
Health Technology Clinical Committee

Findings and Coverage Decision

Date: August 24, 2007

Topic: Pediatric Bariatric Surgery

Number and Coverage Topic

20070801 – Pediatric Bariatric Surgery

HTCC Coverage Determination

Pediatric Bariatric Surgery for patients under age 18 is **not a covered benefit** due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.

Pediatric Bariatric Surgery for patients aged 18 - 20 years is a **covered benefit** only under the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination

❖ **Indications and Limitations of Coverage**

- Patients aged 18 to 20 years old
- Bariatric surgical procedure of Laparoscopic adjustable gastric banding only
- Patients must meet and abide by all other agency bariatric surgery program criteria (e.g. body mass index, presence of co-morbid condition(s), pre-surgical weight loss, specified centers or practitioners)

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

❖ **Non-Covered Indicators**

- Patients under 18 years of age
- Surgical procedures other than laparoscopic adjustable gastric banding

Health Technology Background

Pediatric bariatric surgery, which includes patients 20 years of age and younger, is a surgical intervention intended to induce weight loss and resolve co-morbid conditions linked to obesity (e.g., hypertension, diabetes type II, dyslipidemia, obstructive sleep apnea, asthma, GERD, musculoskeletal disorders). Morbid obesity, in adults, is defined as a body mass index (BMI) of at least 40 or a BMI of 35 with co-morbid conditions. The proportion of overweight and obese individuals has increased for all populations. For pediatric population, the same or higher thresholds have been applied. In Washington State, 11% of adolescents are overweight (190,327), with 2.5% estimated to be morbidly obese or 43,256 children. Washington agencies Medicaid and Uniform Medical plan programs cover approximately 177,177 children aged 13-20. 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.

The potential advantage of pediatric bariatric surgery is that surgically limiting caloric intake can more effectively result in clinically significant weight loss. Sustained and significant weight loss improves or eliminates co-morbid conditions, body image, depression, and social stigmatization. Current alternatives are not as effective at weight loss and comparisons with other treatments for the co-morbid conditions aren't available.

Potential risks of bariatric surgery include: failure of surgery to produce weight loss, patient compliance with required post-operative instructions and diet, complications requiring re-operation, intolerable side-effects resulting in revision/conversion surgery. Common surgical complications (infection, shock, peri/post operative bleeding, and death); procedure specific complications (band slippage, stomach erosion, port/tubing problems, pouch dilation, stomal stenosis, staple line disruption, internal hernia, choleystectomy, gastrointestinal obstructions) and other complications including malnutrition, dumping syndrome, ulcers.

The potential impact on the health system is unknown. Potential benefits include a reduction or elimination of obesity related health care disease burden and future cost savings related to prevention or alleviation of co-morbidities. The potential burden includes the initial intensity of the intervention on health care resources and patient, cost of surgery and pre and post operative care; costs and burden of surgical complications; and long term maintenance for implanted devices.

Summary of Committee Findings

The HTCC reviewed and considered the pediatric bariatric surgery technology assessment report, information provided by the Administrator, and public and agency comments. Based on the technology assessment report, the cited studies, and information presented by the technology assessment center, committee members concluded that there were meaningful differences between the two primary surgical procedure types (RYGB and LAGB) and between individuals in the higher age bracket (18-21 years old) and those under 18 years old. Thus, where relevant to the question, certain findings were separated by the committee in these categories.

Effectiveness: The committee found that there was sufficient scientific evidence, although weak because it was based on small, generally retrospective case studies, to draw conclusions about effectiveness. Three outcomes related to bariatric procedures were important: weight loss, reduction or elimination of medical co-morbidities, and improvement in psychological co-morbidities.

- ❖ The committee was confident that the scientific evidence confirms that both LAGB and RYGB bariatric procedures were effective at inducing clinically significant weight loss.
- ❖ The committee found that there was scientific evidence that confirms both LAGB and RYGB bariatric procedures improve at least some medical co-morbidity, but a majority was not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results).
- ❖ The committee found that the scientific evidence did not confirm that either LAGB or RYGB bariatric procedure improved psychological co-morbidity.

Safety: The committee found that there was sufficient scientific evidence to make certain conclusions about whether LAGB and RYGB bariatric procedures are safe for patients under 21 years.

❖ Patients under 18 years of age

The committee found that there was insufficient scientific evidence to conclude that either LAGB or RYGB bariatric procedures are safe in patients under eighteen. 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.

❖ Patients 18 to 20 years of age

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).

Cost: Committee members found that there were no independent cost analyses in any category. The cost to state agencies for bariatric surgery (including the facility and professional fees) was estimated to be \$16,000. This estimate does not include the pre-surgery multi-disciplinary care and surgery program or post surgical complications or outliers. Data was unavailable on other costs that could be saved through surgery, thus preventing committee members from estimating cost effectiveness.

Benefit Evaluation: A majority of committee members found that there was net benefit in morbidly obese patients aged 18-20 for the LAGB procedure based on the evidence regarding the technology's safety and effectiveness and cost impact relative to currently available treatments. For the RYGB procedure, a majority of members found no net benefit either because there was insufficient evidence or because there was net harm. Considerations included the critical nature of morbid obesity and related medical co-morbid conditions; benefit of intervening after physical maturation but earlier in disease progression; the magnitude of potential benefit in significant weight loss and curing or preventing co-morbid conditions; sufficient, though low confidence, evidence; lack of effective alternative treatments; the relative safety profiles of the procedures; and the current agency selection criteria for adults used to mitigate certain risks. The committee will review this policy when new evidence is available that may inform a revision to this coverage determination.

Committee Authority

Participating state agencies are required by law to comply with the decisions of the Washington State [Health Technology Clinical Committee \(HTCC\)](#), an independent committee of eleven health practitioners. RCW 70.14.090 The HTCC makes coverage determinations for selected health technologies. A health technology may include medical and surgical devices and procedures, medical equipment, and diagnostic tests. The HTCC will also decide under what specific clinical situations the health technology is covered. RCW 70.14.110 HTCC decisions are based on whether evidence that the committee finds most valid, demonstrates that the technology's safety, efficacy and cost effectiveness. Evidence includes a report concerning the technology, provided by a company specializing in objective reviews of the scientific literature, information submitted by the agencies, and public comments. The HCA Administrator considers technologies for re-review within 18 months or if new evidence becomes available. RCW 70.14.100