Clinical Policy Title: Bariatric surgery for children and adolescents

Clinical Policy Number: CCP.1054

Effective Date: March 1, 2014
Initial Review Date: September 18, 2013
Most Recent Review Date: August 30, 2018
Next Review Date: September 2019

Related policies:

CCP.1090 Bariatric surgery for adults

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of bariatric surgery to be clinically proven and, therefore, medically necessary, in children and adolescents with severe obesity, when all of the following criteria are met (Beamish, 2017; Inge, 2016; Michalsky, 2012; National Heart Lung and Blood Institute, 2012):

- Age of member is from 13 years to 17 years.
- At or near skeletal maturity, defined as 95 percent of predicted adult stature based on bone age or reaching Tanner stage IV.
- Evidence of unsuccessful weight loss despite compliance with lifestyle interventions within the last 12 months in a supervised weight-management program.
- Either of the following eligibility criteria for bariatric surgery:
- Severe obesity (body mass index $\geq 35$ kg/m$^2$) with one or more major co-morbidities (e.g., benign intracranial hypertension, heart failure due to obesity, moderate-to-severe obstructive sleep apnea, or type 2 diabetes mellitus).
- Extreme obesity (body mass index $\geq 40$ kg/m$^2$) with one or more minor co-morbidities (e.g., body size precluding ambulation, dyslipidemia, gastro-esophageal reflux disease, hypertension, impaired activities of daily living, impaired fasting glucose, impaired glucose tolerance, mild obstructive sleep apnea, steatohepatitis, urinary incontinence, venous stasis, or weight-related joint disease).

- Adolescent bariatric surgery is delivered by multidisciplinary child/adolescent obesity teams within specialist bariatric centers.
- Medically necessary surgical procedures are limited to Roux-en-Y gastric bypass or sleeve gastrectomy (Inge, 2016; Pratt, 2009).
- Clearance from a mental health provider that the member (Hofmann, 2013):
  - Has the support, but not coercion, from family members.
  - Has the mental competency, understanding of the nature, extent, and possible complications of the surgery, and the ability to sustain the dietary behavioral modifications needed to ensure a successful outcome of surgery, including consistent use of micronutrient supplements.
- No contraindications to bariatric surgery (see Limitations).

Select Health of South Carolina considers surgery to correct complications that occur following the primary bariatric procedure (e.g., obstruction, stricture, or erosion) to be medically necessary.

Select Health of South Carolina considers revision of a primary bariatric surgery procedure to be medically necessary when all of the following criteria are met:

- The member met the medical necessity criteria for his or her initial bariatric surgery.
- The member has been cleared for the revision procedure by a licensed mental health professional provider for presence of any mental health or substance abuse conditions, emotional readiness and ability to make and sustain lifestyle changes, and adequacy of the member’s support system.
- The member has been compliant with a prescribed nutrition and exercise program following the primary bariatric procedure.
- For conversion from a sleeve gastrectomy to Roux-en-Y gastric bypass for members who failed to achieve adequate weight loss (at least 50 percent of excess body weight or failure to achieve body weight to within 30 percent of ideal body weight) at least two years following the primary surgery.

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1 The Centers for Disease Control and Prevention (2018) recommends the body mass index to screen for overweight and obesity in children aged two to 20 years. Body mass index-for-age weight status categories define overweight as the 85th to less than the 95th percentile range, and obese as equal to, or greater than, the 95th percentile.
Select Health of South Carolina considers repair of a hiatal hernia during bariatric surgery to be medically necessary for members with a preoperative diagnosis of hiatal hernia with clinical indications for surgical repair.

Limitations:

All other uses of bariatric surgery in children and adolescents are not medically necessary.

Repeat bariatric surgery in members who initially achieved successful weight loss, but overcame the weight loss with behavioral changes, is not medically necessary, as there is insufficient evidence of effectiveness in this population.

Repair of a hiatal hernia is not medically necessary when diagnosed at the time of bariatric surgery, or in the absence of preoperative clinical indications for surgical repair.

