

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 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 Determination (LCD) will supersed the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Severe obesity in children and adolescents is defined as a body mass index (BMI) that is \geq 120 percent of the 95th percentile or \geq 35 kg/m2 (whichever is lower). Among adolescents in America ages 12 to 19 years, rates for both obesity and extreme obesity has increased significantly. Rates for obesity have increased from 2.6% in 1988 to 10.5% in 1994; for extreme obesity the rate doubled from 9.1% in 1988 to 20.6% in 1994 (Hayes, 2020).

As adults, adolescents are likely to remain in the obese range – 65% will have Class III obesity (BMI ≥40 kg/m2) and have a higher prevalence of cardiovascular risk factors when compared with children who had lesser degrees of obesity. Development of other comorbidities include obstructive sleep apnea, diabetes, hypertension, dyslipidemia, nonalcoholic fatty liver disease, and idiopathic intracranial hypertension, depression and decreased quality of life. Severe obesity also correlates to a shorter life expectancy – treatment may reverse or prevent issues and can improve long-term health outcomes. (Inge, 2021).

Surgical treatment of obesity involves reducing the size of the stomach to restrict calorie intake and/or changing the intestinal anatomy to induce malabsorption. The goals of surgical treatment for obesity are 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. Over the last 40 years, weight loss surgery has produced significant and sustained reductions in adults with respect to BMI, diabetes, and hypertriglyceridemia. Mortality is also reduced as evidenced by the Swedish Obese Subjects Study – a 10-year follow-up of patients undergoing Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), or vertical banded gastroplasty. Bariatric surgery used to treat adolescents with severe obesity has increased over time. The main types of surgery for this population include the sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB). Other procedures may cause significant malabsorption and hence are not recommended for adolescents due to lack of safety data and concerns about long-term nutritional complications. Adjustable gastric banding (AGB) is rarely used due to increasing use of SG. (Inge, 2021). Bariatric surgery procedures are described below: (FDA, 2021; Inge, 2021; FDA, 2015; FDA, 2011; FDA, 2007; Treadwell et al., 2007):

- Roux-en-Y Gastric Bypass (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. The
 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/AGB) achieves weight loss by gastric restriction only. A
 band creating a gastric pouch with a capacity of 15-30 cc's encircles the uppermost portion of the stomach. The
 adjustable 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. This allows the size of the gastric outlet
 to be modified as needed, depending on the rate of weight loss.
- Biliopancreatic Diversion with Duodenal Switch (BPD/DS) 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. Patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (e.g., duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD/DS are a variant of the BPD procedure and involves resection of the

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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) 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) achieves weight loss by gastric restriction only; VGB procedures are essentially no longer performed. The upper part of the stomach is stapled to create a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. A non-adjustable band is also placed around the new inlet in an attempt to prevent future enlargement of the stoma/opening. Patients thus experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less.

Due to the risks of weight loss surgery in children and adolescents, alternatives are recommended as a first line approach to treatment. This includes multidisciplinary approaches utilizing family-based behavioral techniques to achieve success with dietary modification, increasing physical activity and exercise, reducing caloric intake, improving the quality of food intake, and increasing energy expenditure. Pharmacotherapy may also be recommended. Data also suggest that dietary and behavioral interventions alone do not lead to significant long-term success for those with severe obesity. While more drugs are being approved by the FDA for adults to manage obesity, pharmacotherapy options for adolescents are limited. National and professional organizations such as the American Academy of Pediatrics (AAP) recommend a staged approach to weight management based on the child's degree of obesity and response to previous interventions. (Inge, 2021). Additional information can be found under the "National and Professional Organizations" section below.

