBS guidelines related to the following: (1) *Behavioral Assessment of Candidates for Bariatric Surgery: A Patient-Oriented Approach* (Wadden et al., 2006), (2)

Behavioral and Psychological Care in Weight Loss Surgery: Best Practice Update (Greenberg et al., 2009), 3) *How do Mental Health Professionals Evaluate Candidates for Bariatric Surgery? Survey Results* (Fabricatore et al., 2005) and (4) *The Boston Interview for Gastric Bypass: Determining the Psychological Suitability of Surgical Candidates* (Sogg and Mori, 2004). *The Boston Interview for Gastric Bypass* has been renamed "*The Boston Interview for Bariatric Surgery (BIBS)*" (Sogg and Mori, 2008).

A recent article examined how the Minnesota Multiphasic Personality Inventory-2 Restructured Form (MMPI-2-RF) aids in the identification of a broad range of psychological comorbidity among bariatric surgery candidates and the assessment of psychological factors relevant to pre-surgical psychological assessment (Marek et al., 2013). Candidates for bariatric surgery (n=982) were administered the MMPI-2-RF at their psychological evaluation which included a pre-surgical psychological interview. Findings showed that the domains associated with the MMPI-2-RF scales converged well with the factors assessed from the psychological interview, and the researchers concluded that the test can be used to identify a broad range of psychopathology that may lead to diminished outcomes of bariatric surgery.

A recent prospective cohort study assessed the frequency of common psychiatric syndromes in bariatric surgery candidates (n=159) using a computerized version of the Patient Health Questionnaire (PHQ) (Alizai et al., 2015). Median age and median BMI of the patients was 42 years and 49, respectively. Authors found that almost 85 percent of the participants screened positive for a mental health disorder and more than 50 percent of participants had three or more mental health disorders. They suggested that obesity results from an intertwined interaction between biological, psychological and social factors. Pain was the most common syndrome found in the study population, followed by anxiety disorders and depressive syndromes. Twenty percent of participants exhibited a binge eating disorder. Authors suggested that the computerized PHQ is a useful instrument for pre-surgical assessment of bariatric patients (Alizai et al., 2015).

Eating Pathology after Bariatric Surgery

A recent review of literature examined several case studies related to the post-operative development of eating disorders in bariatric surgery patients (Marino et al., 2014). Authors noted that it is difficult to distinguish between normal eating and eating pathology after bariatric surgery, which often necessitates changes in eating. Examination of motivation for any changes in eating after the surgery is important. The behavior may result from concerns about weight and shape. Authors discussed some studies suggesting that binge eating behavior may manifest itself after bariatric surgery as "grazing" (continual eating of small amounts of food with feelings of loss of control). Other studies suggested that postoperative patients may develop vomiting, but in a sample where 60 percent of patients reported vomiting after surgery, only 12 percent admitted that it was to influence shape and weight. Authors noted that the development of eating disorders after bariatric surgery seems to be a rare but serious postoperative problem and that there is a need for controlled studies investigating the factors contributing to eating pathology after bariatric surgery. Authors stress the importance of informing practitioners who work with this population about the potential adverse outcomes of bariatric surgery (Marino et al., 2014).

Dietary Considerations

The U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion provide the administrative leadership for development of the *Dietary Guidelines for Americans – 2015*. The U.S. Department of Agriculture’s Center for Nutrition Policy and Promotion provides support to HHS in publishing the updated guidelines. The updated dietary guidelines, in the process of development, encourage Americans to eat a healthful diet that focuses on foods and beverages that help in the achievement of a healthy weight as well as prevent disease (HHS, 2015). The dietary guidelines will contain the most up-to-date, science-based nutrition recommendations with the goal of preventing disease and promoting healthy and active lifestyles.

(See <http://www.health.gov/dietaryguidelines/2015.asp> for updated information including HHS press releases, fact sheets and other news materials).

