

<b>Subject: Pediatric Bariatric Surgery</b>		<b>Original Effective Date:</b> 4/27/2011
<b>Policy Number:</b> MCP-091	<b>Revision Date(s):</b> 4/2/2014, 3/8/2017	
<b>Review Date:</b> 12/16/2015, 6/15/2016, 7/10/2018, 6/19/2019		
<b>MCPC Approval Date:</b> 3/21/2017, 7/10/2018, 6/19/2019		

**DISCLAIMER**

*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.<sup>1</sup>*

**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. 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. 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. Alternatives to bariatric surgery include: dietary modification, increasing physical activity and exercise, behavioral modification, and pharmacotherapy.

*Bariatric surgery procedures include:*

*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 anastomosis and a lower ileo-ileal anastomosis. 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.

**RECOMMENDATION**

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.

**SUMMARY OF MEDICAL EVIDENCE** <sup>5-37</sup>

The body of 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. The evidence for bariatric surgery in adolescents with severe obesity is limited by the 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, and selection criteria for which surgical procedure is best and for appropriate surgical candidates are unclear. Additionally, the risks of complications, 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.

**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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-10 CM	Description: [For dates of service on or after 10/01/2015]
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

## RESOURCE REFERENCES

### Government Agency

- Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1). Effective date June 27, 2012. Accessed at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=4&bc=BAABAAAAAQAAAA%3d%3d&>

2. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. The lap-band® adjustable gastric banding system. Summary of safety and effectiveness data. February 16, 2011. Accessed at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P000008b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008b.pdf)
3. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. ORBERA™ Intra-gastric Balloon System. Summary of Safety and Effectiveness. No. P14008. August 5, 2015. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p140008>.
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. REALIZE™ Adjustable Gastric Band Model 2200-X. Summary of Safety and Effectiveness. No. P070009.. Sept. 28, 2007. Accessed at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM302775.pdf>.

#### Peer Reviewed Literature

5. PE, Sawyer SM, Laurie C, Brown WA, Skinner S, Veit F, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. *JAMA*. 2010 Feb 10;303(6):519-26.
6. Treadwell JR, Sun F, Schoelles K. Systematic review and meta-analysis of bariatric surgery for pediatric obesity. *Ann Surg*. 2008 Nov;248(5):763-76.
7. Nadler EP, Youn HA, Ren CJ, Fielding GA. An update on 73 US obese pediatric patients treated with laparoscopic adjustable gastric banding: comorbidity resolution and compliance data. *J Pediatr Surg*. 2008 Jan;43(1):141-6.
9. Spear BA, SE Barlow, Ervin C, et al. Recommendations for Treatment of Child and Adolescent Overweight and Obesity. 2007;120;S254-S288. The American Academy of Pediatrics. Accessed at: [http://pediatrics.aappublications.org/cgi/reprint/120/Supplement\\_4/S254](http://pediatrics.aappublications.org/cgi/reprint/120/Supplement_4/S254)
10. Lawson ML, Kirk S, Mitchell T, et al. One-year outcomes of Roux-en-Y gastric bypass for morbidly obese adolescents: a multicenter study from the Pediatric Bariatric Study Group. *Journal of Pediatric Surgery* 2006;41:137-143.
11. Holterman A, Browne A, Tussing L et al. A prospective trial for laparoscopic adjustable gastric banding in morbidly obese adolescents: an interim report of weight loss, metabolic and quality of life outcomes. *Journal of Pediatric Surgery*. January 2010;45(1): 74-79.
12. Apadia FS, Adami GF, Marinari GM et al. Bariatric surgery in adolescents: a long-term follow-up study. *Surgical Obesity Related Dis* 2007;3(4): 465-468.
13. Nadler EP, Youn HA. Ginsburg HB et al. Short-term results in 53 US obese pediatric patients treated with laparoscopic adjustable gastric banding. *Journal of Pediatric Surgery*. 2007;42(1):137-141.
14. Han JC, Lawlor DA, Kimm SY. Childhood Obesity. *Lancet* May 2010;375:1737-48
15. Dillard BE, Gorodner V, Galvani C et al. Initial experience with the adjustable gastric band in morbidly obese US adolescents and recommendations for further investigation. *Journal of Pediatric Gastroenterology Nutrition* 2007;45:240.
16. Tsai WS, Inge TH, Burd RS. Bariatric surgery in adolescents: recent national trends in use and in-hospital outcome. *Arch Pediatric Adolescent Med*. 2007;161(3):217-221.
17. Papadia FS, Adami GF, Marinari GM et al. Bariatric surgery in adolescents: a long-term follow-up study. *Surg Obes Related Disorders* July 2007;3(4): 465-468.
18. Til H, Bluher S, Hirsch W, Kiess W. Efficacy of laparoscopic sleeve gastrectomy (LSG) as a stand-alone technique for children with morbid obesity. *Obesity Surgery* 2008;18:1047.
19. DeMaria, Pate V, Warthen M, Winegar DA. Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. *Surgical Obesity Related Diseases*. 2010 Jul-Aug;6(4):347-55.
20. Marceau P, Marceau S, Biron S et al. Long-term experience with duodenal switch in adolescents. *Obesity Surgery*, 2010. 20;1609-1616.
21. Pratt J, Lenders CM, Dionne EA, et al. Best practice updates for Pediatric/Adolescent weight loss surgery. *Obesity* May, 2009;17(5):901-910.
22. Michalsky M, Kramer Developing Criteria for Pediatric/Adolescent Bariatric Surgery Programs. *Pediatrics* 2011;128;S65.

