Weight Reduction Medications and Programs

Number: 0039

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Note: Many Aetna plan benefit descriptions specifically exclude services and supplies for or related to treatment of obesity or for diet and weight control. Under these plans, claims for weight reduction medications and for physician supervision of weight reduction programs will be denied based on that exclusion. Please check benefit plan descriptions for details.

Aetna considers the following medically necessary treatment of obesity when criteria are met:

1. Weight reduction medications, and
2. Clinician supervision of weight reduction programs.

Weight Reduction Medications:

Note: Many Aetna benefit plans specifically exclude coverage of weight reduction medications under the pharmacy benefit and/or under the health benefits plan. The medical necessity
criteria set forth below do not apply to health plans that specifically exclude services and supplies for or related to treatment of obesity or for diet or weight control. Under these plans, claims for weight loss drugs will be denied based on this exclusion. For members whose medical policies do not exclude weight reduction medications or services and supplies for or related to weight reduction programs, Aetna covers these drugs under the medical benefit, not the pharmacy benefit. Please check benefit plan descriptions for details.

Weight reduction medications are considered medically necessary for members who have failed to lose at least one pound per week after at least 6 months on a weight loss regimen that includes a low calorie diet, increased physical activity, and behavioral therapy, and who meet either of the following selection criteria below:

I. Member has a body mass index (BMI) greater than or equal to 30 kg/m²; or
II. Member has a BMI greater than or equal to 27 kg/m² with any of the following obesity-related risk factors considered serious enough to warrant pharmacotherapy:

   A. Coronary heart disease
   B. Dyslipidemia:

      1. HDL cholesterol less than 35 mg/dL, or
      2. LDL cholesterol greater than or equal to 160 mg/dL, or
      3. Triglycerides greater than or equal to 400 mg/dL

   C. Hypertension (systolic blood pressure [SBP] higher than 140 mm Hg or diastolic blood pressure [DBP] higher than 90 mm Hg on more than one occasion)
   D. Obstructive sleep apnea
   E. Type 2 diabetes mellitus.

Weight reduction medications are considered experimental and investigational when these criteria are not met.
* Body Mass Index (BMI) = weight (kg) / [height (m)]²

Calculate Your Body Mass Index (http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm)

The following medications have been approved by the FDA for weight reduction:

- Benzphetamine [Didrex],
- Diethylpropion [Tenuate],
- Liraglutide [Saxenda],
- Lorcaserin [Belviq],
- Naltrexone and bupropion [Contrave]
- Orlistat [Xenical, Alli],
- Phendimetrazine [Bontril]
- Phentermine [Adipex-P], and
- Phentermine and topiramate [Qsymia].

For reauthorization criteria for weight reduction medications, see Aetna Pharmacy CPB on Antiobesity Agents.

For Aetna’s clinical policy on surgical management of obesity, see CPB 0157 - Obesity Surgery (../100_199/0157.html).

Clinician Supervision of Weight Reduction Programs:

Up to a combined limit of 26 individual or group visits by any recognized provider per 12-month period are considered medically necessary for weight reduction counseling in adults who are obese (as defined by BMI ≥ 30 kg/m²**). The number of medically necessary visits for obese children are left to the discretion of the member's physician.

** For a simple and rapid calculation of BMI, please click below and it will take you to the Obesity Education Initiative:

BMI = weight (kg) / [height (m)]²

Calculate Your Body Mass Index (http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm)
The following services are considered medically necessary for the evaluation of overweight or obese individuals:

- Complete blood count
- Comprehensive history and physical examination
- Dexamethasone suppression test and 24-hour urinary free cortisol measures if symptoms suggest Cushing's syndrome.
- Electrocardiogram (EKG) -- adult
- Glucose tolerance test (GTT)
- Hand x-ray for bone age -- child
- Lipid profile (total cholesterol, HDL-C, LDL-C, triglycerides)
- Metabolic and chemistry profile (serum chemistries, liver tests, uric acid) (SMA 20)
- Thyroid function tests (T3, T4, TSH)
- Urinalysis

**Very Low Calorie Diets (VLCD):**

For obese members who have been prescribed a very low calorie diet (VLCD) (less than 799 Kcal/day) (e.g., Optifast, Medifast), the following services are considered medically necessary for up to 16 weeks after initiation of the VLCD:

1. EKG after 50 lbs of weight loss; and
2. Lipid profile at the beginning and end of the VLCD program; and
3. Serum chemistries and liver function tests (SMA 20) weekly during the rapid weight loss phase of the VLCD, then every 2 weeks thereafter up to 16 weeks.

**Note:** VLCDs extending beyond 16 weeks are subject to medical review to determine if additional services are medically necessary.

**Notes:** Prepackaged food supplements or substitutes and grocery items are generally excluded from coverage under most benefit plans. Diagnostic tests required by, for or as a result of non-covered weight loss programs (e.g., those not requiring physician supervision) are not covered. Please check benefit
Excluded Services:

The following interventions/procedures are considered experimental and investigational for weight reduction:

- Acupuncture for weight loss
- Body plethysmography (diagnostic study) Low-
  level laser therapy
- Dual-energy X-ray (DEXA) body composition (diagnostic study)
- Fat mass and obesity-associated (FTO) genotyping
- FTO genotyping
- Gastric electrical stimulation (see CPB 0678 - Gastric Pacing and Gastric Electrical Stimulation  (../600_699/0678.html))
- Human chorionic gonadotropin (HCG) or vitamin injections for weight loss
- Indirect calorimetry (also known as oxygen uptake analysis; diagnostic study)
- Normobaric hypoxic conditioning

Whole body calorimetry and composition and whole body bioimpedance analysis are considered experimental and investigational for weight reduction and other indications.

Hospital confinement is considered not medically necessary for a weight reduction program.

**Note:** Under most benefit plans, the following services and supplies for weight reduction are specifically excluded from coverage (please check benefit plan descriptions for details)

- Exercise programs or use of exercise equipment
- Rice diet or other special diet supplements (e.g., amino acid supplements, Optifast liquid protein meals, NutriSystem pre-packaged foods, Medifast foods, or phytotherapy), see CPB 0061 - Nutritional Support  (0061.html)
- Weight Watchers, Jenny Craig, Diet Center, Zone diet, or
similar programs.

**Background**

Weight reduction medications should be used as an adjunct to caloric restriction, exercise, and behavioral modification, when these measures alone have not resulted in adequate weight loss. Factors influencing successful weight loss are: weight loss during dieting alone, adherence to diet, eating habits, motivation and personality.