COVERAGE POLICY

Pediatric Bariatric Surgery **is considered not medically necessary** and 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. (AMR, 2020; CMS, 2013).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Evidence relating to bariatric surgery for treatment of severe obesity in adolescents is moderate in size and low in overall quality to assess the safety and/or impact on health outcomes or patient management. There is a lack of large, well-designed clinical trials that provide data on long-term efficacy and safety of these surgeries. Small case series have shown some promising results but also indicate that the individuals regained most (or all) of their weight 5 to 10 years post-surgery. Systematic reviews and prospective cohort studies show concerns about possible nutritional deficiency in growing children and adolescents; selection criteria for which surgical procedure is best and for appropriate surgical candidates are unclear. The risks of complications as well as compliance and follow up are not well defined in the literature for the pediatric and adolescent population. Long-term, prospectively designed studies, with clear reporting of complications and co-morbidity resolution are needed to firmly establish the harms and benefits of bariatric surgery in children and adolescents. For additional peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

Hayes (2020) reviewed 15 studies that support bariatric surgery in the population for those with severe obesity to encourage weight loss and decrease BMI to improve obesity-related outcomes. Data from six comparative effectiveness studies compared bariatric surgery with nonsurgical interventions; four studies compared bariatric surgery outcomes in adolescents versus adults; and four studies compared various bariatric procedures. In addition,

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two large noncomparative studies support the efficacy of bariatric surgery. Surgery resulted in noticeable improvements in weight loss compared to those who did not have surgery and used weight loss management interventions. A potential risk of bariatric surgery among adolescents includes the need for nutritional supplements throughout the patient's life; in addition, future reoperation may also be needed.

National and Professional Organizations

The American Academy of Pediatrics (AAP) published a policy statement on *Metabolic and Bariatric Surgery for Pediatric Patients with Severe Obesity.* The statement supports the use of surgery within the context of a multidisciplinary program with pediatric expertise for treating youth with severe obesity. In addition to providing clinical guidance, the policy statement highlighted concerns about access to care, which represents a barrier to the appropriate use of bariatric surgery among eligible adolescents. (Bolling et al., 2019).

The AAP also published a position statement titled *Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practices* (Armstrong et al., 2019). Highlights of recommendations are noted below:

- Recognize the risks that severe obesity places on adolescents (e.g., liver disease, type 2 diabetes mellitus, dyslipidemias, sleep apnea, orthopedic complications, and mental health conditions).
- Understand the efficacy, risks, benefits, and long-term health implications of the common metabolic and bariatric surgery procedures. This will aid pediatricians to assist the family with medical decision-making.
- Provide timely referrals for patients with severe obesity (and meet criteria for surgery as noted in the Position Statement) for comprehensive, multidisciplinary, pediatric-focused metabolic and bariatric surgery programs.
- Coordinate pre- and postoperative care with the patient and family as well as the multidisciplinary care team (e.g., anesthesia, surgical).
- Monitor patients postoperatively for micronutrient deficiencies iron, folate, and vitamin B12 should be used, as needed. In addition, monitor patients for risk-taking behavior and mental health problems.

The American Heart Association (AHA) published a scientific statement regarding bariatric surgery for children and adolescents. The statement provides recommendations of a standardized definition of severe obesity in children and adolescents as well as to increase awareness of the issue through a summary of current medical literature. The AHA determined that bariatric surgery is only appropriate for some of the adolescent population who demonstrate medical necessity and psychological readiness (Kelly et al., 2013).

The American Society for Metabolic and Bariatric Surgery (ASMBS) updated the guidelines for *Pediatric and Metabolic Bariatric Surgery Guidelines* in 2018. (Pratt et al., 2018). A comprehensive literature search was conducted that spanned from 2009–2017; a total of 1387 articles and supporting evidence were reviewed. Data show an increase of support for the use of metabolic and bariatric surgery (MBS) in adolescents. Early intervention is likely to reduce the risks of obesity, including organ damage and long-term comorbidities. A lifelong, multidisciplinary approach is necessary and may include a combination of lifestyle changes, nutrition, medications, and MBS. The authors also recommend using the Centers for Disease Control and Prevention definitions of severe obesity in children, including the age- and sex-matched growth charts defining class II obesity as 120% of the 95th percentile and class III obesity as 140% of the 95th percentile. Adolescents with class II obesity and a co-morbidity or with class III obesity should be considered for MBS. Surgery should also be considered for adolescents with cognitive disabilities, a history of mental illness or eating disorders that are treated, immature bone growth, or low Tanner stage.