The U.S. Department of Health and Human Services produced an Evidence Report, *Managing Overweight and Obesity in Adults: Systematic Evidence Review from the Obesity Expert Panel, 2013*, which includes summary data on studies evaluating dietary interventions (HHS, 2013). The Obesity Expert Panel concluded that several dietary approaches used to create energy deficits are successful in promoting weight loss. The techniques for reducing dietary energy intake included the following:

- An energy intake target, usually 1,200 to 1,500 kcal/day for women and 1,500 to 1,800 kcal/day for men (adjusted for individual’s body weight and physical activity level)
- Individual energy requirement estimated and energy deficit of 500 kcal/day or 750 kcal/day or 30 percent energy deficit prescribed
- Lower calorie intake achieved by restriction or elimination of particular food groups or provision of prescribed foods.

Diets based on a variety of dietary approaches can produce weight loss in obese adults. The Evidence Report provided summary data examining a variety of dietary approaches, e.g., higher protein diet, low-calorie diet with prescribed energy restriction, low-fat, vegan-style diet, low-fat diet, Mediterranean-style diet with prescribed energy restriction. The Obesity Expert Panel found that all prescribed diets that achieved an energy deficit were associated with weight loss with no superiority of one approach over another (HHS, 2013).

According to the Evidence Report, average weight loss is maximal at six months with smaller losses maintained for up to two years while treatment and follow-up tapers. The Obesity Expert Panel suggested future studies to identify strategies to prevent or minimize weight regain after successful dieting. The Obesity Expert Panel emphasized that dietary interventions are a critical part of losing weight and maintaining weight loss. They stressed the need for studies that test the impact of tailoring choice of dietary interventions to the individual’s ability to follow-through and adhere to the intervention over the long term. The Obesity Expert Panel discussed how understanding the physiologic response to weight reduction could help in defining better dietary methods of caloric restriction during weight reduction and maintenance (HHS, 2013).

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* (Dietary Guidelines for Americans, 2010). The guidelines recommend that Americans consume an appropriate energy intake for a healthy weight as well as consume food and beverages that are dense in nutrients. In a recent study, participants (n=44) were randomized to one of three interventions: (1) low-energy density (ED) condition, (2) low-energy, low-fat condition, or (3) low-ED, low-energy, low-fat condition (Raynor et al., 2012). Results of the study found that the low-ED condition increased fruit intake and enhanced weight loss when compared with the other weight loss prescriptions. Researchers suggested that focusing on only one dietary focus, i.e., lowering energy density, eases the implementation of traditional cognitive behavioral strategies, e.g., self-monitoring, that are useful in changing dietary intake.

A large study (n=811) published in February 2009 by Sacks et al, compared the efficacy of reduced-calorie diets featuring different macronutrient profiles (Sachs et al., 2009). 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/m². 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 (Sachs et al., 2009; Wood et al., 2009).

The main outcome of the study was the change in body weight at two years, waist circumference, and 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 (Sachs et al., 2009; Wood et al., 2009).

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 based on their personal and cultural preferences, and may impact the chances of long-term success (Sachs et al. 2009).

A later study tested the hypothesis that consumption of a low glycemic load (GL) diet results in less adipose tissue during both weight maintenance and weight loss conditions when compared to higher GL diet under both eucaloric and hypocaloric conditions (Goss et al., 2012). Healthy overweight or obese men and women (n=69) were blinded to either the low GL diet or the high GL diet during the 16-week dietary intervention which included an eight-week eucaloric phase and an eight-week hypocaloric phase. Results of this study showed that following the eucaloric phase, participants who consumed the low GL diet had 11 percent less intra-abdominal fat (IAAT) than those who consumed the high GL diet. This result was specific to women on the low GL diet. Following the hypocaloric diet, both women and men who consumed the low GL diet had significantly greater total body fat loss than those who consumed the high GL diet. According to the researchers, this was the first tightly controlled dietary intervention study reporting differences in IAAT and total body fat loss after consuming a low GL diet. Researchers suggested further studies to identify the mechanisms linking low GL diet to loss of total body fat and the gender-specific effects.