Weight loss due to weight reduction medication use is generally temporary. In addition, the potential for development of physical dependence and addiction is high. Because of this, their use to aid in weight loss is not regarded as therapeutic, but rather involves a risk/benefit ratio, which makes it medically inappropriate in most cases.

Individuals who cannot maintain weight loss through behavioral weight loss therapy and are at risk of medical complications of obesity are an exception to this; for these persons, the risk of physical dependence or other adverse effects may present less of a risk than continued obesity. For such individuals, use of weight reduction medication may need to be chronic.

Tests with weight loss drugs have shown that initial responders tend to continue to respond, while initial non-responders are less likely to respond even with an increase in dosage. If a person does not lose 2 kg (4.4 lb) in the first four weeks after initiating therapy, the likelihood of long-term response is very low. If weight is lost in the initial 6 months of therapy or is maintained after the initial weight loss phase, this should be considered a success and the drug may be continued.

Orlistat is a reversible inhibitor of gastric and pancreatic lipases. Binding of orlistat to these enzymes forms inactive intermediates in the gut. This non-systemic action does not allow fat to be broken down and absorbed. Rather, an oil phase that includes triglycerides and cholesterol is excreted in feces.
This effect may lead to weight loss.

Xenical (orlistat) is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. It is also indicated to reduce the risk for weight regain after prior weight loss.

Orlistat is available as Xenical in 120mg capsules and as Alli in 60mg capsules. Alli is available over-the-counter. Recommended dosage of Xenical is one 120-mg capsule three times a day with each main meal containing fat (during or up to 1 hour after the meal).

Supplementation with fat-soluble vitamins (A, D, E, K) and beta carotene is recommended in some patients as these may not be adequately absorbed when given orlistat therapy.

Comorbidities associated with obesity appear to be improved through weight loss in orlistat treated patients. However, studies are limited in time span and comparison with other pharmacologic agents is needed to determine place in therapy.

Dosage reductions of hypoglycemic agents may be necessary when glycemic control is improved with weight loss.

Risk of cholelithiasis increases with substantial weight loss.

Pharmacologic treatment of exogenous obesity should be adjunctive to caloric restriction, increased physical activity, and behavioral modification.

Other than orlistat (Xenical), which is approved for use in adolescents aged 12 years or older, weight reduction medications have not been proven to be safe and effective for treatment of obesity in children and adolescents. Orlistat (Xenical) is contraindicated in persons with chronic malabsorption syndromes and cholestasis. Qsymia is contraindicated in pregnancy, glaucoma, hyperthyroidism, hypersensitivity to sympathomimetic amines,
and within 14 days of taking monoamine oxidase inhibitors. Belviq is contraindicated in pregnancy. Other drugs listed in this policy are contraindicated in the following conditions: hypertension, atherosclerosis, coronary artery disease, and stroke.

Ioannides-Demos et al (2006) stated that there is limited safety and effectiveness data for amfepramone (diethylpropion) and phentermine and their approvals for the management of obesity are limited to short-term use. The authors stated that, although the benefit-risk profiles of sibutramine and orlistat appear positive, sibutramine continues to be monitored because of long-term safety concerns. The safety and effectiveness of currently approved drug therapies have not been evaluated in children and elderly patient populations.

On October 8, 2010, Abbott Laboratories announced that that it was withdrawing its diet drug Meridia (sibutramine) from the United States, Australian and Canadian markets as a consequence of heightened concerns that the medication can trigger heart attack or stroke, especially in patients with underlying cardiovascular disease.

Dual-energy X-ray (DEXA) was developed for the diagnosis of osteoporosis and was employed originally to clinically significant locations of the forearm, femoral neck, and lumbar spine. With body composition measurements by means of DEXA, a controlled x-ray beam scans the entire body to ascertain bone mineral content, body fat and lean tissue mass. The comprehensive view of body composition provided by DEXA is thought to be the method of choice for evaluating body composition by its advocates because of its speed, ease of application as well as relatively low-dose of ionizing radiation. Its purported uses entail determining appropriate nutritional support during disease progression and monitoring response to therapeutic interventions.

Available evidence does not support the use of whole body DEXA for managing obesity. There is a lack of reliable evidence
demonstrating that whole body DEXA measurement improves the management of persons with obesity over simpler methods of measuring body composition (including BMI and anthropomorphic measures), such that clinical outcomes are significantly improved. Published data have focused on the level of agreement between whole body DEXA and various other methods of measuring body composition, and on the use of DEXA as an endpoint in research studies. Well-designed studies are needed to assess the clinical value of whole body DEXA scanning (Ball and Altena, 2004; Williams et al, 2006; Ritz et al, 2007; Pineau et al, 2007; Pineau et al, 2009).

There is currently no established role for whole body bioimpedance for weight reduction or other indications. Current ACC/AHA guidelines on obesity mention no role for bioimpedance analysis (Jensen, et al., 2013). Current NICE obesity guidance (NICE, 2014) states: “Do not use bioimpedance as a substitute for BMI as a measure of general adiposity.”

Balázs (2010) stated that the rapidly increasing prevalence of over-weight and diabetes mellitus is a serious global threat to healthcare. Nowadays, medicinal plants and natural treatments are becoming more and more popular. Diabetes has historically been treated with plants or plant-derived formulations in different cultures, mainly in China, Asia and India. Different mechanisms for the anti-diabetic effect of plants have been proposed: increased release of insulin, reduction of intestinal glucose absorption, as well as enhancement of glycogen synthesis. The scientific evidences for most of these plants are still incomplete. The large market for plant remedies has resulted in an array of unauthorized products or marketed as dietary supplements and, at the same time, no reliable pharmaceutical-grade products are registered for this purpose.

Borel et al (2012) conducted a prospective intervention study in 104 viscerally obese men classified according to their glucose tolerance status. They were followed for one year while participating in a healthy eating-physician activity/exercise
lifestyle modification program while their insulin sensitivity was tracked. The goals of the study were to evaluate glucose tolerance as well as to evaluate the respective contribution so fo changes in body fat distribution versus changes in cardiorespiratory fitness (CRF) to the improvements in indices of plasma glucose/insulin homeostasis. The results showed insulin sensitivity improved in association with decreases in both visceral (VAT) and subcutaneous adiposity (SAT) as well as improvement in CRF, regardless of baseline glucose tolerance. The results of this study also shoed that reduction in VAT was associated with an improvement in homeostasis model assessment of insulin resistance, whereas reduction in SAT was rather associated with improvement of the insulin sensitivity index of Matsuda. The authors concluded that a one year lifestyle intervention improved plasma glucose/insulin homeostasis in viscerally obese men, including those with normal glucose tolerance status at baseline.

