Clinical Policy Title: Bariatric surgery for children and adolescents

Clinical Policy Number: 08.03.01

Effective Date: March 1, 2014
Initial Review Date: September 18, 2013
Most Recent Review Date: September 21, 2016
Next Review Date: September 2017

Policy contains:
- Bariatric surgery.
- Obesity.
- Adolescents.

Related policies:

CP# 08.03.02  Bariatric surgery for adults

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

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of bariatric surgery in children and adolescents to be investigational and, therefore, not medically necessary.

While there is a need to help obese minors avoid serious health problems, there is little high quality evidence on safety, outcomes and cost effectiveness for bariatric surgery in this population. Noncompliance with medical regimens is particularly common among adolescents with chronic illnesses, and available evidence does not show directly that bariatric surgery during adolescence confers additional benefit, compared with bariatric surgery during early adulthood.

Limitations:

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

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:
Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

43645 - Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption.

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).

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.

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

**Background**

Childhood obesity is a serious public health problem in the United States. Childhood obesity has more than doubled in children and tripled in adolescents in the past 30 years. In 2010, approximately 17 percent of children and adolescents ages two to 19 years of age were obese and 32 percent were either overweight or obese. Obesity prevalence continues to be higher among non-Hispanic black and Hispanic children and adolescents than among non-Hispanic white youth (Ogden 2012).

Childhood obesity has both immediate and long-term effects on health and well-being. According to the Centers for Disease Control and Prevention (CDC), obese youth are more likely to have risk factors for cardiovascular disease and are at greater risk for major comorbidities, including: Type 2 diabetes, severe and/or progressive nonalcoholic fatty liver disease and nonalcoholic steatohepatitis (NASH), bone and joint problems, sleep apnea, and social and psychological problems, such as stigmatization and poor self-esteem (CDC 2013, Pratt 2009). Obese adolescents are more likely to have pre-diabetes. Obese youths are likely to become obese adults and are therefore more at risk for adult health problems, including: heart disease, type 2 diabetes, stroke, several types of cancer, and osteoarthritis (CDC 2013).
The fundamental cause of obesity in childhood is a greater imbalance between energy intake and expenditure, than is expected for normal growth and development. Usually, this occurs over a period of time and in the setting of a susceptible genetic background and environmental factors. Infants of mothers with diabetes and mothers who smoke during pregnancy have increased risk of subsequent obesity. Some medications cause excess weight gain. Other factors, such as a shortened period of breast-feeding and a reduced amount of sleep during infancy, may increase the risk of obesity (Daniels 2009).

Populations that are at special risk for obesity are children with a body mass index (BMI) between the 85th and 95th percentiles, a positive family history of obesity in one or both parents, early onset of increasing weight beyond that appropriate for increase in height, excessive increase in weight during adolescence, particularly in African-American girls, children who have been previously very active and become inactive, or adolescents who are inactive in general (NHLBI 2012).

The CDC recommends the use of BMI to screen for overweight and obesity in children beginning at two years of age (CDC 2013). BMI is a reliable indicator of adiposity for most children and teens and is calculated from a child’s height and weight. The BMI number is plotted on the CDC BMI-for-age growth charts (for either girls or boys) to obtain a percentile ranking. The percentile indicates the relative position of the child’s BMI number among children of the same sex and age. BMI-for-age weight status categories define overweight as the 85th to less than the 95th percentile range, and obese as equal to, or greater than, the 95th percentile (CDC 2013). However, BMI alone is not a diagnostic tool in children. BMI should be integrated with other evaluations of diet, physical activity, attitudes, family history, and psychosocial and behavioral assessments (CDC 2013, Daniels 2009).

The general goals of weight loss and management are to reduce body weight, maintain a lower body weight over the long term and prevent further weight gain. A range of effective multidisciplinary options exist for the management of overweight and obese patients, including dietary therapy, altering physical activity patterns, behavior therapy techniques, pharmacotherapy, surgery, and combinations of these techniques. The objective of surgical interventions in overweight and obese children and adolescents is sustained weight loss and prevention or amelioration of obesity-related co-morbidities (NHLBI 2012).