As sugary drink portion sizes have increased in the last forty years from 6.5 ounces to the typical 20-ounce plastic bottle today, consumption of sugar-sweetened beverages (SSBs) has also increased. An update to a previous meta-analysis of 12 studies (Mattes et al., 2011) evaluated and summarized the currently available evidence on the effects of SSB reduction on weight and obesity (Kaiser et al., 2013). Researchers acknowledged that as SSB consumption has risen, obesity rates have also increased, but they point out that association does not establish causation. This update including six new studies showed that the randomized evidence currently available for the effects of reducing SSBs on obesity is weak. Researchers stress that although a beneficial effect of SSB reduction on obesity has not been demonstrated, additional, larger, stronger studies may provide convincing evidence that lowering SSB consumption will reduce obesity and obesity-related disease prevalence. They state that they “are certainly not arguing against the common-sense recommendation that for individuals who wish to lose weight and who presently drink large amounts of SSBs, reducing intake of these and other sources of energy seems wise” (Kaiser et al., 2013). This is in conformity with the Obesity Society’s position supporting efforts to reduce consumption of sugar-sweetened beverages due to their contribution to increased calorie intake, potentially contributing to the obesity epidemic. The American Medical Association (AMA) announced a new policy in June 2013 calling for the AMA “to work to remove sugar-sweetened beverages from the Supplemental Nutrition Assistance Program (SNAP) and encourage state health agencies to include nutrition information in routine materials sent to SNAP recipients.” The AMA’s president stated, “Removing sugar-sweetened beverages from the SNAP will help encourage healthier beverage choices” (AMA, 2013).

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” (American Dietetic Association, 2009).

Acknowledging previous clinical studies and the documented success of Internet-delivered weight loss programs, the research team of Burke et al. 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/m² 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 > 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 (Burke et al, 2011).

A narrative review examined randomized controlled trials of the treatment of obesity by primary care practitioners (PCP) who deliver lifestyle counseling to obese patients in their practices (Carvajall et al, 2013). The effects of brief weight loss counseling in primary care practice in four randomized trials including obese/overweight patients (n=1646) with type 2 diabetes, hyperlipidemia, and hypertension suggested that low- to moderate-intensity, brief lifestyle counseling provided by primary care providers did not produce clinically significant weight loss (≥5 percent of initial weight). Three randomized controlled trials assessed the effectiveness of PCP lifestyle counseling plus pharmacotherapy (orlistat or sibutramine which has been removed from the market) in primary care patients (n=891). These trials suggested that the addition of pharmacotherapy to brief lifestyle counseling increases the likelihood that clinically significant weight loss will occur, as compared with brief counseling alone. Future studies are needed to determine whether the recently FDA approved drugs, lorcaserin hydrochloride and phentermine/topiramate, may significantly improve weight loss when added to brief lifestyle counseling, compared with counseling alone. In four randomized controlled trials, obesity treatment incorporating auxiliary health providers as lifestyle coaches were modestly more effective than PCP counseling alone in treating obesity in primary care settings. Researchers suggested that the greater frequency of visits offered by auxiliary health professionals as compared with PCPs may have contributed to the greater weight loss. In another study including obese patients (n=390), those receiving increased number of treatment modalities, e.g., intensive medical intervention, group behavior modification, weight loss medication, monthly group lifestyle modification and meal replacements, lost significantly more weight than patients receiving fewer treatment modalities. Five studies examining the use of remotely delivered counseling with patients in primary care practices suggested that

remotely-delivered, high-intensity behavioral counseling may help patients receive clinically meaningful weight loss. Researchers concluded that low intensity behavioral weight loss counseling by PCPs and auxiliary health providers results in limited success and suggested that the Centers for Medicare and Medicaid Services' decision to support high intensive behavioral weight loss counseling seems appropriate (Carvajal et al., 2013).

A recent study suggested that behavioral interventions leading to lifestyle changes target hospitalized obese patients (Harris et al., 2013). Hospitalized patients (n=204) with a body mass index (BMI) $\geq 30\text{kg/m}^2$ were surveyed at bedside for a cross-sectional study to determine receptivity to inpatient weight loss interventions. Patients provided comments affirming those interventions such as education and counseling, nutritional guidance, and exercise assessments with coaching may be beneficial. Counseling was welcomed by greater than half of the patients surveyed who were influenced by their beliefs that losing weight would result in better health outcomes. Researchers concluded that accurate perceptions of one's weight risk status and belief that weight reduction may lead to better health were the best predictors of patients' willingness to participate in weight management interventions (Harris et al., 2013).