Garvey et al (2012) conducted a placebo-controlled, double-blind, 52-week extension study to evaluate the long-term efficacy and safety of controlled-release phentermine/topiramate (PHEN/TPM CR) in overweight and obese subjects with cardiometabolic disease. Subjects were randomly assigned to placebo, 7.5 mg phentermine/46 mg controlled-release topiramate, or 15 mg phentermine/92 mg controlled-release topiramate. Of the 676 extension study participants, 84% completed the study. At week 108 PHEN/TPM-CR was associated with significant, sustained weight loss. Significantly more PHEN/TPM CR-treated subjects at each dose achieved ≥ 5%, ≥ 10%, ≥ 15%, and ≥ 20% weight loss compared with placebo (P < 0.001). The authors therefore concluded that PHEN/TPM CR, in conjunction with lifestyle modification, may provide a well-tolerated and effective option for the sustained treatment of obesity complicated by cardiometabolic disease.

Mulholland et al (2012) stated that evidence from the literature supports the safe use of very-low-energy diets (VLED) for up to 3 months in supervised conditions for patients who fail to meet
a target weight loss using a standard low-fat, reduced-energy approach. There is, however, a need for longer-term outcomes on obesity and associated morbidities following a VLED. These researchers investigated longer-term outcomes from studies using VLED, with a minimum duration of 12 months, published between January 2000 and December 2010. Studies conducted in both children and adults, with a mean/median BMI of greater than or equal to 28 kg/m2 were included. PubMed, Medline, Web of Science and Science Direct were searched. Reference lists of studies and reviews were manually searched. Weight loss or prevention of weight gain and morbidities were the main outcomes assessed. A total of 32 out of 894 articles met the inclusion criteria. The duration of the studies ranged from 12 months to 5 years. Periods of VLED ranged from 25 d to 9 months. Several studies incorporated aspects of behavior therapy, exercise, low-fat diets, low-carbohydrate diets or medication. Current evidence demonstrated significant weight loss and improvements in blood pressure, waist circumference and lipid profile in the longer term following a VLED. Interpretation of the results, however, was restricted and conclusions with which to guide best practice were limited due to heterogeneity between the studies. The authors concluded that the present review clearly identified the need for more evidence and standardized studies to assess the longer-term benefits from weight loss achieved using VLED.

Indirect calorimetry is designed to measure an individual’s oxygen consumption. Using this measurement, the device calculates a person’s resting energy expenditure (REE), also known as resting metabolic rate (RMR). Clinicians supposedly can screen for abnormally low metabolic rates, teach energy balance, and identify the precise caloric intake needed for weight loss. Clinical applications of indirect calorimetry include obesity treatment, as well as treating obesity related diseases such as diabetes, dysmetabolic syndrome X, hypothyroidism, hyperthyroidism, hypertension, cardiovascular disease, as well as sleep apnea. Under strict laboratory protocol, indirect calorimetry can also be used to measure basal metabolic rate.
Published studies of indirect calorimetry in weight management have focused on its accuracy (Frankenfeld, et al., 2010; Henes, et al., 2015; Wilms, et al., 2010). There is a lack of reliable evidence that indirect calorimetry measurements result in improved clinical outcomes in obesity management.

McDoniel, et al., (2008) evaluated the efficacy of a weight management program using indirect calorimetry to set energy goals. Fifty-four overweight, active duty adult employees of the US Air Force (age 18-46 years, BMI 25.2–35.6 kg/m2) participated in this quasi-experimental control design study. All participants were enrolled in a four-session US Air Force ‘Sensible Weigh’ group weight control program. Treatment participants received a personalized nutrition energy goal message developed using measured resting metabolic rate (RMR) from a hand-held indirect calorimeter (MedGem®). Usual care participants received a nutritional message using a standard care equation (25 kcal/day × body weight) to set energy intake goals. Investigators reported that treatment participants lost significantly more weight than usual care participants (p ≤ 0.05). Ten of the 54 subjects dropped from the study before completion. Difference in weight loss between the treatment and usual care group were –4.3 kg ± 3.3 vs. –1.8 kg ± 3.2, respectively. The investigators reported that were no significant differences in reported food intake or energy expenditure between groups. The investigators posited that a possible reason why experimental individuals experienced greater weight loss from measured resting metabolic rate may be that the individualized nutrition message influenced psychobehavioral constructs (i.e. motivation, self-efficacy, etc.) for weight loss change. The investigators noted that study limitations include small sample size, short duration, and small treatment effect. An additional issue is the generalizability of the findings, given that, at the time of the study, the Air Force had regulations that all personnel maintain a desired body weight and body fat percentage, or these individuals could be discharged from service. The investigators stated that future research is needed to determine the long-term efficacy of using indirect calorimetry as part of a comprehensive weight control
An UpToDate review on “Palliative care: Assessment and management of anorexia and cachexia” (Bruera and Dev, 2013) states that “Handheld indirect calorimetry, which is more accurate than equations at estimating basal energy needs but less precise than traditional devices used in the research setting, may be useful in the outpatient setting. Close to one-half of cancer patients being evaluated in an outpatient cachexia clinic are noted to be hypermetabolic by indirect calorimetry. These assessments are appropriate in the research setting, but have little if any utility in the clinic”.

Whiting et al (2014) stated that capsaicinoids are a group of chemicals naturally occurring in chilli peppers with bioactive properties that may help to support weight management. These investigators conducted a meta-analysis investigating the potential effects of capsaicinoids on energy intake, clarified previous observations and formed evidence-based conclusions about possible weight management roles. Medical databases (Medline, Web of Knowledge and Scopus) were systematically searched for papers. Search terms were: 'capsaicin(*)' or 'red pepper' or 'chilli(*)' or 'chili(*)' with 'satiety' or 'energy intake'. Of the 74 clinical trials identified, 10 were included, 8 of which provided results suitable to be combined in analysis (191 participants). From the studies, 19 effect sizes were extracted and analyzed using MIX meta-analysis software. Data analysis showed that capsaicinoid ingestion prior to a meal reduced ad libitum energy intake by 309.9kJ (74.0kcal) during the meal (p < 0.001). However, results should be viewed with some caution as heterogeneity was high (I(2) = 75.7 %). Study findings suggested a minimum dose of 2 mg of capsaicinoids is needed to contribute to reductions in ad libitum energy intake, which appears to be attributed to an altered preference for carbohydrate-rich foods over foods with a higher fat content. The authors concluded that meta-analysis findings suggested that daily consumption of capsaicinoids may contribute to weight management through reductions in energy intake. Subsequently, there may be potential for capsaicinoids to be
used as long-term, natural weight-loss aids. They stated that further long-term randomized trials are now needed to investigate these effects.