The United States Preventive Services Task Force (USPSTF) (2017) recommends screening for obesity in children and adolescents 6 years and older. Comprehensive, intensive behavioral interventions should be referred to promote improvements in weight status. Bariatric surgery was not addressed as it was outside the scope of the review.

The American Association of Clinical Endocrinologists, the Obesity Society, the American Society of Metabolic and Bariatric Surgery, the Obesity Medicine Association, and the American Society of Anesthesiologists published *Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures* (Mechanick et al., 2019). The updated guidelines include new and updated topics regarding contextualization in an adiposity-based, chronic disease complications–centric model, nuance-based, and algorithm/checklist-assisted clinical decision-making about procedure selection, novel bariatric procedures, enhanced recovery after bariatric surgery protocols, and logistical concerns (including cost factors) in the current healthcare arena. In addition, 85 numbered recommendations have updated supporting evidence.

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SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes CPT Description gastric restrictive 43644 surgical, procedure; with Laparoscopy, 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 Gastric restrictive procedure, open; removal of subcutaneous port component only 43887 43888 Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

HCPCS Code

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

ICD-10 Codes

ICD-10	Description	
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	

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Z68.53	Body mass index BMI ped 85th % to < 95th % age
Z68.54	Body mass index ped >/equal to 95th % for age

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/10/2022	Policy reviewed, no changes to coverage criteria. Renamed to include "adolescent" population. Updated Overview, Summary of Medical Evidence (inclusion of national and professional organization guidelines), and Reference sections.
8/11/2021	Policy reviewed, no changes, updated references. No new evidence to change the non-coverage criteria for the pediatric and adolescent population.
7/10/2018, 6/19/2019, 6/17/2020 3/8/2017 12/16/2015, 6/15/2016 4/2/2014	Policy reviewed, no changes. Policy reviewed, no changes. Updated the Summary of Medical Evidence section and references. Policy reviewed, no changes. Policy reviewed; no new evidence was found to change the non-coverage criteria for pediatric population.

REFERENCES

Government Agencies

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Evidence Based Reviews and Publications

- 1. Advanced Medical Reviews (AMR) Peer Review. Policy reviewed in June 2020 by an AMR practicing, board-certified physician in the areas of Surgery General, Surgery Vascular, Surgical Critical Care.
- 2. Hayes. Comparative effectiveness review: Bariatric surgeries for treatment of obesity in adolescents. Available from <u>Hayes</u>. Published January 21, 2019. Updated January 20, 2020. Accessed June 23, 2022. Registration and login required.
- 3. Inge TH. Surgical management of severe obesity in adolescents. Available from <u>UpToDate</u>. Updated August 25, 2021. Accessed June 23, 2022. Registration and login required.

National and Specialty Organizations

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- 5. Pratt JSA, Browne A, Browne NT, Bruzoni M, Cohen M, Desai A, et al. American Society for Metabolic and Bariatric Surgery (ASMBS) pediatric metabolic and bariatric surgery guidelines, 2018. Surg Obes Relat Dis 2018;14:882–901. Available <u>here</u>. Accessed July 6, 2022.
- United States Preventive Services Task Force (USPSTF). Final recommendation statement: Obesity in children and adolescents screening. Available from <u>USPSTF</u>. Published June 20, 2017 (update in progress). Accessed June 23, 2022.

Peer Reviewed Publications

- 1. Alqahtani AR, Elahmedi M, Qahtani AR, et al. Laparoscopic sleeve gastrectomy in children and adolescents with Prader-Willi syndrome: A matched-control study. Surg Obes Relat Dis. 2016 Jan;12(1):100-10. doi: 10.1016/j.soard.2015.07.014. Accessed July 16, 2021.
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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

Washington

If bariatric surgery is requested or prescribed under the Early Periodic Screening Development and Testing (EPSDT) program, it is evaluated as a covered service under EPSDT's standard of coverage that requires the service to be medically necessary, safe and effective, and non – experimental.