Subject: Pediatric Bariatric Surgery			Original Effective Date: 4/27/11
Molina Clinical Policy:	MCP-091	Revision Date(s): 4/2/14	
Molina Clinical Policy: Approval Date:	4/2/14		

PREFACE

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.1Molina Clinical Policy

FDA INDICATIONS

Bariatric surgery is procedural and not subject to FDA regulation. The FDA has approved two adjustable gastric band devices for use in adults; these devices are not FDA approved for adolescents or children younger than age 18. The FDA approved devices are as follows:

On June 5, 2001, the FDA granted marketing approval for the LAP-BAND® Adjustable Gastric Banding (LAGB®) System (BioEnterics, Inc.).[1] The device is indicated in severely obese adults who have been obese for ≥ 5 years and for whom conservative medical treatment has been unsuccessful. Patients must have a body mass index (BMI) ≥ 40, BMI ≥ 35 with one or more severe morbid (unhealthy) conditions, or be ≥ 100 pounds over their estimated ideal weight. According to the FDA, the device is contraindicated in patients who are poor candidates for surgery, have certain stomach or intestinal disorders, have an infection, need to take aspirin frequently, or are addicted to alcohol or drugs. Patients must be willing to make major changes in their dietary habits and lifestyle. Therefore, this device should not be used on patients who are not able or willing to follow the rules for eating and exercise that are recommended by the doctor following surgery. ***The device has not been approved for children or adolescents.***

On September 28, 2007, the FDA issued an approval for the REALIZE™ Adjustable Gastric Band formerly known as Swedish Adjustable Gastric Band.[2] It was approved for use in weight reduction for patients with morbid obesity and is indicated for individuals with a Body Mass Index (BMI) of at least 40 kg/m2, or a BMI of at least 35 kg/m2 with one or more co-morbid conditions. It is for use in morbidly obese ***adult patients*** who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.

On February 16, 2011, the FDA approved Allergan's LAP-BAND Adjustable Gastric Banding System, a device implanted around the upper part of the stomach to limit the amount of food that can be eaten at one time.[58] The

LAP-BAND is intended to be used for weight loss ***in adults*** who have not lost weight using non-surgical weight loss methods. The newly-approved indication is limited to patients with a BMI of 30 to 34 and at the highest risk of obesity-related complications. This represents a narrower indication than originally sought by Allergan. The company had also proposed to expand the indication to include people with a BMI of 35 to 39 and no obesity related condition. Patients using the LAP-BAND must be willing to make major changes to their lifestyle and eating habits. The LAP-BAND should not be used in certain people, for example, those who are poor candidates for surgery, have certain stomach or intestinal disorders or an infection, take aspirin frequently, or are addicted to alcohol and/or drugs. It should also not be used in those not able or willing to follow dietary and other recommendations.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

There is a National Coverage Determination available for Bariatric Surgery for the Treatment of Morbid Obesity (100.1).[3] Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS), laparoscopic adjustable gastric banding (LAGB), and stand-alone laparoscopic sleeve gastrectomy (LSG) are covered for Medicare beneficiaries who have a body-mass index $\geq$ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. These procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence. The following bariatric surgery procedures are non-covered for all Medicare members:

- Open adjustable gastric banding;
- Open sleeve gastrectomy; and,
- Laparoscopic sleeve gastrectomy (prior to June 27, 2012)
- Open and laparoscopic vertical banded gastroplasty

INITIAL COVERAGE CRITERIA

Pediatric Bariatric Surgery may not be authorized in persons who are under the age of 18 or in those who have not attained an adult level of physical development and maturation because there is insufficient evidence to conclude that it is safe and efficacious in this population.

CONTINUATION OF THERAPY

Not applicable

COVERAGE EXCLUSIONS

Pediatric Bariatric Surgery may not be authorized in persons who are under the age of 18 or in those who have not attained an adult level of physical development and maturation because there is insufficient evidence to conclude that it is safe and efficacious in this population.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Surgical treatment of obesity involves reducing the size of the stomach to restrict calorie intake and/or changing the intestinal anatomy to induce malabsorption.[4] The goal of surgical treatment for obesity is to induce significant weight loss and, thereby, reduce the incidence or progression of obesity-related comorbidities, as well as to improve quality of life. The purpose of performing bariatric surgery in pediatric patients is to reduce the lifelong impact of severe obesity. The two most common bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB), which is a purely restrictive procedure, and Roux-en-Y gastric bypass (RYGB), which is both restrictive and malabsorptive.[4,8,31,46] Alternatives to bariatric surgery include: dietary modification, increasing physical activity and exercise, behavioral modification, and pharmacotherapy.