In a systematic review, Onakpoya et al (2014a) evaluated the evidence for or against the effectiveness of glucomannan, a soluble fiber, in body weight reduction. Electronic searches were conducted in Medline, Embase, Amed, and The Cochrane Library. Hand searches of bibliography were also conducted. Outcomes of interest were body weight and BMI. Studies involving only over-weight and/or obese participants were included. Two reviewers independently determined the eligibility of studies and assessed the reporting quality of included randomized controlled trials (RCTs), using the CONSORT and PRISMA guidelines. A total of 18 trials were identified, and 9 were included. There was a variation in the reporting quality of the included RCTs. A meta-analysis (random effect model) of 8 RCTs revealed a non-statistically significant difference in weight loss between glucomannan and placebo (mean difference [MD]: -0.22 kg; 95 % confidence interval [CI]: -0.62, 0.19; I(2) = 65 %). Adverse events included abdominal discomfort, diarrhea, and constipation. The authors concluded that the evidence from available RCTs does not show that glucomannan intake generates statistically significant weight loss. They stated that future trials should be more rigorous and better reported.

Onakpoya et al (2014b) noted that several slimming aids being sold as food supplements are widely available. One of them is pyruvate. Its effectiveness in causing weight reduction in humans has not been fully established. The objective of this systematic review was to examine the effectiveness of pyruvate in reducing body weight. Electronic and non-electronic searches were conducted to identify all relevant human RCTs. The bibliographies of all located articles were also searched. No restrictions in language or time were applied. Two independent reviewers extracted the data according to predefined criteria. A fixed-effect model was used to calculate MD and 95 % CI. A total of 9 trials were identified and 6 were included. All had
methodological weaknesses. The meta-analysis revealed a statistically significant difference in body weight with pyruvate compared to placebo (MD: -0.72 kg; 95 % CI: -1.24 to -0.20). The magnitude of the effect is small, and its clinical relevance is uncertain. Adverse events included gas, bloating, diarrhea, and increase in low-density lipoprotein (LDL) cholesterol. The authors concluded that the evidence from RCTs does not convincingly show that pyruvate is effective in reducing body weight; limited evidence exists about the safety of pyruvate. They stated that future trials involving the use of this supplement should be more rigorous and better reported.

The FDA has approved liraglutide [rDNA origin] injection (Saxenda), a once-daily injection of a glucagon-like peptide-1 (GLP-1) receptor agonist, for chronic weight management (Novo Nordisk, 2014). Liraglutide is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI ≥30 kg/m2) or who are overweight (BMI ≥27 kg/m2) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) (FDA, 2014).

The labeling of Saxenda states that liraglutide should not be used with insulin (FDA, 2014). It also states that the effects of liraglutide on cardiovascular morbidity and mortality have not been established. The labeling states that the safety and efficacy of coadministration with other products for weight loss have not been established. In addition, liraglutide has not been studied in patients with a history of pancreatitis.

Liraglutide for chronic weight management is contraindicated in the following conditions: personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2); patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components; and pregnancy (FDA, 2014).

The FDA approval of liraglutide was based upon the SCALE (Satiety and Clinical Adiposity–Liraglutide Evidence in Non-
diabetic and Diabetic adults) phase 3 clinical trial program, which included study participants who have obesity (BMI ≥30 kg/m²) or who are overweight (BMI ≥27 kg/m²) with comorbidities (Novo Nordisk, 2014). Trial data showed that liraglutide, in combination with a reduced-calorie diet and increased physical activity, resulted in significantly greater weight loss than diet and physical activity alone.

The SCALE phase 3 clinical trial program of the safety and effectiveness of liraglutide for chronic weight management included three clinical trials that included approximately 4,800 obese and overweight patients with and without significant weight-related conditions (FDA, 2014). All patients received counseling regarding lifestyle modifications that consisted of a reduced-calorie diet and regular physical activity.

Results from a clinical trial that enrolled patients without diabetes showed that patients had an average weight loss of 4.5 percent from baseline compared to treatment with a placebo at one year (FDA, 2014). In this trial, 62 percent of patients treated with liraglutide lost at least 5 percent of their body weight compared with 34 percent of patients treated with placebo. Results from another clinical trial that enrolled patients with type 2 diabetes showed that patients had an average weight loss of 3.7 percent from baseline compared to treatment with placebo at one year. In this trial, 49 percent of patients treated with liraglutide lost at least 5 percent of their body weight compared with 16 percent of patients treated with placebo.

The FDA approved labeling states that patients using liraglutide should be evaluated after 16 weeks to determine if the treatment is working (FDA, 2014). If a patient has not lost at least 4 percent of baseline body weight, liraglutide should be discontinued, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Saxenda is a glucagon-like peptide-1 (GLP-1) receptor agonist
and should not be used in combination with any other drug belonging to this class, including Victoza, a treatment for type 2 diabetes (FDA, 2014). Saxenda and Victoza contain the same active ingredient (liraglutide) at different doses (3 mg and 1.8 mg, respectively). However, Saxenda is not indicated for the treatment of type 2 diabetes, as the safety and efficacy of Saxenda for the treatment of diabetes has not been established.

Saxenda has a boxed warning stating that thyroid C-cell tumors have been observed in rodent studies with liraglutide but that it is unknown whether liraglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans (FDA, 2014). Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether liraglutide causes thyroid C-cell tumors, including MTC, in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

The labeling states that liraglutide is contraindicated in patients with a personal or family history of MTC or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2) (FDA, 2014). The labeling states that patients should be counseled regarding the risk of MTC with use of liraglutide and informed of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). The labeling states that routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with liraglutide.

In clinical trials, the most common adverse reactions, reporting in ≥5%, were: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase (Novo Nordisk, 2014).

Serious side effects reported in patients treated with liraglutide for chronic weight management include pancreatitis,
gallbladder disease, renal impairment, and suicidal thoughts (FDA, 2014). Liraglutide can also increase heart rate and should be discontinued in patients who experience a sustained increase in resting heart rate.