Routine liver biopsy during obesity surgery is not medically necessary in the absence of preoperative clinical suspicion of liver disease.

Gastric banding is not medically necessary, as it is not U.S. Food and Drug Administration-approved (2017) for use in members < 18 years of age.

Contraindications to bariatric surgery include:

- A medically correctable cause of obesity.
- An ongoing substance abuse problem (within the preceding year).
- A medical, psychiatric, psychosocial, or cognitive condition that prevents compliance with postoperative dietary and medication regimens or impairs decisional capacity.
- Current or planned pregnancy within 12 to 18 months of the procedure.
- Inability of the patient or parent/guardian to comprehend the risks and benefits of the surgical procedure.
- Eating disorders based on deteriorations in the satiety regulation such as melanocortin 4 receptor mutation, leptin resistance, or Prader–Willi syndrome, as the eating behavior will not be normalized after bariatric surgery.

Alternative covered services:

- Physician office visits and nutritional counseling.
- Behavioral health services.
- Weight loss drug for adolescents (e.g., orlistat).

Background
Childhood obesity is a serious public health problem in the United States with both immediate and long-term effects on health and well-being (Centers for Disease Control and Prevention, 2018; Pratt, 2009). From 2015 to 2016, nearly one in five school age children and young people (six to 19 years) in the United States are obese. Obesity prevalence continues to be higher among non-Hispanic black and Hispanic children and adolescents than among non-Hispanic white youth (Ogden, 2012). The fundamental cause of obesity in childhood is a greater imbalance between energy intake and expenditure than is expected for normal growth and development. Usually, this occurs over a period of time and in the setting of a susceptible genetic background and environmental factors (Daniels, 2009).

A range of effective multidisciplinary options exist for the management of overweight and obese patients, including dietary therapy, altering physical activity patterns, behavior therapy techniques, pharmacotherapy, surgery, and combinations of these techniques (National Heart Lung and Blood Institute, 2012). When behavioral or pharmacological interventions fail to achieve lasting weight loss, bariatric surgery may be an effective short-term option.

Bariatric surgery is designed to restrict food intake and decrease the absorption of food in the stomach and intestines, enabling patients to lose weight and decrease their risk for obesity-related health risks or disorders. Surgery may use an “open” laparotomy approach or a laparoscopic approach. Increasingly, laparoscopic procedures are preferred to open surgery, because fewer extensive cuts are required. This may lead to potentially minimal tissue damage, fewer post-operative complications, and earlier hospital discharge.

Common types of bariatric surgery are (U.S. Food and Drug Administration, 2018):

- Gastric bypass (Roux-en-Y gastric bypass, gastrojejunal anastomosis).
- Vertical-banded gastroplasty (sleeve gastroplasty).
- Sleeve gastrectomy (vertical gastrectomy).
- Gastric banding using one of two U.S. Food and Drug Administration-approved laparoscopic adjustable gastric band devices — LAP-BAND® (Allergan Inc., Irvine, California) and the REALIZE® Adjustable Gastric Band (Ethicon Endo-Surgery Inc., Blue Ash, Ohio). These devices have not been approved for use in persons < 18 years of age.
- Biliopancreatic diversion with or without duodenal switch.

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.
We conducted searches on July 10, 2018. Search terms were “bariatric surgery” (MeSH) restricted to articles of child and adolescent populations.

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Patients with a higher body mass index and more significant medical illness are at increased risk during bariatric surgery, but the long-term outcome of bariatric surgery in children and adolescents is unknown. The American Academy of Pediatrics (Spear, 2007) and other professional organizations (see references) have set guidelines to protect children but do not offer comparative evidence of long-term effectiveness. There are important concerns of harm, as up to 10 percent of surgically treated patients suffer significant complications.

Psychosocial outcomes after bariatric surgery have not been adequately studied, particularly in adolescents. Data suggest short-term improvements in depression, eating disturbances, and quality of life after bariatric surgery, but sustained improvement over the long term is unknown. Noncompliance with medical regimens is particularly common among adolescents with chronic illnesses. Consistent attendance and compliance with medical interventions is an important measure of whether a patient and family are likely to comply with postoperative care (Pratt, 2009).