The following are descriptions of various bariatric surgery procedures: [3,8,31]

Roux-en-Y Gastric Bypass (RYGBP)-The RYGBP achieves weight loss by gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. RYGBP procedures can be open or laparoscopic.

Laparoscopic Adjustable Gastric Banding (LAGB)-LAGB/AGB achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. AGB procedures are generally performed as a laparoscopic procedure.

Biliopancreatic Diversion with Duodenal Switch (BPD/DS)-BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD /DS are a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastamosis and a lower ileo-ileal anastamosis. BPD/DS procedures can be open or laparoscopic.

Vertical Sleeve Gastrectomy (VSG)-Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP. Sleeve gastrectomy procedures can be open or laparoscopic.

Vertical Gastric Banding or Vertical Banded Gastroplasty (VGB or VBG)-The VBG achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VGB procedures are essentially no longer performed.

GENERAL INFORMATION

Summary of Medical Evidence for Bariatric Surgeries

Roux-en-Y Gastric Bypass (RYGBP)

There were no randomized-control or minimally biased prospective cohort/comparison studies found in this population of patients. Case studies and retrospective studies are not considered sufficient evidence.[32] This procedure has limited data for adolescents and is associated with a high rate of malabsorptive complications.[11,13,17,18,20,31,33,53] Limited data from retrospective case series have suggested that RYGBP does lead to sustained and clinically significant weight loss compared to non-operative approaches but the procedure also increases the risk of nutrient deficiency and protein energy malnutrition.[11,13,17,18,20,33,53] Long term effects on this population are not clear.[4,8] Potentially life threatening complications such as shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstructions were reported in the RYGB studies.[8]

Laparoscopic adjustable gastric banding (LAGB) procedures

The FDA has not approved gastric banding devices for use in individuals under the age of 18 years.[1,2] Long-term results in younger patients demonstrate high reoperative rates for dysphagia, band migration, port disruption, and infection Despite the marketed reversibility of the LAGB, banding may cause scar tissue in the stomach and increase complication rates in patients undergoing revisional surgery. Additional studies are required to better characterize the complication rate and long-term outcomes of LAGB in the adolescent population. [70]

Holterman et al. (2012) compared the baseline and the 18-month follow-up for weight and metabolic characteristics of super obese (SO) (body mass index [BMI] ≥50 kg/m(2)) and morbidly obese (MO) (BMI <50 kg/m(2)) adolescents who participated in a prospective longitudinal study of gastric banding delivered in an adolescent multidisciplinary treatment program. Other than BMI, MO (n = 11) and SO (n = 7) patients have similar degree of insulin resistance, dyslipidemia, and nonalcoholic fatty liver disease. Serum C-reactive protein (10.2 ± 5.6 SO vs 4 ± 3.9 µg/mL MO [P < .02]) and leptin (71 ± 31 SO vs 45 ± 28 MO ng/mL [P = .04]) were more elevated in SO patients. Although weight loss is similar (30 ± 19 kg MO vs 28 ± 12 kg SO, P = .8 at 18 months; mean percent change in BMI, 22.8% ± 11.6% vs 20.5% ± 10.3% SO, P = .2), SO patients has less resolution of insulin resistance and dyslipidemia but experienced significantly improved health-related quality of life. The authors concluded that The SO adolescents demonstrate equivalent short-term weight loss and improved quality of life but delayed metabolic response to a gastric banding-based weight loss treatment program compared with MO patients, illustrating the importance of early referral for timely intervention of MO patients. [68]