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide (Novo Nordisk, 2014). After initiation of liraglutide, patients should be observed for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, liraglutide should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, liraglutide should not be restarted.

Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in liraglutide-treated patients than in placebo-treated patients even after accounting for the degree of weight loss (Novo Nordisk, 2014). If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

When liraglutide is used with an insulin secretagogue (e.g., a sulfonylurea) serious hypoglycemia can occur (Novo Nordisk, 2014). The labeling recommends lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

Renal impairment has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration, which may sometimes require hemodialysis (Novo Nordisk, 2014). The labeling recommends using caution when initiating or escalating doses of liraglutide in patients with renal impairment.

Serious hypersensitivity reactions (e.g., anaphylaxis and angioedema) have been reported during postmarketing use of
liraglutide (Novo Nordisk, 2014). The labeling recommends that patients stop taking liraglutide and seek medical advice if symptoms of hypersensitivity reactions occur.

The labeling states that patients treated with liraglutide should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior (Novo Nordisk, 2014). Liraglutide should be discontinued in patients who experience suicidal thoughts or behaviors. Liraglutide should be avoided in patients with a history of suicidal attempts or active suicidal ideation.

The labeling states that nursing mothers should either discontinue liraglutide for chronic weight management or discontinue nursing (Novo Nordisk, 2014). The labeling states that the safety and effectiveness of liraglutide have not been established in pediatric patients and is not recommended for use in pediatric patients.

The FDA is requiring the following post-marketing studies for liraglutide for chronic weight management (FDA, 2014): clinical trials to evaluate dosing, safety, and efficacy in pediatric patients; a study to assess potential effects on growth, sexual maturation, and central nervous system development and function in immature rats; an MTC case registry of at least 15 years duration to identify any increase in MTC incidence related to liraglutide; and an evaluation of the potential risk of breast cancer with liraglutide in ongoing clinical trials. In addition, the cardiovascular safety of liraglutide is being investigated in an ongoing cardiovascular outcomes trial.

The FDA approved Saxenda with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a communication plan to inform health care professionals about the serious risks associated with Saxenda (FDA, 2014).

Lingwood (2013) stated that there is a critical need for improved technologies to monitor fluid balance and body composition in neonates, particularly those receiving intensive
care. Bioelectrical impedance analysis (BIA) meets many of the criteria required in this environment and appears to be effective for monitoring physiological trends. These researchers reviewed the literature regarding the use of bioelectrical impedance in neonates. It was found that prediction equations for total body water, extracellular water and fat-free mass have been developed, but many require further testing and validation in larger cohorts. Alternative approaches based on Hanai mixture theory or vector analysis are in the early stages of investigation in neonates. The authors concluded that further research is needed into electrode positioning, bioimpedance spectroscopy and Cole analysis in order to realize the full potential of this technology.

de Miguel-Etayo et al (2013) noted that nutrition, physical activity and behavior-modifying techniques are widely applied components of interventions treating obesity. These investigators reviewed available information on the short- and long-term effects of intervention treatment on body fat composition of overweight and obese children and adolescents and, to obtain a further understanding on how different body composition techniques detect longitudinal changes. A total of 13 papers were included; 7 included a multi-disciplinary intervention component, 5 applied a combined dietary and physical activity intervention and 1 a physical activity intervention. Body composition techniques used included anthropometric indices, BIA, and dual energy X-ray absorptiometry. Percentage of fat mass change was calculated in when possible. Findings suggested, no changes were observed in fat free mass after 16 weeks of nutritional intervention and the lowest decrease on fat mass percentage was obtained. However, the highest fat mass percentage with parallel increase in fat free mass, both assessed by DXA was observed in a multi-component intervention applied for 20 weeks. The authors concluded that more studies are needed to determine the best field body composition method to monitor changes during overweight treatment in children and adolescents.
Talma et al (2013) stated that BIA is a practical method to estimate percentage body fat (% BF). In this systematic review, these researchers evaluated validity, responsiveness, reliability and measurement error of BIA methods in estimating % BF in children and adolescents. They searched for relevant studies in PubMed, Embase and Cochrane through November 2012. Two reviewers independently screened titles and abstracts for inclusion, extracted data and rated methodological quality of the included studies. These investigators performed a best evidence synthesis to synthesize the results, thereby excluding studies of poor quality. They included 50 published studies. Mean differences between BIA and reference methods (gold standard [criterion validity] and convergent measures of body composition [convergent validity]) were considerable and ranged from negative to positive values, resulting in conflicting evidence for criterion validity. These investigators found strong evidence for a good reliability, i.e., (intra-class) correlations greater than or equal to 0.82. However, test-retest mean differences ranged from 7.5 % to 13.4 % of total % BF in the included study samples, indicating considerable measurement error. The authors concluded that the findings of this systematic review suggested that BIA is a practical method to estimate % BF in children and adolescents. However, they stated that validity and measurement error were not satisfactory.

Goldberg et al (2014) stated that the sensory and gastrointestinal changes that occur with aging affect older adults' food and liquid intake. Any decreased liquid intake increases the risk for dehydration. This increased dehydration risk is compounded in older adults with dysphagia. The availability of a non-invasive and easily administered way to document hydration levels in older adults is critical, particularly for adults in residential care. This pilot study investigated the contribution of BIA to measure hydration in 19 older women in residential care: 13 who viewed themselves as healthy and 6 with dysphagia. Mann-Whitney U analyses documented no significant between-group differences for total body water (TBW), fat free mass (FFM), Fat Mass (FM), and % BF. However,
when compared to previously published data for age-matched women, the TBW and FFM values of the 2 participant groups were notably less, and FM and % BF values were notably greater than expected. The authors concluded that if results are confirmed through continued investigation, such findings may suggest that long-term care facilities are unique environments in which all older residents can be considered at-risk for dehydration and support the use of BIA as a non-invasive tool to assess and monitor their hydration status.