A systematic review and meta-analysis of eleven randomized controlled trials investigated the effectiveness of motivational interviewing for reducing body mass in overweight and/or obese participants (n=1448) (Armstrong et al., 2011). Motivational interviewing delivery modes varied from individual face-to-face to both telephone and group sessions with motivation for change elicited from individuals rather than conveyed by healthcare providers. Placebo conditions varied including usual care, to print materials, etc. Results of this analysis showed that motivational interviewing significantly increased weight loss, with those in the intervention groups losing 1.47 kg more than those in control groups. Researchers pointed out that although this "medium" effect on weight loss seems promising; achievement of long-term, sustainable weight loss is difficult. This analysis also found that motivational interviewing over a period longer than six months increased the amount of weight loss in the intervention group. Researchers suggest further research is warranted due to the small number of studies included in this analysis.

In a recent study, authors examined primary (weight loss) and secondary (quality of life) outcomes of behavioral health interventions for adult obesity from recent meta-analyses, systematic reviews, and randomized controlled trials (Prost et al., 2015). Behavioral health interventions examined in the studies included motivational interviewing, standard behavioral treatment, acceptance-based treatment, financial incentives, and dietary and lifestyle interventions. Outcomes targeted weight loss and reduced body mass index as well as the promotion of physical activity, self-efficacy and physical activity/energy expenditure. Results showed that behavioral health interventions were associated with positive, though modest, outcomes. In this review, authors sought to identify and evaluate the role of social workers, psychologists and other mental health professionals, but most of the studies were silent about the professional background and skill sets of the behavioral health interventionists. Prost et al. referred to a lack of coherent psychosocial theories underlining the significance of psychosocial interventions for obesity, suggesting that adding a theory-driven dimension to future investigations of adult obesity may enhance interventions and interdisciplinary research in healthcare settings and communities. Due to the increasing impact of obesity in the lives of Americans, authors emphasized the need for integration of behavioral health intervention

techniques into the healthcare professional curriculum to reinforce an integrated healthcare system meeting the needs of adults facing obesity (Prost et al., 2015).

In a study reviewing the evidence on the efficacy of lifestyle interventions for obesity in patients with severe mental illness, Ratliff et al discussed behavioral changes necessary for weight reduction (Ratliff et al., 2012). Authors discussed behavioral interventions as the cornerstone for many approaches to obesity treatment, indicating that “the key elements of behavioral approaches are: giving participants a set of structured methods for gradual lifestyle change in order to modify diet and physical activity, utilizing cognitive techniques to change attitude, and implementing strategies that increase social support” (Ratliff et al., p. 132). They suggested that one of the most important techniques taught is self-monitoring. Authors reviewed published studies of weight control in psychiatric populations, e.g., patients with schizophrenia or schizoaffective disorder with conventional antipsychotic weight gain. The results of these studies showed that “individual or group lifestyle interventions are more effective in reducing or attenuating antipsychotic-induced weight gain than ‘usual care,’” suggesting that “a combination of individual and group instruction may provide enhanced results” (Ratliff et al., p. 138). Authors emphasized monitoring weight change after starting patients on psychotropic medications and incorporating behavioral strategies for weight control into routine office visits. Further, they suggested that psychiatrists should have a scale (weight) in their offices to weigh patients often, calculate BMI, and discuss weight issues with patients, stressing the importance of patients learning self-monitoring techniques (Ratliff et al., 2012).

A recent study investigated treatment beliefs and preferences for psychological weight loss therapies in overweight individuals (n=80) trying to manage their weight (Moffitt et al., 2015). Authors indicated that little research has investigated treatment beliefs and preferences for psychological therapies, specifically for weight management. They discussed previous findings that consideration of treatment preferences (satisfying three psychological needs: competence, autonomy and relatedness) results in decreased attrition from therapy and improved outcomes, attributed to increased motivation. In this study, overweight adults (n=80) who were trying to manage their weight read therapy descriptions of cognitive behavioral therapy (CBT), behavioral therapy (BT), cognitive therapy (CT), and acceptance and commitment therapy (ACT). They then ranked the treatments in order of preference, explaining the reasons for their preferences. CBT and BT delivered face-to-face or technologically were the preferred options. The primary reason provided for those who preferred CBT was comprehensiveness, whereas the primary reason for those who preferred BT was practicality. Authors noted that an all-inclusive treatment approach teaching practical behavioral strategies was preferred over a treatment approach targeting internal processes. Authors concluded more research is needed to “ascertain the stability of treatment beliefs and the efficacy of modifying the treatment context to meet individual needs” (Moffitt et al, p. 584).