Limited evidence suggests access to bariatric surgery earlier in life may reduce obesity-related mortality and morbidity, but it does not show directly that bariatric surgery during adolescence confers additional benefit compared with bariatric surgery during early adulthood. Early timing must be weighed against the patient’s possible psychological immaturity and the risk of decreased compliance and long-term follow-up (Pratt, 2009).

Nutritional deficiency is common in the majority of patients undergoing bariatric surgery, and is of particular concern among developing adolescents. Low levels of iron, vitamin B12, vitamin D, and calcium are common problems after Roux-en-Y gastric bypass, and adolescents may be at particular risk for thiamine deficiency and osteopenia. Adolescent girls are particularly vulnerable to nutritional deficiencies. This group is at substantial risk of developing iron deficiency anemia and vitamin B deficiencies during menstruation and pregnancy. Limited data suggest that pregnancy after Roux-en-Y...
gastric bypass and adjustable gastric band is safe, but there may be an increased risk of pregnancy in adolescents undergoing bariatric surgery (Pratt, 2009).

**Concerns for true informed consent:**

A systematic review identified a range of values, viewpoints, and arguments that are important for making open and transparent decisions on bariatric surgery for children and adolescents (Hofmann, 2013). Performing bariatric surgery in obese children and adolescents in order to discipline their behavior warrants reflection and caution. There is a moral imperative to help obese minors avoid serious health problems, but there is little high quality evidence on safety, outcomes, and cost effectiveness for bariatric surgery in this group. Conceptual issues such as definition of obesity and treatment end points further complicate data interpretation and decision making. Lack of maturity and poor family relations poses a series of challenges with autonomy, informed consent, assent, and assessing the best interest of children and adolescents. Social aspects of obesity such as medicalization, prejudice, and discrimination raise problems with justice and trust in health professionals (Hofmann, 2013).

As part of a carefully considered risk–benefit decision, it is important for the care team, patient and family to recognize and consider the specific risks of bariatric surgery, and particularly those relevant to the younger patient. Problems arise when the adolescent and the parents disagree about bariatric surgery.

**Policy updates:**

In 2016, we added one new systematic review and recent results of the prospective, multicenter Teen-Longitudinal Assessment of Bariatric Surgery study (Inge, 2016; Ells, 2015). New evidence from one small randomized controlled trial in Australia found laparoscopic adjustable gastric band led to greater weight loss compared to a multi component lifestyle program up to two years after surgery (Ells, 2015). Results of the Teen-Longitudinal Assessment of Bariatric Surgery longitudinal study highlight significant improvements in weight, cardiometabolic health, and weight-related quality of life three years after Roux-en-Y gastric bypass or sleeve gastrectomy. Final data collection will take place in 2016 (Clinicaltrials.gov Identifier: NCT00474318).

In 2017, although randomized controlled trial data are lacking, current evidence suggests that carefully selected adolescents with severe obesity achieve greater body mass index reduction and improvement in obesity-related co-morbidities with bariatric surgery (either sleeve gastrectomy or Roux-en-Y gastric bypass) than lifestyle interventions in the short-to-intermediate term (one to three years postoperatively) (Inge, 2016). These benefits should be viewed in the context of the risks of micronutrient deficiencies, the potential for post-surgical weight loss failure, uncertainty about the morbidity and mortality beyond three years after surgery, and ethical considerations regarding giving consent to bariatric surgery procedures that are irreversible (Beamish, 2017; National Heart Lung and Blood Institute, 2012).
Screening potential candidates pre-operatively is necessary to identify those adolescents who will benefit most from bariatric surgery. However, reliable screening instruments are not yet available. Based on the current evidence, bariatric surgery would be medically necessary for a limited group of adolescents, in whom the benefits appear to significantly outweigh the risks. Specific patient factors to consider include (Beamish, 2017; National Heart Lung and Blood Institute, 2012):