**Bariatric surgery:**

When behavioral or pharmacological interventions fail to achieve lasting weight loss, bariatric surgery has been used as an effective short-term option. Bariatric surgery is designed to restrict food intake and decrease the absorption of food in the stomach and intestines, enabling patients to lose weight and decrease their risk for obesity-related health risks or disorders. Surgery may be performed using an “open” laparotomy approach or by laparoscopy. Increasingly, laparoscopic procedures are preferred because when they are compared with open surgery, less extensive cuts are required. This may lead to potentially minimal tissue damage, fewer post-operative complications and earlier hospital discharge.

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1BMI is calculated as weight (kg)/height squared (m²). To estimate BMI using pounds and inches, use: [weight (pounds)/height squared (inches²)] x 703.
Common types of bariatric surgery include:

- Gastric bypass (Roux-en-Y gastric bypass (RYGB), gastrojejuninal anastomosis).
- Vertical-banded gastroplasty (VBG)(sleeve gastroplasty).
- Sleeve gastrectomy (vertical gastrectomy).
- Gastric banding using one of two FDA approved laparoscopic adjustable gastric band (LAGB) devices — LAP-BAND® (Allergan Inc., Irvine CA) and the REALIZE® Adjustable Gastric Band (Ethicon Endo-Surgery Inc., Blue Ash, OH).
- Biliopancreatic diversion (BPD) with or without duodenal switch (BPD-DS).

**Searches**

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s (AHRQ) National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 8, 2016. Search terms were "bariatric surgery" [MeSH] restricted to articles of child and adolescent populations.

We included:

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

**Findings**

 Patients with a higher BMI and more significant medical illness are at increased risk during bariatric surgery, but the long-term outcome of bariatric surgery in children and adolescents is unknown. A systematic review found no long-term outcome studies or randomized controlled trials (RCTs) comparing surgical treatment in children or adolescents to other obesity treatments (Canoy 2011). The American Academy of Pediatrics and other professional organizations (see references) have set guidelines to protect children but do not offer evidence of comparative evidence of long-term effectiveness. There are important concerns of harm, as up to 10 percent of surgically treated patients suffer significant complications.

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

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

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

**Concerns for true informed consent:**

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

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

**Policy updates:**

In 2016, we added one new systematic review and recent results of the prospective, multicenter Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study (Ells 2015, Inge 2016). New evidence from one small RCT in Australia found LAGB led to greater weight loss compared to a multi component lifestyle program up to two years after surgery (Ells 2015). Results of the Teen-LABS longitudinal study highlight significant improvements in weight, cardiometabolic health and weight-related quality of life three years
after RYGB or SG. Final data collection in the Teen-LABS study will take place in 2016 (Clinicaltrials.gov Identifier: NCT00474318). These benefits should be viewed in the context of the risks of micronutrient deficiencies and the potential need for future abdominal procedures. Longer-term studies are needed to provide a better understanding of the role of bariatric surgery in the treatment of severe obesity in adolescents. These results do not change the original conclusions; therefore, no policy changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Inge (2016)</strong></td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Teen-LABS study (Clinicaltrials.gov Identifier: NCT00474318) | - Prospective, multisite observational study of 242 patients age 12 to 19 years.  
- Analysis included RYGB (161 participants) or SG (67 patients).  
- Mean (+/-SD) baseline age 17 +/- 1.6 years, mean BMI 53; 75% female, and 72% white.  
- Mean weight decrease (95% CI): 27% (25 to 29) in the total cohort, 28% in RYGB (25 to 30) and 26% in SG (22 to 30).  
- Remission rates (95% CI):  
  - Type 2 diabetes 95% (85 to 100).  
  - Abnormal kidney function 86% (72 to 100).  
  - Prediabetes 76% (56 to 97).  
  - Elevated blood pressure 74% (64 to 84).  
  - Dyslipidemia 66% (57 to 74).  
- Significant improvement in weight-related quality of life.  
- Hypoferritinemia 57% (50 to 65).  
- One or more additional intra-abdominal procedures 13% (9 to 18). |
| **Ells (2015)** | **Key points:** |
| Cochrane review Surgery for obesity in children and adolescents | - Systematic review of one RCT comparing LAGB (25 patients) to a multi component lifestyle program (25 patients) in Australia.  
- Overall quality: low with high risk of bias (no blinding).  
- LAGB versus lifestyle program:  
  - Mean age: 16.5 and 16.6 years, respectively.  
  - Mean weight reduction at 2 years: 34.6 kg (95% confidence interval [CI] 30.2 to 39.0) versus 3.0 kg (95% CI 2.1 to 8.1) (P < 0.001).  
  - Change in BMI 12.7 (95% CI 11.3 to 14.2) versus 1.3 (95% CI 0.4 to 2.9)(P < 0.001).  
  - Adverse events: 12/25 (48%) versus 11/25 (44%), 28% of the adolescents undergoing LAGB required revision.  
- No data for all-cause mortality, behavior change, participants’ perspectives and socioeconomic effects.  
- Insufficient evidence to assess efficacy across populations from different countries, socioeconomic and ethnic backgrounds, who may respond differently, and lack of RCTs and long-term follow-up. |
| **Treadwell (2008)** | **Key points:** |
| Bariatric surgery in pediatric obesity | - Systematic review and meta-analysis of 19 studies with at least one-year follow up; no RCTs available. |
## Citation

