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.¹

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 5-37**

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.

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<td>43770</td>
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<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)</td>
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<td>Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only</td>
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**S2083** Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

**ICD-10 CM**

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</tbody>
</table>

**RESOURCE REFERENCES**

**Government Agency**

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http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008b.pdf
3. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. ORBERA™ Intragastric Balloon
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. REALIZE™ Adjustable Gastric Band
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevices
AdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM302775.pdf.

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adolescents: a multicenter study from the Pediatric Bariatric Study Group. Journal of Pediatric Surgery 2006;41:137-
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15. DeMaria, Pate V, Warthen M, Vinegar DA. Baseline data from American Society for Metabolic and Bariatric
Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database.
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Professional Society Guidelines

- Sleeve gastrectomy as a bariatric procedure. 2012.  
- Intragastric Balloon Therapy Endorsed by SAGES. 2015.  
- Gastric Plication. 2011.


Hayes and Other Resources


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- Xanthakos SA, Inge TH, Klish WJ et al. Surgical management of severe obesity in adolescents.
43. Hayes: Search & Summary: Winifred Hayes Inc. Lansdale, PA.


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.