A 2010 prospective randomized-control trial[5] (n=50) compared the outcomes of adolescents between the ages of 14 and 18 with a BMI > 35 and with medical complications (e.g., metabolic syndrome, hypertension, asthma, back pain, physical limitations, difficulties with activities of daily living, psychosocial difficulties or subject to bullying) and attempts to lose weight by lifestyle means for more than 3 years. These individuals were assigned either to a supervised lifestyle intervention or to undergo gastric banding. The study was limited by a 28 percent dropout rate. In the gastric banding group 24/25 participants completed the study versus 18/25 subjects in

lifestyle group. An excess weight loss of 78.8% (95% CI, 66.6%-91.0%) was reported in the gastric banding group compared to an excess weight loss of 13.2% (95% CI, 2.6%-21.0%) in the lifestyle group. At 24 months, none of the gastric banding group had metabolic syndrome p=0.008 compared to 4/18 (22%) in the lifestyle group (P= .13). Surgical revision was required in seven patients (28%). Six proximal pouch dilatations caused reflux, heartburn or vomiting. One patient developed acute cholecystitis requiring cholecystectomy. Study limitations included short term outcome evaluation of 2 years, high drop dropout rate. The study was powered to measure differences in weight outcomes rather than differences in adverse events or health measures.

A small prospective longitudinal study (n=20) of the safety and efficacy of laparoscopic adjustable gastric banding for morbidly obese adolescents aged 14 to 17 years with 12 month (n=20) and 18 month follow-up (n=12).[14] Body mass index was 50 $\pm$ 10 kg/m^2, and excess weight was 178 $\pm$ 53lb. Comorbidities included hypertension (45%), dyslipidemia (80%), insulin resistance (90%), metabolic syndrome (95%), and biopsy-proven nonalcoholic steatohepatitis (88%). The 12 month % excess weight loss was 34% and 41% after 18 months. The metabolic syndrome was resolved in 63% and 82% of the patients at 12 and 18 months. The band related complications included 3 wound explorations for tube and port related issues, (2, 5, and 13 months post op) and the need for 2 laparoscopic revisions for 1 band malfunction at 2 months and a hiatal hernia repair at 15 months. The reliability of the study is limited by the small sample size and short term follow-up of outcomes. There was also a 20 percent dropout rate (5 of 25 patients) were unavailable for data collection.

A case series (n=73) by Nadler et al.[7] (2008) reported outcomes for adolescents between the ages of 13 and 17 who underwent LABG. The mean preoperative BMI was 48. The %EWL at six-, 12- and 24-month follow-up was 35% +/- 16%, 57% +/- 23%, and 61% +/- 27%, respectively. Gastric perforation after a reoperation for band replacement occurred in one patient. Band slippage occurred in a total of six patients, and three patients developed symptomatic hiatal hernias. Two patients were lost to follow-up in the first year, and 3 patients were lost to follow-up in the second year, for an overall compliance rate of at least 89.5%.

Biliopancreatic Diversion with Duodenal Switch

There is insufficient data to support biliopancreatic diversion with duodenal switch in the pediatric/adolescent populations.[31] There were no randomized-control or minimally biased prospective cohort/comparison studies found in this population of patients. The largest studies performed in adolescents are from case series. Case studies and retrospective studies are not considered sufficient evidence.[32] This procedure has limited data in adolescents and is associated with malabsorptive complications, concerns of long-term nutritional complications have not been resolved.[31] Reports describing the outcomes related to biliopancreatic diversion and duodenal switch, exist but currently are not robust. Concerns regarding associated fat-soluble vitamin deficiencies and long-term protein malnutrition limit the ability to offer specific recommendations at present. [64]

The largest case series (n=68) with mean follow-up range of 11 years (range 2-23). Their mean age was 16.8 years.[37] The investigators conducted a bilio-pancreatic diversion (BPD) with distal gastrectomy and 50cm common channel. They reported 78% excess weight loss at the cost of protein deficiency at 16%. A total of 19 reoperations were performed in 14 patients (20%), including 7 revisions (13%). The long term mortality rate was 5%. It was not clear if the results improved over time. A smaller series of 32 children with a mean age of 16 years conducted various operations including gastric bypass with various intestinal limb lengths.[13] A 33%

overall excess weight loss was reported after follow-up of 1-15 years. Weight regain of 18% was defined as a failure rate.