Content, Methods, Recommendations

- For LAGB = eight studies (n = 352 patients with mean BMI 45.8); Roux-en-Y gastric bypass (RYGB) = six studies (n = 131 patients with mean BMI 51.8); other surgical procedures = five studies (n = 158 patients with mean BMI 48.8). Average patient age was 16.8 years (range, 9 to 21 years).
- Results of meta-analyses: Sustained and clinically significant BMI reductions for LAGB and RYGB.
- Comorbidity resolution was sparsely reported, but surgery appeared to resolve some, including diabetes and hypertension.
- Most frequent complications:
  - For LAGB, band slippage and micronutrient deficiency, with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation.
  - For RYGB, pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition.
- Conclusions: Weak evidence supporting sustained and clinically significant weight loss, but with potential for serious complications.

### Whitlock (2008) for AHRQ

**Weight management programs**

**Key points:**

- Systematic review of 18 case series (612 total patients) of highly selected morbidly obese adolescents. LAGB (six case series), laparoscopic RYGB (2), open RYGB and other procedures including VBG; BPD, jejunoeval bypass (JIB); GP (9).
- Overall quality: Fair or poor, retrospective with incomplete reporting of outcomes, complications and comorbidities, and limited follow up beyond one year.
- Moderate, substantial weight loss in the short to medium term and resolution of comorbidities, such as sleep apnea and asthma.
- Laparotomy and gastric bypass associated with more severe obesity than LAGB.


**Best practice updates for pediatric/adolescent weight loss surgery**

<table>
<thead>
<tr>
<th>Banding surgical technique</th>
<th>Open or laparoscopic RYGB</th>
</tr>
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<tbody>
<tr>
<td>Short-term weight reduction</td>
<td>5.0 to 10.2 kg/m² (n = 122).</td>
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<tr>
<td>Maintenance 1 – 5 years</td>
<td>7.3 to 12.7 kg/m² (n = 59).</td>
</tr>
<tr>
<td>Complications</td>
<td>Band slip or removal in 10% to 13%. Nutritional related 17%.</td>
</tr>
</tbody>
</table>

**Key points:**

- Systematic review of 18 total case series: RYGB (10 series, including one multicenter study); AGB (eight); other (seven).
- Recommendations based on extracted evidence from case series and expert opinions and literature from bariatric surgery in severely obese adults.
- RYGB is considered a safe and effective option for extremely obese adolescents with appropriate long-term follow-up and attention to potential vitamin deficiency.
- AGB not FDA-approved for use in adolescents and should be considered investigational. Off-label use can be considered under IRB–approval.
- BPD and DS procedures not recommended in adolescents based on substantial risks of protein.
Citation | Content, Methods, Recommendations
---|---
Black (2013) | Bariatric surgery for obese children and adolescents

**Key points:**
- Systematic review and meta-analysis of 23 studies (637 total patients) using AGB, SG, RYGB or BPD.
- For all procedures, significant decreases in BMI at one year (average weighted mean BMI difference: -13.5 kg/m²; 95% CI -14.1 to -11.9).
- Bariatric surgery leads to significant short-term weight loss in obese children and adolescents, but risks of complications are not well defined.
- Long-term, prospectively designed studies, with clear reporting of complications and comorbidity resolution and measures of HRQoL are needed to firmly establish the harms and benefits.