- Severe obesity (body mass index $\geq 35$ kg/m$^2$) with major co-morbidities or extreme obesity (body mass index $\geq 40$ kg/m$^2$) with minor co-morbidities.
- At or near skeletal maturity.
- Ability to provide informed consent either alone or with parental or family support.
- Ability to comply with post-surgical requirements.
- Demonstration of unsuccessful weight loss despite compliance with lifestyle interventions.
- No psychiatric or developmental comorbidities that would impede their ability to understand the risks and benefits of the procedure or adhere to post-operative requirements.
- No eating disorders based on deteriorations in the satiety regulation such as melanocortin 4 receptor mutation, leptin resistance, or Prader–Willi syndrome, as the eating behavior will not be normalized after bariatric surgery.

These new findings change previous conclusions. Therefore, policy changes allowing for bariatric surgery in the adolescent population are warranted.

In 2018, we added three clinical studies that provide longer-term outcomes (greater than 5 years) in adolescent bariatric surgical cohorts: the Follow-up of Adolescent Bariatric Surgery at 5 Plus Years extension study (Inge, 2017); the Adolescents with Morbid Obesity study (Olbers, 2017); and the Teen-Longitudinal Assessment of Bariatric Surgery study (Sarwer, 2017). The new data confirm previous findings that Roux-en-Y gastric bypass surgery is safe for carefully selected adolescents, when performed by dedicated specialty centers for adolescent bariatric surgery, and it results in substantial and durable bodyweight reduction and cardiometabolic benefits that extend into their adult years. No policy changes are warranted.