A more recent retrospective case series of patients (n=13) aged 15-17 years that underwent an open biliopancreatic diversion with duodenal switch were followed for 2 to 16 years.[50] An average estimated excess weight loss of 82% was reported with 15% of participants requiring reoperations. There were unresolved calcium and parathyroid level issues. The authors indicated the clinical significance was not clear. These issues are consistent with other reports of greater risks for vitamin deficiencies.[31, 51,52]

Sleeve Gastrectomy (SG)

Laparoscopic sleeve gastrectomy is a promising but unproven procedure for adolescents. It has the advantage of avoiding intestinal bypass and implantation of a foreign body. In adults, the procedure appears to have outcomes comparable to LRYGB in terms of weight loss and resolution of comorbidities. Whether LSG is equivalent to LRYGB in the treatment of T2DM remains unclear. Further studies should certainly be undertaken to better characterize the efficacy and safety of LSG in this population. [70]

The updated 2012 Position Statement on Sleeve Gastrectomy from the Committee of the American Society for Metabolic and Bariatric Surgery (ASMBS) recognizes SG as an acceptable option as a primary bariatric procedure and as a first-stage procedure in high-risk patients as a part of a planned staged approach. From the current published data, SG has a risk/benefit profile between LAGB and laparoscopic RYGB. As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this can be managed effectively with reintervention. Informed consent for SG used as a primary procedure should be consistent with the consent provided for other bariatric procedures and should include the risk of long-term weight gain. There is no mention of pediatric or adolescent patient selection criteria within the position statement. [67]

Alqahtani et al (2012) performed a retrospective review of all patients who underwent LSG by a single surgeon between March 2008 and February 2011 was performed. The 222 patients included 108 pediatric patients aged 21 years or younger and 114 adult patients older than 21 years. Baseline, operative, perioperative, and available follow-up data were abstracted. Pediatric patients had a mean age of 13.9 ± 4.3 years and a mean baseline body mass index (BMI) of 49.6 kg/m(2), whereas adults had a mean age of 32.2 ± 9.4 years and a mean baseline BMI of 48.3 kg/m(2). Our pediatric group achieved a mean percent of excess weight loss (%EWL) of 32.4, 52.1, 65.8, and 64.9 % at 3, 6, 12, and 24 months postoperative, respectively, compared with a mean %EWL of 30.9, 55.2, 68.5, and 69.7 %, respectively, in our adult group ($p > 0.05$). During the 24-month follow-up period, pediatric patients attended 71.7 % of follow-up visits, whereas adults attended 61.2 % of follow-up visits ($p = 0.01$). Postoperative complications occurred in six (5.6 %) and eight (7 %) pediatric and adult patients, respectively. The authors concluded that laparoscopic sleeve gastrectomy in the pediatric age group is of similar safety and effectiveness compared with adults. Pediatric patients had fewer major complications and were more compliant with follow-up than adults. Nevertheless, long-term results are required to further clarify the safety and effectiveness of LSG in pediatric patients. [69]

Vertical Gastric Banding/Vertical Banded Gastroplasty (VGB or VBG)

There is insufficient data to support VGB/VBG in the pediatric/adolescent populations. There were no randomized-control or minimally biased prospective cohort/comparison studies found in this population of

patients. A limited number of retrospective case studies are available with small study groups, high loss to follow-up. There was inconclusive evidence to draw conclusions due to low quantity and quality of evidence.[8] It has been reported that RYGB and LAGB have almost completely replaced VGB.[52,54]

Bariatric Surgeries (Meta-analysis)

Bretault et al (2013) performed a meta-analysis of bariatric surgery following treatment for craniopharyngioma. Mean age at the time of craniopharyngioma surgery was 16 years, and mean BMI was 23.5 kg/m2. Before bariatric surgery, mean age was 24 years, and mean BMI was 49.6 kg/m2. The mean BMI before bariatric surgery was 55.2 kg/m2 for the RYGB group, 48.9 kg/m2 for the SG group, and 45.6 kg/m2 for the LAGB group. A total of 21 cases were included: 6 with adjustable gastric banding, 8 with sleeve gastrectomy, 6 with Roux-en-Y gastric bypass, and 1 with biliopancreatic diversion. After data pooling, mean weight difference was -20.9 kg after 6 months (95% confidence interval [CI], -35.4, -6.3) and -15.1 kg after 12 months (95% CI, -31.7, +1.4). The maximal mean weight loss was achieved by the gastric bypass group: -31.0 kg (95% CI, -77.5, +15.5) and -33.7 kg (95% CI, -80.7, +13.3) after 6 and 12 months, respectively. In conclusion, this systematic review and meta-analysis indicates that bariatric surgery induces important weight loss at 1 year, in obese patients after treatment of craniopharyngioma, even if the impact seems less important than for common obese patients. There are no current guidelines for bariatric surgery in patients with lesional HyOb. Well-designed prospective studies, with appropriate follow- up, are needed to clarify the role of specific bariatric procedures in HyOb due to craniopharyngioma. Larger studies are warranted to establish appropriate selection criteria and the best surgical technique to perform bariatric surgery. [71]

