Clinical Policy Bulletin:

Weight Reduction Medications and Programs

Number:Â 0039Policy

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.Â Please check benefit plan descriptions for details.

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

Weight reduction medications, and

ClinicianÂ 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.Â 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:

Member has a body mass index** (BMI) greater than or equal to 30 kg/m²; or

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:

Coronary heart disease
Dyslipidemia:

- HDL cholesterol less than 35 mg/dL, or
- LDL cholesterol greater than or equal to 160 mg/dL, or
- Triglycerides greater than or equal to 400 mg/dL

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)

Obstructive sleep apnea

Type 2 diabetes mellitus.

Weight reduction medications are considered experimental and investigational when these criteria are not met.

**BMI = weight (kg) / [height (m)]^2

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

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

For Aetna’s clinical policy on surgical management of obesity, see CPB 0157 - Obesity Surgery.

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  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:

EKG after 50 lbs of weight loss; and

Lipid profile at the beginning and end of the VLCD program; and

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 plan descriptions for details.

Excluded Services:
The following interventions are considered experimental and investigational for weight reduction:

- Acupuncture for weight loss
- Body plethysmography (diagnostic study)
- Dual-energy X-ray (DEXA) body composition (diagnostic study)
- Gastric electrical stimulation (see CPB 0678 - Gastric Pacing and Gastric Electrical Stimulation)
- Human chorionic gonadotropin (HCG) or vitamin injections for weight loss
- Indirect calorimetry (e.g., ReeVue Indirect Calorimeter) (diagnostic study)

Whole body calorimetry and composition is 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, or phytotherapy), see CPB 0061 - Nutritional Support
- Weight Watchers, Jenny Craig, Diet Center, Zone diet, or similar programs.

Background

This policy is supported by NHLBI Guidelines on Diagnosis and Management of Obesity.

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.

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 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.

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 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 showed 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.

The ReeVue Indirect Calorimeter (KORR Medical Technologies, Salt Lake City, UT) was 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 the ReeVue Indirect Calorimeter 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, the ReeVue can also be used to measure basal metabolic rate.

Fioravante et al (2012) evaluated nutritional status, body composition, and (REE in patients with chronic hepatitis C before and during treatment with pegylated interferon and ribavirin. This was a prospective study with the evaluation of patients with hepatitis C virus before and after 12 weeks of treatment with pegylated interferon and ribavirin. The evaluation consisted of anthropometry (weight, height, BMI, and waist circumference), and body composition was determined by bioelectrical impedance analysis. The REE of each individual was obtained by indirect calorimetry. To compare the 2 phases of treatment, the Wilcoxon test was used. The significance level was 5 %. Subjects had significant weight loss during treatment with a consequent decrease in BMI. This weight decrease was accompanied by a significant decrease in body fat and no decrease in fat-free mass. There was a significant decrease in energy intake as assessed by 24-hour recall. However, there was no change in REE and in REE corrected for fat-free mass. The authors concluded that patients with hepatitis C treatment had significant weight loss and this was not associated with changes in energy expenditure.

Furthermore, 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".

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:

Height
Weight (lbs.)

5'2"
<table>
<thead>
<tr>
<th>Height (in)</th>
<th>Weight (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5'9&quot;</td>
<td>151</td>
</tr>
<tr>
<td>5'10&quot;</td>
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<td>5'11&quot;</td>
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</tr>
<tr>
<td>Height</td>
<td>Small Frame</td>
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<td>--------</td>
<td>-------------</td>
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<td>4'10&quot;</td>
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<tr>
<td>4'11&quot;</td>
<td>113</td>
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Ideal weights for adult women:
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<th>Height (&quot;inch&quot;)</th>
<th>Weight (Pounds)</th>
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<td>159</td>
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<tr>
<td>5'7&quot;</td>
<td>136</td>
</tr>
</tbody>
</table>
CPT codes covered if selection criteria are met:

97802
97803
CPT codes not covered for indications listed in the CPB:

94690
94726
97810
+ 97811
97813
+ 97814

Other CPT codes related to the CPB:

77072
80048
80053
80076
80418
80420
81000
81001
81050
82465
82530
82533
82951
82952
83718
83719
83721
HCPCS codes covered if selection criteria are met:

G0270
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

G0271
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

HCPCS codes not covered for indications listed in the CPB:

S9449
Weight management classes, non-physician provider, per session

Other HCPCS Codes related to the CPB:

S9451
Exercise classes, non-physician provider, per session

S9452
Nutrition classes, non-physician provider, per session

ICD-9 codes covered if selection criteria are met:

278.00 - 278.02
Overweight and obesity
Body mass index 27.0-70 and over, adult

Other ICD-9 Codes related to the CPB:

250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 280.82, 250.90, 250.92

Diabetes

255.0

Cushing's syndrome

259.8 - 259.9

Other and unspecified endocrine disorders

272.0

Pure hypercholesterolemia

327.23

Obstructive sleep apnea (adult) (pediatric)

401.0 - 405.99

Hypertensive disease

414.00 - 414.9

Coronary atherosclerosis

783.1

Abnormal weight gain

783.6

Polyphagia

V85.0 - V85.22

Body mass index less than 19-26.9, adult

The above policy is based on the following references:

American Obesity Association, C. Everett Koop Foundation, and Shape Up America! Guidance for treatment of adult obesity. Bethesda, MD: Shape Up America!; October 1996.Â Available at:


Bruera E, Dev R. Palliative care: Assessment and management of anorexia and cachexia. Last reviewed October 2013. UpToDate Inc., Waltham, MA.

http://link.reuters.com/kuq24t