CMS (2013) | Facility certification requirements

**Key points:**
- Technology assessment of eight studies published since 2006 NCD for facility accreditation requirements.
- Sufficient evidence demonstrates continuing the requirement for certification of bariatric surgery facilities would not improve health outcomes for Medicare beneficiaries.
- CMS proposes to remove this certification requirement.
- ASMBS and ACS accreditation programs have established general accepted standards in bariatric surgery, and the ongoing establishment of a unified accreditation program by these two professional societies will continue to evolve, to address quality improvement in this field.

Canoy (2011) | Obesity in children

**Key points:**
- Literature review comparing multiple medical, nutritional, environmental, behavioral and surgical approaches to obesity in childhood.
- No RCTs available involving surgical approaches compared to any of the non-surgical options.

**Glossary**

**Biliopancreatic diversion (BPD)** — Involves removing part of the stomach and connecting the remaining part to the lower portion of the small intestine, bypassing the duodenum. BPD with a duodenal switch (BPD-DS) involves removing part of the stomach, but leaving the pylorus intact. The pylorus is connected to a lower segment of the intestine and the duodenum is connected to the lower part of the small intestine.

**Duodenum** — The shortest segment and first part of the small intestine, which receives partially digested food from the stomach and begins the absorption of nutrients.

**Gastrectomy** — Surgical removal of all or part of the stomach.

**Gastric banding** — Uses an adjustable band placed around the stomach near its upper end, creating a small pouch and a narrow passage into the larger remainder of the stomach. Gastric banding avoids the problems associated with malabsorptive techniques and is technically reversible.
**Gastric bypass** — Combines the creation of a small stomach pouch to restrict food intake, and construction of a bypass of the duodenum and other segments of the small intestine, to produce malabsorption.

**Gastroplasty** — Also referred to as stomach stapling, gastroplasty involves the stapling of the upper portion of the stomach horizontally. A small opening is left for food to pass through to the lower portion. The outlet of the pouch is restricted by a band, which slows emptying, allowing the person to feel full after only a few bites of food.

**Ileum** — The final and longest segment of the small intestine. It is specifically responsible for the absorption of vitamin B12 and the reabsorption of conjugated bile salts.

**Jejunoileal bypass** — The proximal jejunum is joined to the distal ileum, bypassing a large segment of the small bowel.

**Jejunum** — The middle part of the small intestine, connecting the duodenum and the ileum.

**Roux-en-Y gastric bypass** — The most commonly performed gastric bypass procedure. A small stomach pouch is created by stapling or by vertical banding, to restrict food intake.

**Sleeve gastrectomy** — Also known as partial or vertical gastrectomy, is a restrictive procedure involving resection of the greater curvature of the stomach. May be used as the first procedure in a staged surgical approach, or as a stand-alone procedure. Can be open or laparoscopic, but is not reversible.

**Vertical banded gastroplasty** — A restrictive procedure that uses both a band and staples to create a small stomach pouch. The pouch limits the amount of food that can be eaten at one time and slows passage of the food into the remainder of the stomach and gastrointestinal tract.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Overview of the IOM’s Childhood Obesity Prevention Study: Fact Sheet. September 2004. Institute of Medicine of the National Academies website.


**Clinical trials:**


**CMS National Coverage Determinations (NCDs):**

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

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

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)</td>
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<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
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<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)</td>
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<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component and subcutaneous port components</td>
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<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)</td>
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<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty</td>
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<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty</td>
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<tr>
<th>ICD-10 Code</th>
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<tr>
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<td>Morbid (severe) obesity due to excess calories</td>
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<td>Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age</td>
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