A systematic review and metaanalysis (2008) was conducted to evaluate the evidence on pediatric obesity and bariatric surgery.[6] The studies evaluated LAGB (n=8 studies; 352 patients; mean BMI 45.8), RYGB (n=6 studies; 131 patients; mean BMI 51.8), and other bariatric procedures (n=5 studies; 158 patients; mean BMI 51.8). The average patient age was 16.8 years (range, 9-21). Meta-analyses of body mass index (BMI) reductions at longest follow-up indicated sustained and clinically significant BMI reductions for both LAGB and RYGB. Comorbidity resolution was infrequently reported, but surgery appeared to resolve some conditions such as diabetes and hypertension. Reoperations were performed in 8% (28/352) patients to correct various complications such as band slippage (most frequently reported in 3% of cases), intragastric band migration, gastric dilation, hiatal hernia, psychological intolerance of the band, tubing crack and cholecystitis in LAGB patients. Micronutrient iron deficiencies were reported in 8 cases and 5 cases of mild hair loss. For RYGB, more severe complications have been documented, such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. One patient died 9 months following surgery due to severe Clostridium difficile colitis, severe diarrhea, multiple organ failure and profound hypovolemia.[11] Three additional patients died several years following surgery that have been reported unlikely to be directly related to the bariatric surgeries (one patient in the Barnett study died 4 years following surgery,[12] 2 patients in the Sugerman study[13] died 2 years and 6 years following surgery). One study reported a lower compliance of postsurgical dietary regimens, dietary supplements, and exercise recommendations in the pediatric population. Only 13% followed the regimen as instructed in one study. The authors concluded that bariatric surgery in pediatric patients results in sustained and clinically significant weight loss, but has the potential for serious complications.

ECRI Institute is an independent nonprofit organization that provides evidence-based healthcare research. This organization has been designated as both a Collaborating Center of the World Health Organization and an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research and Quality. ECRI performed an evaluation of the evidence on bariatric surgery in the pediatric population.[8] A total of 17 studies with 553 pediatric patients met inclusion criteria, reporting outcomes after laparoscopic adjustable gastric banding LAGB (n=8), RYGB (n=6), VBG (n=2), and banded bypass (n=1). The average age ranged from 15.6 years to 18.1 years, with little difference in mean age among bariatric procedures. Prior to surgery, all patients had undergone multiple unsuccessful attempts at weight loss using non-surgical methods. The report defined clinically significant weight loss as 7% of body weight. The most frequently reported complication after LAGB was band slippage. Reoperations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications. No reported in-hospital or postoperative death. The most frequently reported complication after RYGB was related to protein-calorie malnutrition and micronutrient deficiency. One postoperative death was reported for RYGB; no in-hospital death was reported. Multiple potentially life-threatening complications (e.g., shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstructions) were reported in the RYGB studies. The health technology assessment provided the following summarization:

- Laparoscopic Adjustable Gastric Banding (LAGB) and Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. LAGB-Strength of evidence at longest follow-up after surgery 1.7 to 3.3 years: Weak; Strength of evidence at one year after surgery: Moderate. RYGB- Strength of evidence at longest follow-up after surgery 1 to 6.3 years: Weak; Strength of evidence at one year after surgery: Moderate.
- The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss in specific age groups (18-21, 13-17, 12 or less).

<u>Hayes, Cochrane, UpToDate etc.</u>

A Hayes Directory report for Pediatric Bariatric Surgery for Morbid Obesity was archived July, 2012 as it is outdated.