Policy ID changed from CP# 08.03.01 to CCP.1054.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Inge (2017)</td>
<td>Key points:</td>
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| Long-term outcomes of bariatric surgery in adolescents with severe obesity. | • A follow-up analysis of 58 persons aged 13-21 years who underwent Roux-en-Y gastric bypass for clinically severe obesity between May, 2001 and February, 2007 at a U.S. hospital; outcomes were assessed five to 12 years after surgery.  
• Mean follow-up=8.0 years (standard deviation [SD] 1.6, range 5.4 to 12.5); mean cohort age = |
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<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Follow-up of Adolescent Bariatric Surgery at 5 Plus Years extension study | 25.1 years (SD 2.4); mean body mass index = 41.7 kg/m² (SD 2.0); mean change in body mass index = -29.2% (SD 13.7).  
- Outcomes reported as prevalence at baseline versus at long-term follow-up:  
  - Elevated blood pressure 47% versus 16%; P = .001.  
  - Dyslipidaemia 86% versus 38%; P < .0001.  
  - Type 2 diabetes 16% versus 2%; P = 0.03.  
- At follow-up, 46% had mild anemia (not requiring intervention), 45% had hyperparathyroidism, and 16% had low amounts of vitamin B12 (below the normal cutpoint). |
| Olbers (2017) | Key points:  
- Nationwide, prospective, non-randomized controlled study comparing outcomes of 81 adolescents (aged 13 - 18 years) with severe obesity undergoing Roux-en-Y gastric bypass at three specialized pediatric obesity treatment centers in Sweden versus 80 matched adolescent controls undergoing conservative treatment versus 81 matched adult controls undergoing Roux-en-Y gastric bypass.  
- Roux-en-Y gastric bypass cohort characteristics: mean age 16.5 years (SD 1.2); bodyweight 132.8 kg (SD 22.1); and body mass index 45.5 kg/m² (SD 6.1).  
- Adolescents with severe obesity undergoing Roux-en-Y gastric bypass had substantial and durable weight loss over five years, along with improvements in comorbidities and risk factors, but also additional surgical interventions and nutritional deficiencies.  
- Conventional non-surgical treatment was associated with weight gain and a quarter of patients had bariatric surgery within five years. |
| Sarwer (2017) | Key points:  
- A prospective study comparing outcomes of bariatric surgery (n = 119) versus lifestyle modification (n = 169) at six, 12, and 24 months (surgery patients only) after treatment. Measures included changes in weight, macronutrient intake, eating behavior, and relevant demographic and physiological variables.  
- Compared to lifestyle modification, bariatric surgery was associated with significantly greater reductions in both weight loss and the number of disordered eating symptoms (self-reported weight consciousness, craving for sweets, and consumption of zinc at six to 12 months postoperatively).  
- The two groups differed in self-reported intake of a number of macronutrients at six and 12 months from baseline, but not total caloric intake. |
| Inge (2016) | Key points:  
- Prospective, U.S. multisite observational study of 242 patients ages 12 to 19 years who underwent; Roux-en-Y gastric bypass (161 participants) or sleeve gastrectomy (67 patients); Mean (+/- standard deviation) baseline age 17 +/- 1.6 years, mean body mass index 53; 75% female, and 72% white.  
- Mean weight decrease: 27% (95% confidence interval [CI] 25 to 29) in the total cohort, 28% in Roux-en-Y gastric bypass (95% CI 25 to 30), and 26% in sleeve gastrectomy (95% CI 22 to 30).  
- Remission rates at 3 years, 95% CI:  
  - Type 2 diabetes: 95%, 85% to 100%.  
  - Abnormal kidney function: 86%, 72% to 100%.  
  - Prediabetes: 76%, 56% to 97%. |
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<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Ells (2015) Cochrane review Surgery for obesity in children and adolescents | **Key points:**  
- Systematic review of one randomized controlled trial comparing laparoscopic adjustable gastric band (25 patients) to a multi component lifestyle program (25 patients) in Australia.  
- Overall quality: low with high risk of bias (no blinding).  
- Laparoscopic adjustable gastric band versus lifestyle program:  
  - Mean age: 16.5 versus 16.6 years.  
  - Mean weight reduction at 2 years: 34.6 kg (95% CI 30.2 to 39.0) versus 3.0 kg (95% CI 2.1 to 8.1) \( (P < .001) \).  
  - Change in body mass index 12.7 (95% CI 11.3 to 14.2) versus 1.3 (95% CI 0.4 to 2.9) \( (P < .001) \).  
  - Adverse events: 12/25 (48%) versus 11/25 (44%), 28% of adolescents undergoing laparoscopic adjustable gastric band required revision.  
- No data for all-cause mortality, behavior change, participants' perspectives, or socioeconomic effects.  
- Insufficient evidence to assess efficacy across populations from different countries, socioeconomies, and ethnic backgrounds, who may respond differently, and lack of randomized controlled trials and long-term follow-up. |
| Black (2013) Bariatric surgery for obese children and adolescents | **Key points:**  
- Systematic review and meta-analysis of 23 studies (637 total patients) using adjustable gastric band, sleeve gastrectomy, Roux-en-Y gastric bypass, or biliopancreatic diversion.  
- For all procedures, significant decreases in body mass index at one year (average weighted mean body mass index difference: \(-13.5\) kg/m\(^2\); 95% CI \(-14.1\) to \(-11.9\)).  
- Bariatric surgery leads to significant short-term weight loss in obese children and adolescents, but risks of complications are not well defined.  
- Long-term, prospectively designed studies, with clear reporting of complications and comorbidity resolution and measures of health-related quality of life are needed to firmly establish the harms and benefits. |
| National Heart Lung and Blood Institute (2012) Guidelines for cardiovascular health and risk reduction in children and adolescents | **Key points:**  
- Bariatric surgery is an option for persons ages 12 to 21 years if their body mass index is far above 35 kg/m\(^2\), they have significant comorbidities unresponsive to lifestyle therapy for more than one year, and they are referred to a center with bariatric surgical expertise.  
- Recommendation was based on small case series suggesting that bariatric surgery performed on a research protocol in conjunction with a comprehensive lifestyle weight loss program improved weight loss, body mass index, and other outcomes (e.g., insulin resistance, glucose tolerance, and cardiovascular measures). |
Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare& Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
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<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)</td>
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<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
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<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components</td>
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<td>43845</td>
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