Weight Loss Pharmacotherapy

In a recent *Position Statement on Anti-Obesity Medications by the American Society of Bariatric Physicians* (ASBP, 2015), authors discussed obesity as a chronic disease with a high risk of relapse when treatment is discontinued, advising that treatment should be appropriate for chronic use. They stated that pharmacotherapy for patients with obesity should be part of a comprehensive obesity management program, which includes a thorough medical evaluation

and lifestyle change support. Authors suggested that anti-obesity medications added to a properly supervised intensive behavioral program improves the odds of achieving a 5-10 percent weight loss. This weight loss reduces the health risks of obesity according to the National Institutes of Health (NIH, 2015).

The American Society of Bariatric Physicians considers that defining overweight and obesity according to BMI alone is too narrow and suggests expanding the definition to include the presence of commonly used measures of excess body fat. Further, they believe “there should be no absolute contra-indications for the use of pharmacotherapy for obesity based on BMI, body-fat percentage, or waist circumference” and that “because overweight and obesity are chronic medical conditions, there should be no time limitation on the use of any existing pharmacotherapy for obesity” (ASBP, 2015). The FDA recommends monitoring of patients who receive long-term pharmacotherapy during the first twelve weeks of therapy for both efficacy and side effects. Continued monitoring is required in order to ensure optimum treatment of the patient.

The *JAMA Patient Page* specifies that unless a patient loses at least 5 percent of his or her starting weight after taking a full dose of medication for three months, the medication stop, with the doctor deciding upon other types of treatment (Jin, 2015). It further states that obesity medications not be used by women who plan to become pregnant or who are pregnant. It notes that like other medications taken for chronic conditions, gradual weight gain may occur after discontinuation of the drug.

According to the adopted guideline, weight loss drugs should be prescribed only as part of a comprehensive treatment plan that includes behavioral therapy, diet and physical exercise. Currently, orcaserin hydrochloride (serotonergic agent), phentermine and topiramate combination (anorectic and monosaccharide), 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. The FDA has approved these medications for the chronic management of obesity (Bragg et al., 2015):

- *Orlistat (Xenical)* – The FDA approved this medication in 1999 for the treatment of chronic obesity in conjunction with a reduced caloric diet. Orlistat (marketed as ALLI) was approved for over the counter use for weight loss in overweight adults in 2007. Orlistat is associated with significant improvements in cardiovascular risk factors and in slowing the progression to diabetes in patients with one risk factor. Adverse effects of orlistat include significant GI events, which decrease with chronic use and reduction of fat intake.
- *Lorcaserin hydrochloride (Belviq)* – The FDA approved Belviq, a serotonin 2C receptor agonist, as an addition to a reduced calorie diet and exercise, to treat adults with a BMI of 30 or more, or adults with a BMI of 27 or greater and who have at least one weight-related condition, on June 27, 2012 (U.S. Food and Drug Administration, 2012). Belviq should not be used during pregnancy and may cause side effects, e.g., serotonin syndrome, when taken with medicines that activate serotonin receptors. On June 18, 2013, Belviq became available to certain patients by prescription (CNN Health, 2013).