UpToDate

In a report entitled “Surgical management of severe obesity in adolescents” [66], the following is summarized:

- Surgical weight loss is an appropriate consideration for adolescents with severe obesity and with medical comorbidities who have failed to lose weight through conventional dietary interventions and behavioral modification.
- The most widely performed procedures in adolescents and adults are the roux-en-Y gastric bypass (RYGB) and adjustable gastric banding (AGB). Vertical sleeve gastrectomy (VSG) is increasing in use

as well in adolescents, but there are no published data yet on the frequency of this procedure in the adolescent age group. Other procedures that cause significant malabsorption are generally not recommended for adolescents due to lack of safety data in this age group and concerns about long-term nutritional complications.

- Weight loss surgery for adolescents should be performed in the context of a multidisciplinary program with specific expertise in adolescent medicine and extensive expertise in bariatric surgery.
- Patient selection criteria include: a BMI of ≥35 kg/m2 as a minimum threshold for consideration of weight loss surgery in an adolescent with significant medical comorbidities; physical maturity, lack of medically correctable causes of obesity, and adequate emotional maturity and stability to ensure competent decision-making and good adherence to medical follow-up; and the patient should have failed organized and sustained attempts to lose weight through lifestyle intervention.

Professional Organizations

The American Society for Metabolic & Bariatric Surgery (ASMBS) pediatric committee published an update to the best practice guidelines for surgery in morbid obesity in 2011. These guidelines indicate that according to review of the current data indicates that patient safety and weight loss outcomes for extremely obese adolescents undergoing bariatric surgery are comparable or better than those seen in adults. [64]

The Endocrine Society Prevention and treatment of pediatric obesity guidelines [73] indicate that bariatric surgery may be considered only under the following conditions:

- Must have reached Tanner 4 or 5 pubertal development and final or near-final adult height with a BMI greater than 50 kg/m2 or has BMI above 40 kg/m2 and significant, severe comorbidities.
- The guidelines recommend against bariatric surgery for preadolescent children, for pregnant or breastfeeding adolescents, and for those planning to become pregnant within 2 years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved eating disorder, untreated psychiatric disorder, or Prader-Willi syndrome.

The National Institute for Health and Clinical Excellence states “Surgical intervention is not generally recommended in children or young people. Bariatric surgery may be considered for young people only in exceptional cases, and if they have achieved physiological maturity”. This guideline was reviewed again in 2011 and indicates that there is no new evidence that would contradict the current guideline. [30]

Washington State Health Technology Assessment on Pediatric Bariatric Surgery (2007) evaluated the analysis by ECRI (an evidence based analysis group) and found that there was “insufficient scientific evidence to conclude that either LAGB or RYGB bariatric procedures are safe in patients under eighteen.[8] Compelling concerns included the lack of evidence on the impact of performing the surgery on patients that have not yet reached full maturity, small but significant surgical complications, and concern over the ability of the patient to legally consent as well as adequately appreciate the long term impacts. The committee found that there was sufficient scientific evidence to conclude that the LAGB bariatric procedure is safe in patients aged eighteen to twenty, though a majority of committee members were not confident in the evidence. The committee found that

there was insufficient scientific evidence to conclude that RYGB was safe in patients aged eighteen to twenty. Compelling concerns included the long term issues related to irreversibility, the more invasive surgical procedure, nutrition deficiency and malabsorption, and the increased and more serious procedural risks (reported post-operative death and serious surgical complications). This report has not been updated since 2007.[8]

CODING INFORMATION (NOT COVERED)

CPT	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

HCPCS	Description
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD-9	Description-HOSPITAL PROCEDURES (NOT COVERED)
43.82	Laparoscopic vertical (sleeve) gastrectomy
44.31	High gastric bypass
44.38	Laparoscopic gastroenterostomy
44.39	Other gastroenterostomy
44.68	Laparoscopic gastroplasty
44.95	Laparoscopic gastric restrictive procedure
44.96	Laparoscopic revision of gastric restrictive procedure
44.97	Laparoscopic removal of gastric restrictive device(s)
44.98	Laparoscopic adjustment of size of adjustable gastric restrictive device