23. Holterman AX, Holterman M, Browne A, Henriques S, Guzman G, Fantuzzi G. Patterns of surgical weight loss and resolution of metabolic abnormalities in superobese bariatric adolescents. *J Pediatr Surg*. 2012 Sep;47(9):1633-9. doi: 10.1016/j.jpedsurg.2012.02.002.
24. Alqahtani A, Alamri H, Elahmedi M, Mohammed R. Laparoscopic sleeve gastrectomy in adult and pediatric obese patients: a comparative study. *Surg Endosc*. 2012 Nov;26(11):3094-100. doi: 10.1007/s00464-012-2345-x. Epub 2012 May 31
25. Bondada S, Jen HC, Deugarte DA. Outcomes of bariatric surgery in adolescents. *Curr Opin Pediatr*. 2011 Oct;23(5):552-6. doi: 10.1097/MOP.0b013e32834a1b49.
26. Bretault M, Boillot A, Muzard L, Poitou C, Oppert JM et al. Clinical review: Bariatric surgery following treatment for craniopharyngioma: a systematic review and individual-level data meta-analysis. *J Clin Endocrinol Metab*. 2013 Jun;98(6):2239-46. doi: 10.1210/jc.2012-4184. Epub 2013 Mar 26.
27. Hsia DS, Fallon SC, Brandt ML. Adolescent Bariatric Surgery. *Arch Pediatr Adolesc Med*. 2012;166(8):757-766. doi:10.1001/archpediatrics.2012.1011. Accessed at: <http://archpedi.jamanetwork.com/article.aspx?articleid=1263348>
28. Zeller MH; Reiter-Purtill J; Ratcliff MB; Inge TH; Noll JG. Two-year trends in psychosocial functioning after adolescent Roux-en-Y gastric bypass. *Surgery for Obesity & Related Diseases*. 7 (6) (pp 727-32), 2011.
29. Bondada S(1), Jen HC, Deugarte DA. Outcomes of bariatric surgery in adolescents. *Curr Opin Pediatr*. 23 (5) (pp 552-6), 2011.
30. Black J.A., White B., Viner R.M., Simmons R.K. Bariatric surgery for obese children and adolescents: A systematic review and meta-analysis. *Obesity Reviews*. 14 (8) (pp 634-644), 2013.
31. Barnett SJ. Bariatric surgical management of adolescents with morbid obesity. *Curr Opin Pediatr*. 25 (4) (pp 515-20), 2013.
32. Cozacov Y., Roy M., Moon S., Marin P., Menzo E.L., Szomstein S., Rosenthal R. Mid-term results of laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass in adolescent patients. *Obesity Surgery*. 24 (5) (pp 747-752), 2014.
33. Paulus GF, de Vaan LE, Verdam FJ, et al. Bariatric surgery in morbidly obese adolescents: a systematic review and meta-analysis. *Obes Surg* 2015; 25:860.
34. Alqahtani A, Elahmedi M, Qahtani AR. Laparoscopic Sleeve Gastrectomy in Children Younger Than 14 Years: Refuting the Concerns. *Ann Surg* 2016; 263:312.
35. Alqahtani AR, Elahmedi MO, Al Qahtani AR, et al. Laparoscopic sleeve gastrectomy in children and adolescents with Prader-Willi syndrome: a matched-control study. *Surg Obes Relat Dis* 2016; 12:100.
36. Inge TH, Courcoulas AP, Jenkins TM, et al. Weight Loss and Health Status 3 Years after Bariatric Surgery in Adolescents. *N Engl J Med* 2016; 374:113.
37. Alqahtani A, Elahmedi M, Qahtani AR. Laparoscopic Sleeve Gastrectomy in Children Younger Than 14 Years: Refuting the Concerns. *Ann Surg* 2016; 263:312.