Buffa et al (2014) defined the effectiveness of bioelectrical impedance vector analysis (BIVA) for assessing 2-compartment body composition. These researchers performed a systematic literature review using MEDLINE database up to February 12, 2014. The list of papers citing the first description of BIVA, obtained from SCOPUS, and the reference lists of included studies were also searched. Selection criteria included studies comparing the results of BIVA with those of other techniques, and studies analyzing bioelectrical vectors of obese, athletic, cachectic and lean individuals. A total of 30 articles met the inclusion criteria. The ability of classic BIVA for assessing 2-compartment body composition has been mainly evaluated by means of indirect techniques, such as anthropometry and BIA. Classic BIVA showed a high agreement with body mass index, which can be interpreted in relation to the greater body mass of obese and athletic individuals, whereas the comparison with BIA showed less consistent results, especially in diseased individuals. When a reference method was used, classic BIVA failed to accurately recognize FM % variations, whereas specific BIVA furnished good results. The authors concluded that specific BIVA is a promising alternative to classic BIVA for assessing 2-compartment body composition, with potential application in nutritional, sport and geriatric medicine.

Haverkort et al (2015) noted that BIA is a commonly used method for the evaluation of body composition. However, BIA estimations are subject to uncertainties. These researchers explored the variability of empirical prediction equations used in BIA estimations and evaluated the validity of BIA estimations
in adult surgical and oncological patients. Studies developing new empirical prediction equations and studies evaluating the validity of BIA estimations compared with a reference method were included. Only studies using BIA devices measuring the entire body were included. Studies that included patients with altered body composition or a disturbed fluid balance and studies written in languages other than English were excluded. To illustrate variability between equations, fixed normal reference values of resistance values were entered into the existing empirical prediction equations of the included studies and the results were plotted in figures. The validity was expressed by the difference in means between BIA estimates and the reference method, and relative difference in %.

Substantial variability between equations for groups (including men and women) was found for TBW and FFM. The gender-specific existing general equations assume less variability for TBW and FFM. BIA mainly under-estimated TBW (range relative difference -18.8 % to +7.2 %) and FFM (range relative differences -15.2 % to +3.8 %). Estimates of the FM demonstrated large variability (range relative difference -15.7 % to +43.1 %). The authors concluded that application of equations validated in healthy subjects to predict body composition performs less well in oncologic and surgical patients. They suggested that BIA estimations, irrespective of the device, can only be useful when performed longitudinally and under the same standard conditions.

Ketogenic Diets for Weight Loss:

Gibson et al (2015) stated that VLEDs and ketogenic low-carbohydrate diets (KLCDs) are 2 dietary strategies that have been associated with a suppression of appetite. However, the results of clinical trials investigating the effect of ketogenic diets on appetite are inconsistent. To evaluate quantitatively the effect of ketogenic diets on subjective appetite ratings, these researchers conducted a systematic literature search and meta-analysis of studies that assessed appetite with visual analog scales (VAS) before (in energy balance) and during (while in ketosis) adherence to VLED or KLCD. Individuals were less
hungry and exhibited greater fullness/satiety while adhering to VLED, and individuals adhering to KLCD were less hungry and had a reduced desire to eat. Although these absolute changes in appetite were small, they occurred within the context of energy restriction, which is known to increase appetite in obese people. Thus, the clinical benefit of a ketogenic diet is in preventing an increase in appetite, despite weight loss, although individuals may indeed feel slightly less hungry (or more full or satisfied). Ketosis appears to provide a plausible explanation for this suppression of appetite. The authors concluded that future studies should investigate the minimum level of ketosis required to achieve appetite suppression during ketogenic weight loss diets, as this could enable inclusion of a greater variety of healthy carbohydrate-containing foods into the diet.

Medium-Chain Triglycerides for Weight Loss:

Bueno and colleagues (2015) examined the effect of replacing dietary long-chain triacylglycerols (LCTs) with medium-chain triacylglycerols (MCTs) on body composition in adults. These researchers conducted a meta-analysis of RCTs, to examine if individuals assigned to replace at least 5 g of dietary LCTs with MCTs for a minimum of 4 weeks show positive modifications on body composition. They systematically searched, through July 2013, the CENTRAL, EMBASE, LILACS, and MEDLINE databases for RCTs that investigated the effects of MCT intake on body composition in adults. Two authors independently extracted data and assessed risk of bias. Weighted mean differences (WMDs) were calculated for net changes in the outcomes. These investigators assessed heterogeneity by the Cochran Q test and I(2) statistic and publication bias with the Egger's test. Pre-specified sensitivity analyses were performed. A total of 11 trials were included, from which 5 presented low risk of bias. In the overall analysis, including all studies, individuals who replaced dietary LCT with MCT showed significantly reduced body weight (WMD, -0.69 kg; 95 % CI: -1.1 to -0.28; p = 0.001); body fat (-0.89 kg; 95 % CI: -1.27 to -0.51; p < 0.001), and WC (-1.78 cm; 95 % CI: -2.4 to -1.1; p < 0.001). The overall quality
of the evidence was low-to-moderate. Trials with a cross-over design were responsible for the heterogeneity. The authors concluded that despite statistically significant results, the recommendation to replace dietary LCTs with MCTs must be cautiously taken, because the available evidence is not of the highest quality.

Mumme and Stonehouse (2015) conducted a systematic review and meta-analysis of RCTs comparing the effects of MCTs, specifically C8:0 and C10:0, to long-chain triglycerides (LCTs) on weight loss and body composition in adults. Changes in blood lipid levels were secondary outcomes. Randomized controlled trials of greater than 3 weeks' duration conducted in healthy adults were identified searching Web of Knowledge, Discover, PubMed, Scopus, New Zealand Science, and Cochrane CENTRAL until March 2014 with no language restriction. Identified trials were assessed for bias. Mean differences were pooled and analyzed using inverse variance models with fixed effects. Heterogeneity between studies was calculated using I(2) statistic. An I(2) > 50 % or p < 0.10 indicated heterogeneity. A total of 13 trials (n = 749) were identified. Compared with LCTs, MCTs decreased body weight (-0.51 kg [95 % CI: -0.80 to -0.23 kg]; p < 0.001; I(2) = 35 %), waist circumference (-1.46 cm [95 % CI: -2.04 to -0.87 cm]; p < 0.001; I(2) = 0%), hip circumference (-0.79 cm [95 % CI: -1.27 to -0.30 cm]; p = 0.002; I(2) = 0 %), total body fat (standard mean difference -0.39 [95 % CI: -0.57 to -0.22]; p < 0.001; I(2) = 0%), total subcutaneous fat (standard mean difference -0.46 [95 % CI: -0.64 to -0.27]; p < 0.001; I(2) = 20 %), and visceral fat (standard mean difference -0.55 [95 % CI: -0.75 to -0.34]; p < 0.001; I(2) = 0 %). No differences were seen in blood lipid levels. Many trials lacked sufficient information for a complete quality assessment, and commercial bias was detected. Although heterogeneity was absent, study designs varied with regard to duration, dose, and control of energy intake. The authors concluded that replacement of LCTs with MCTs in the diet could potentially induce modest reductions in body weight and composition without adversely affecting lipid profiles. However, they stated that further research is needed by independent research groups using large, well-designed
studies to confirm the effectiveness of MCT and to determine the dosage needed for the management of a healthy body weight and composition.