- *Phentermine/Topiramate (Qsymia)* – On July 17, 2012 the FDA approved Qsymia (formerly known as Qnexa) for chronic weight management and as an addition to a reduced-calorie diet and exercise (U.S. Food and Drug Administration, 2012). Qsymia should not be used during pregnancy as it may cause harm to a fetus and it should not be used to treat patients with glaucoma or hyperthyroidism as it can increase heart rate. The FDA has required the manufacturer to have a risk evaluation and mitigation strategy (REMS) to explain the need to avoid becoming pregnant while taking Qsymia. This medication is considered a controlled substance; phentermine, one of its ingredients, has the potential for abuse.
- *Naltrexone/Bupropion (Contrave)* – The FDA approved Contrave on September 10, 2014 as a treatment for chronic weight management in addition to a reduced-calorie diet and physical activity. Approval of this drug is for use in adults with a BMI of 30 or more or adults with a BMI of 27 or greater who also have at least one weight-related condition (e.g., high blood pressure). Contrave has a boxed warning alerting patients and healthcare professionals to the increased risk of suicidal thoughts and behaviors. Because it can cause seizures, it should not be used in patients with seizure disorders. Additionally, patients with uncontrolled high blood pressure should not use Contrave as it can also raise blood pressure and heart rate. Other products that contain bupropion should not be taken along with Contrave. Patients who have eating disorders and those using opioids should not take Contrave.
- *Liraglutide (Saxenda)* – Saxenda was approved by the FDA on December 23, 2014 as a treatment option for chronic weight management in addition to a reduced-calorie diet and physical activity. It is approved for adults with a BMI of 30 or more or adults with a BMI of 27 or more and one weight-related condition such as hypertension. A glucagon-like peptide-1 (GLP-1) receptor agonist, it should not be used in combination with other drugs belonging to this class, including Victoza, a treatment for type 2 diabetes. The safety and efficacy of Saxenda for the treatment of diabetes is not established. This drug has a boxed warning cautioning it is unknown whether Saxenda causes thyroid C-cell tumors, and it should not be used in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasias. The FDA approved Saxenda with the requirement that a REMS inform doctors about the serious risks associated with this medication.

Exercise/Improved Fitness and Weight Loss

In a recent analysis of data from the National Health and Nutrition Examination Survey (NHANES) from a more than 20 year period from 1988 to 2010 (based on a series of cross-sectional surveys), researchers found a sharp drop in leisure-time physical activity as well as an increase in average BMI (Ladabaum et al., 2014). The proportion of adult women and adult men who reported no leisure-time physical activity increased from 19.1 percent to 51.7 percent and from 11.4 percent to 43.5 percent in women and men, respectively. In both women and men, average BMI increased by 0.37 percent, and average waist circumference increased by 0.37 percent and 0.27 percent in women and men, respectively. While the obesity rate among Americans continued to rise, there was no evidence that average daily caloric intake increased or substantial changes occurred in the intake of daily fat, carbohydrate, and protein during the study period. Among women and men reporting no leisure-time physical activity, the associated changes in adjusted BMIs were 8.3 percent and 1.7 percent higher, respectively, than in individuals with leisure-time activity. Researchers concluded that “Physical activity can protect against weight gain and attenuates the increased mortality risk associated with

obesity” although “an ideal level of physical activity does not by itself ensure a normal weight” (Ladabaum et al., p 725).

Investigative Treatments

Technological advancements, e.g., cognitive conditioning for weight reduction, are being developed to assist in controlling and modifying behavior (Kumar et al., 2015). Examples may include the following: a spoon that vibrates if it detects a person is eating too quickly; a fork that measures how long a person eats and vibrates to facilitate cognitive conditioning. These technologies provide feedback on eating habits and allow online viewing of the results and trends. Although these technologies lack FDA approval for use in weight loss, they represent a “promising, not to mention important, area for future research” (Kumar et al., p. 183).

In an overview of obesity and deep brain stimulation (DBS), authors cited studies identifying three potential neural targets that may be associated with excessive food consumption: the lateral hypothalamus, the ventromedial hypothalamus, and the nucleus accumbens (Kumar et al., 2015). Authors noted consideration of these three neural targets for placement of electrodes for DBS in obesity treatment. Three human trials are currently investigating the safety and efficacy of DBS as a treatment option for treatment-refractory obesity.

Obesity Myths, Presumptions, and Facts

A sampling of myths, presumptions and facts about obesity were examined in a recent review of both popular media and scientific literature (Casazza et al., 2013). Authors suggested that the promulgation of false and unsupported beliefs about obesity may result in inaccurate clinical and public health recommendations and may divert attention away from evidence-based information. Below are some of the myths, presumptions and facts about obesity discussed by the authors:

Myths (false beliefs about obesity persisting despite refuting evidence):

- Large, long-term weight changes will result from small sustained changes in energy intake or expenditure
- Goals for weight loss must be realistic to prevent patients from becoming frustrated and losing less weight
- When compared with slow gradual weight loss, large rapid weight loss is associated with poorer long-term weight-loss outcomes
- Assessment of the stage of change or diet readiness is important in helping patients requesting weight-loss treatment
- Physical education classes in their current form help reduce/prevent childhood obesity
- Breast feeding protects against obesity
- Sexual activity burns 100-300 kcal for each participant.