### Professional Society Guidelines

38. American Society for Metabolic & Bariatric Surgery (ASMBS). Position Statements: Accessed at: <https://asmbs.org/>
  - Sleeve gastrectomy as a bariatric procedure. 2012.
  - Bariatric Surgery in Class I Obesity. 2012.
  - Intra-gastric Balloon Therapy Endorsed by SAGES. 2015.
  - Gastric Plication. 2011.
39. American Society for Bariatric Surgery. Guidelines on Bariatric Surgery. Accessed at: <http://www.lapsurgery.com/BARIATRIC%20SURGERY/ASBS.htm>.
40. Mechanick JI, Youdim A, Jones DB, et al. American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (AAACE/TOS/ASMBS) practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient—2013 Update. *Surg Obes Rel Dis*. 2013; 9(2):159-191.

### Hayes and Other Resources

41. Advanced Medical Review (AMR: Policy reviewed by a practicing physician Board certified in Surgery General, Surgery Vascular, Surgical Critical Care, Surgery. Jan 31, 2014.
42. UpToDate: [website]: Waltham, MA: Walters Kluwer Health; 2019
  - Xanthakos SA, Inge TH, Klish WJ et al. Surgical management of severe obesity in adolescents.

43. Hayes: Search & Summary: Winifred Hayes Inc. Lansdale, PA.
- Roux-en-Y Gastric Bypass for Treatment of Obesity in Children. Feb 12, 2015. [Archived]
  - Roux-en-Y Gastric Bypass (RYGB) for Treatment of Obesity in Adolescent Patients. Nov 30, 2017. [Archived]
  - Sleeve Gastrectomy for Treatment of Obesity in Children. Feb 12, 2015. [Archived]
  - Sleeve Gastrectomy for Treatment of Obesity in Adolescent Patients. Dec, 2017. [Archived]
  - Comparative Effectiveness Review. Bariatric Surgeries for Treatment of Obesity in Adolescents. Jan, 2019.
44. ECRI Institute. Treadwell J, Sun F, Bruening W, et al. Bariatric surgery. Health Technology Assessment and additional guidance information. Prepared for the WSHA Health Technology Assessment Program by the ECRI Institute. Olympia, WA: Washington State Healthcare Authority (WSHA); August 20, 2007; updated in 2016. Accessed at: <http://www.hca.wa.gov/about-hca/health-technology-assessment>

***Review/Revision History:***

*4/2/14: This policy was reviewed and updated. No new evidence was found to change the non-coverage criteria for the pediatric population.*

*12/16/15 & 6/15/16: Policy was reviewed, no changes.*

*3/8/17: Policy was reviewed and the clinical criteria section did not change. The following sections were updated:*

*Summary of medical evidence, guidelines and references.*

*7/10/18, 6/19/19: Policy was reviewed, no changes.*