**FTO Genotyping:**

Xiang and colleagues (2016) noted that studies have suggested that the fat mass and obesity-associated (FTO) genotype is associated with individual variability in weight loss in response to diet/lifestyle interventions, but results are inconsistent. These investigators provided a summary of the literature evaluating the relation between the FTO genotype and weight loss in response to diet/lifestyle interventions. They performed a search of English-language articles in the PubMed and Embase databases (through April 30, 2015). Eligible studies were diet/lifestyle weight-loss intervention studies conducted in adults that reported changes in body weight or BMI by the FTO variant rs9939609 (or its proxy). Differences in weight loss between FTO genotypes across studies were pooled with the use of fixed-effect models. A meta-analysis of 10 studies (comprising 6,951 participants) that reported the results of additive genetic models showed that individuals with the FTO TA genotype and AA genotype (those with the obesity-predisposing A allele) had 0.18-kg (95% CI: -0.09 to 0.45-kg; p=0.19; NS) and 0.44-kg (95% CI: 0.09- to 0.79-kg; p = 0.015) greater weight loss, respectively, than those with the TT genotype. A meta-analysis of 14 studies (comprising 7,700 participants) that reported the results of dominant genetic models indicated a 0.20-kg (-0.43- to 0.04-kg) greater weight loss in the TA/AA genotype than in the TT genotype (p = 0.10). In addition, differences in weight loss between the AA genotype and TT genotype were significant in studies with a diet intervention only, adjustment for baseline BMI or body weight, and several other subgroups. However, the relatively small number of studies limited these stratified analyses, and there was no statistically significant difference between subgroups. The authors concluded that the findings of this meta-analysis suggested that individuals carrying the homozygous FTO obesity-predisposing allele may lose more weight through
diet/lifestyle interventions than non-carriers; and clinical applications of these findings need further investigations. They stated that these findings provided some support for considering genetic variability in response to diet/lifestyle interventions in the development of more effective strategies for weight loss; nevertheless, more studies are needed to explore which types of diet/lifestyle interventions most powerfully facilitate the FTO genetic effect on weight loss.

**Normobaric Hypoxic Conditioning:**

Hobbins and colleagues (2017) stated that normobaric hypoxic conditioning (HC) is defined as exposure to systemic and/or local hypoxia at rest (passive) or combined with exercise training (active). Hypoxic conditioning has been previously used by healthy and athletic populations to enhance their physical capacity and improve performance in the lead up to competition. Recently, HC has also been applied acutely (single exposure) and chronically (repeated exposure over several weeks) to over-weight and obese populations with the intention of managing and potentially increasing cardio-metabolic health and weight loss. At present, it is unclear what the cardio-metabolic health and weight loss responses of obese populations are in response to passive and active HC. Exploration of potential benefits of exposure to both passive and active HC may provide pivotal findings for improving health and well-being in these individuals. These researchers carried out a systematic literature search for articles published between 2000 and 2017. Studies investigating the effects of normobaric HC as a novel therapeutic approach to elicit improvements in the cardio-metabolic health and weight loss of obese populations were included. Studies investigated passive (n = 7; 5 animals, 2 humans), active (n = 4; all humans) and a combination of passive and active (n = 4; 3 animals, 1 human) HC to an inspired oxygen fraction between 4.8 and 15.0 %, ranging between a single session and daily sessions per week, lasting from 5 days up to 8 months. Passive HC led to reduced insulin concentrations (-37 to -22 %) in obese animals and increased energy expenditure (+12 to +16 %) in obese humans,
whereas active HC led to reductions in body weight (-4 to -2 %) in obese animals and humans, and blood pressure (BP; -8 to -3 %) in obese humans compared with a matched workload in normoxic conditions. Inconclusive findings, however, exist in determining the impact of acute and chronic HC on markers such as triglycerides, cholesterol levels, and fitness capacity. More importantly, most of the studies that included animal models involved exposure to severe levels of hypoxia (= 5.0 %; simulated altitude greater than 10,000 m) that are not suitable for human populations. The authors concluded that normobaric HC demonstrated observable positive findings in relation to insulin and energy expenditure (passive), and body weight and BP (active), which may improve the cardio-metabolic health and body weight management of obese populations. However, they stated that further evidence on responses of circulating biomarkers to both passive and active HC in humans is needed.

**Appendix**

**Ideal Weight Chart:**

The following indicates maximum ideal weight in shoes with one-inch heels based on body frame and height:

**Ideal weights for adult men**

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight (lbs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small Frame</td>
</tr>
<tr>
<td>5'2&quot;</td>
<td>134</td>
</tr>
<tr>
<td>5'3&quot;</td>
<td>136</td>
</tr>
<tr>
<td>5'4&quot;</td>
<td>138</td>
</tr>
<tr>
<td>5'5&quot;</td>
<td>140</td>
</tr>
<tr>
<td>5'6&quot;</td>
<td>142</td>
</tr>
<tr>
<td>5'7&quot;</td>
<td>145</td>
</tr>
<tr>
<td>Height</td>
<td>Weight (lbs.)</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>Small Frame</td>
</tr>
<tr>
<td>4'10&quot;</td>
<td>111</td>
</tr>
<tr>
<td>4'11&quot;</td>
<td>113</td>
</tr>
<tr>
<td>5'0&quot;</td>
<td>115</td>
</tr>
<tr>
<td>5'1&quot;</td>
<td>118</td>
</tr>
<tr>
<td>5'2&quot;</td>
<td>121</td>
</tr>
<tr>
<td>5'3&quot;</td>
<td>124</td>
</tr>
<tr>
<td>5'4&quot;</td>
<td>127</td>
</tr>
<tr>
<td>5'5&quot;</td>
<td>130</td>
</tr>
<tr>
<td>5'6&quot;</td>
<td>133</td>
</tr>
<tr>
<td>5'7&quot;</td>
<td>136</td>
</tr>
<tr>
<td>5'8&quot;</td>
<td>139</td>
</tr>
<tr>
<td>5'9&quot;</td>
<td>142</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td><strong>CPT codes covered if selection criteria are met:</strong></td>
</tr>
<tr>
<td>97802</td>
<td>Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes</td>
</tr>
<tr>
<td>97803</td>
<td>re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes</td>
</tr>
<tr>
<td>97804</td>
<td>group (2 or more individual(s)), each 30 minutes</td>
</tr>
<tr>
<td></td>
<td><strong>CPT codes not covered for indications listed in the CPB:</strong></td>
</tr>
<tr>
<td>0358T</td>
<td>Bioelectrical impedance analysis whole body composition assessment, with interpretation and report</td>
</tr>
<tr>
<td>94690</td>
<td>Oxygen uptake, expired gas analysis; Rest, indirect (separate procedure) [Indirect calorimetry]</td>
</tr>
<tr>
<td>94726</td>
<td>Plethysmography for determination of lung volumes and, when performed, airway resistance</td>
</tr>
<tr>
<td>97810</td>
<td>Acupuncture, one or more needles without electrical stimulation; initial 15 minutes of personal one-on-one contact with patient</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>+ 97811</td>
<td>without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>97813</td>
<td>Acupuncture, one or more needles with electrical stimulation; initial 15 minutes of personal one-on-one contact with the patient</td>
</tr>
<tr>
<td>+ 97814</td>
<td>each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77072</td>
<td>Bone age studies</td>
</tr>
<tr>
<td>80048</td>
<td>Basic metabolic panel (Calcium, total)</td>
</tr>
<tr>
<td>80053</td>
<td>Comprehensive metabolic panel</td>
</tr>
<tr>
<td>80076</td>
<td>Hepatic function panel</td>
</tr>
<tr>
<td>80418</td>
<td>Combined rapid anterior pituitary evaluation panel</td>
</tr>
<tr>
<td>80420</td>
<td>Dexamethasone suppression panel, 48 hour</td>
</tr>
<tr>
<td>81000</td>
<td>Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urinobilogen, any number of these constituents; non-automated, with microscopy</td>
</tr>
<tr>
<td>81001</td>
<td>automated, with microscopy</td>
</tr>
<tr>
<td>81050</td>
<td>Volume measurement for timed collection, each</td>
</tr>
<tr>
<td>82465</td>
<td>Cholesterol, serum or whole blood, total</td>
</tr>
<tr>
<td>82530</td>
<td>Cortisol, free</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>82533</td>
<td>total</td>
</tr>
<tr>
<td>82951</td>
<td>Glucose; tolerance test (GTT), three specimens (includes glucose)</td>
</tr>
<tr>
<td>82952</td>
<td>tolerance test, each additional beyond 3 specimens (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>83718</td>
<td>Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)</td>
</tr>
<tr>
<td>83719</td>
<td>direct measurement, VLDL cholesterol</td>
</tr>
<tr>
<td>83721</td>
<td>direct measurement; LDL cholesterol</td>
</tr>
<tr>
<td>84443</td>
<td>Thyroid stimulating hormone (TSH)</td>
</tr>
<tr>
<td>84478</td>
<td>Triglycerides</td>
</tr>
<tr>
<td>84479</td>
<td>Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)</td>
</tr>
<tr>
<td>84550</td>
<td>Uric acid; blood</td>
</tr>
<tr>
<td>84560</td>
<td>other source</td>
</tr>
<tr>
<td>85025</td>
<td>Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count</td>
</tr>
<tr>
<td>85027</td>
<td>complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count</td>
</tr>
<tr>
<td>93000 - 93010</td>
<td>Electrocardiogram, routine ECG with at least 12 leads</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0270</td>
<td>Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face to face with patient, each 15 minutes</td>
</tr>
<tr>
<td>G0271</td>
<td>Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), group, (2 or more individuals), each 30 minutes</td>
</tr>
<tr>
<td>J0725</td>
<td>Injection, chorionic gonadotropin, per 1,000 USP units</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7336</td>
<td>Capsaicin 8% patch, per sq cm</td>
</tr>
<tr>
<td>S8948</td>
<td>Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes</td>
</tr>
<tr>
<td>S9449</td>
<td>Weight management classes, non-physician provider, per session</td>
</tr>
</tbody>
</table>

**Other HCPCS Codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9451</td>
<td>Exercise classes, non-physician provider, per session</td>
</tr>
<tr>
<td>S9452</td>
<td>Nutrition classes, non-physician provider, per session</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E66.01 - E66.9</td>
<td>Overweight and obesity</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:

9. United States Pharmacopeial Convention, Inc. Appetite...


20. Shepherd TM. Effective management of obesity. J Fam


68. Pineau JC, Filliard JR, Bocquet M. Ultrasound techniques


77. Bruera E, Dev R. Palliative care: Assessment and management of anorexia and cachexia. UpToDate [serial online]. Waltham, MA: UpToDate; reviewed October 2013.


79. Whiting S, Derbyshire EJ, Tiwari B. Could capsaicinoids help to support weight management? A systematic review and


impedance analysis to estimate body composition in 
children and adolescents: A systematic review and 
evidence appraisal of validity, responsiveness, reliability 

89. Goldberg LR, Heiss CJ, Parsons SD, et al. Hydration in older 
adults: The contribution of bioelectrical impedance 

impedance vector analysis (BIVA) for the assessment of 

91. Haverkort EB, Reijven PL, Binnekade JM, et al. Bioelectrical 
impedance analysis to estimate body composition in 
surgical and oncological patients: A systematic review. Eur 

really suppress appetite? A systematic review and meta-
analysis. Obes Rev. 2015;16(1):64-76.

93. Bueno NB, de Melo IV, Florêncio TT, Sawaya AL. Dietary 
medium-chain triacylglycerols versus long-chain 
triacylglycerols for body composition in adults: Systematic 
review and meta-analysis of randomized controlled trials. J 

94. Mumme K, Stonehouse W. Effects of medium-chain 
triglycerides on weight loss and body composition: A 
meta-analysis of randomized controlled trials. J Acad Nutr 
Diet. 2015;115(2):249-263.

95. Wilms B, Schmid SM, Ernst B, et al. Poor prediction of 
resting energy expenditure in obese women by established 

Metabolic Rate in Overweight and Obese Adolescents 
With a Portable Indirect Calorimeter: A Pilot Study for 

97. Frankenfield D, Roth-Yousey L, Compher C. Comparison of 
predictive equations for resting metabolic rate in healthy 
nonobese and obese adults: A systematic review. J Am Diet 


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0039 Weight Reduction Medications and Programs

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

revised 3/9/2018