Presumptions (scientifically unsupported but persisting beliefs about obesity):

- Eating breakfast regularly protects against obesity (results of observational studies)
- Exercise and eating habits learned in early childhood influence our weight throughout life

- Eating more fruits and veggies results in weight loss or less weight gain whether or not other changes to environment or behavior are made
- Weight cycling is associated with increased mortality
- Snacking is a factor in weight gain and obesity
- Association between risk of obesity and parks, roads and architecture.

Facts (propositions with sufficient evidence to consider empirically proved):

- Moderate environmental changes can promote weight loss
- Reduced energy intake diets effectively reduce weight, but going on a diet does not work well in long term
- Increased level of exercise increases health, regardless of body weight or weight loss
- Long-term weight maintenance is improved by physical activity or exercise
- Maintenance of lower weight is promoted by continuation of conditions promoting weight loss
- Programs involving parents and home setting promotes greater weight loss or maintenance for overweight children
- Greater weight loss is promoted by provision of meals and use of meal-replacement products
- Pharmaceutical agents can help patients achieve and maintain weight loss as long as they continue to be used
- For severely obese persons, bariatric surgery results in long-term weight loss as well as reductions in the rate of incident diabetes and mortality.

Researchers suggested that the above facts about obesity help establish a framework of intervention and preventive techniques, offer tools to be conveyed to the public, and/or are suited to clinical settings.

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.andeal.org/files/files/WeightManagement.pdf> and by obtaining this article as published in the Journal of the American Dietetic Association, 2009: 109 (2):330-346.

Obtaining Copies of Referenced Guidelines and Resources

Copies of the referenced guideline, ***Position of the Academy of Nutrition and Dietetics: Total Diet Approach to Healthy Eating*** may be accessed at <http://www.ncbi.nlm.nih.gov/pubmed/?term=Position+of+the+Academy+of+Nutrition+and+Dietetics%3A+Total+Diet+Approach+to+Healthy+Eating>.

Copies of the referenced guideline, ***Position of the Academy of Nutrition and Dietetics: Interventions for the Prevention and Treatment of Pediatric Overweight and Obesity*** may be accessed at <http://www.ncbi.nlm.nih.gov/pubmed/?term=Position+of+the+Academy+of+Nutrition+and+>

[Dietetics%3A+Interventions+for+the+prevention+and+treatment+of+pediatric+overweight+and+obesity.](#)

Copies of the referenced guideline, 2013 AHA/ACC/TOS **Guideline for the Management of Overweight and Obesity in Adults** may be accessed at <http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee.full.pdf?viewType=Print&viewClass=Print>.

Copies of the referenced guideline, **Managing Overweight and Obesity in Adults: Systematic Evidence Review from the Obesity Expert Panel, 2013** may be accessed at <http://www.ncbi.nlm.nih.gov/pubmed/?term=Managing+Overweight+and+Obesity+in+Adults+%3A+Systematic+Evidence+Review+from+the+Obesity+Expert+Panel%2C+2013>.

Copies of the referenced guideline, **Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline**, may be accessed at http://press.endocrine.org/doi/10.1210/jc.2014-3415?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed.

Copies of the referenced guideline, **Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient - 2013 Update**: Cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery may be acquired through the American Association of Clinical Endocrinologists, The Obesity Society and American Society for Metabolic and Bariatric Surgery at <https://www.ace.com/files/publish-ahead-of-print-final-version.pdf>.

Copies of the referenced **Dietary Guidelines for Americans 2010** may be acquired through the 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 and Psychological Care in Weight Loss Surgery: Best Practice Update*. Obesity 2009; 17:880-884.
- *How Do Mental Health Professionals Evaluate Candidates for Bariatric Surgery? Survey Results*. Obes Surg 2005; 15:567-573.
- *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 Healthcare
6950 Columbia Gateway Dr.
Columbia, Maryland 21046
CPG@MagellanHealth.com

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