ICD-10 CM	Description- (NOT COVERED)
E 66.8	Other obesity
E66.01	Morbid severe obesity d/t excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug induced obesity
E66.9	Obesity unspecified
Z68.51	Body mass index BMI pediatric < 5th % for age
Z68.52	Body mass index BMI ped 5th % to < 85th % age
Z68.53	Body mass index BMI ped 85th % to < 95th % age
Z68.54	Body mass index ped >/equal to 95th % for age

ICD-10 PCS	Description-HOSPITAL PROCEDURES (NOT COVERED)
0D16079	Bypass stomach to duodenum auto tiss subst open
0D1607A	Bypass stomach to jejunum auto tissue subst open
0D1607A	Bypass stomach to jejunum auto tissue subst open
0D1607B	Bypass stom to ileum auto tiss subst open
0D1607L	Bypass stom to trans colon auto tiss subst open
0D160J9	Bypass stomach to duodenum synth subst open
0D160JA	Bypass stomach to jejunum synthetic subst open approach
0D160JB	Bypass stom to ileum synth subst open
0D160JL	Bypass stom to trans colon synth subst open
0D160K9	Bypass stomach to duodenum nonauto tiss subst open
0D160KA	Bypass stomach to jejunum nonauto tissue subst open
0D160KB	Bypass stomach to ileum nonauto tiss subst open
0D160KL	Bypass stomach trans colon nonauto tiss subst open
0D160Z9	Bypass stomach to duodenum open approach
0D160ZA	Bypass stomach to jejunum open approach
0D160ZB	Bypass stomach to ileum open approach
0D160ZL	Bypass stomach trans colon open approach
0D16479	Bypass stom to duod auto tiss subst perq endo

0D1647A	Bypass stom to jejunum auto tiss subst perq endo
0D1647B	Bypass stom to ileum auto tiss subst perq endo
0D1647L	Bypass stom trns colon auto tiss subst perq endo
0D164J9	Bypass stom duodenum synth subst perq endo
0D164JA	Bypass stom to jejunum synth subst perq endo
0D164JB	Bypass stom to ileum synth subst perq endo
0D164JL	Bypass stom trns colon synth subst perq endo
0D164K9	Bypass stom to duodenum non auto tiss subst perq endo
0D164KA	Bypass stom to jejunum nonauto tiss subst perq endo
0D164KB	Bypass stom to ileum nonauto tiss subst perq endo
0D164KL	Bypass stom trns colon nonauto tiss subst perq endo
0D164Z9	Bypass stom to duodenum perq endo approach
0D164ZA	Bypass stom to jejunum perq endo approach
0D164ZB	Bypass stom to ileum perq endo approach
0D164ZL	Bypass stom to transverse colon perq endo
0D16879	Bypass stomach duod auto tiss nat/art opening endo
0D1687A	Bypass stomach to jejunum auto tissue nat/art opening endo
0D1687B	Bypass stomach ileum auto tiss nat/art opening endo
0D1687L	Bypass stomach trns colon auto nat/art opening endo
0D168J9	Bypass stom duod synth sub nat/art opening endo
0D168JA	Bypass stomach to jejunum synth sub nat/art opening endo
0D168JB	Bypass stom ileum synth sub nat/art opening endo
0D168JL	Bypass stom trns colon synth sub nat/art opening endo
0D168K9	Bypass stomach duod nonauto tiss nat/art opening endo
0D168KA	Bypass stomach to jejunum nonauto tiss nat/art opening endo
0D168KB	Bypass stomach ileum nonauto tiss nat/art opening endo
0D168KL	Bypass stomach trns colon nonauto tiss nat/art opening endo
0D168Z9	Bypass stomach to duodenum nat/art opening endo
0D168ZA	Bypass stomach to jejunum nat/art opening endo
0D168ZB	Bypass stomach to ileum nat/art opening endo
0D168ZL	Bypass stomach to trans colon nat/art opening endo
0DB60ZZ	Excision of stomach open approach
0DB63ZZ	Excision stomach percutaneous approach
0DB67ZZ	Excision stomach via natural/artificial opening
0DQ64ZZ	Repair stomach percutaneous endoscopc approach
0DV64CZ	Restriction stomach extralum device perq endo
0DW643Z	Revision infus device stomach perq endo approach
0DW64CZ	Revision extralum device stomach perq endo approach

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