Health Evidence Review Commission (HERC)

Coverage Guidance: Metabolic and Bariatric Surgery

Approved 10/6/2016

HERC Coverage Guidance

Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI ≥ 35) with
  - Type 2 diabetes *(strong recommendation)* OR
  - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
- Adult obese patients (BMI ≥ 40) *(strong recommendation)*

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*
- Children and adolescents *(weak recommendation)*

Note: Definitions for strength of recommendation are provided in Appendix B: GRADE Informed Framework – Element Descriptions.

Rationale for guidance development

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline

Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

GRADE-Informed Framework

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome)*	Odds ratio: 0.48 (95% CI 0.35 to 0.64) Crude event rates 3.6% with surgery and 11.4% without surgery Number needed to treat = 13 ●●○○ *(low certainty based on consistent but indirect observational studies)*	Bariatric surgery costs tens of thousands of dollars per surgery, but has been shown to be cost effective across BMI thresholds and surgery types.	Patients would balance surgery and its risks with risks of living with morbid obesity. Many patients who have failed conservative attempts at weight loss may elect surgery. The benefits of decreased mortality, dramatic weight loss, and regression of diabetes are important	The greatest benefit may be with BMI ≥ 40 but otherwise specific subpopulations which would benefit the most from bariatric surgery are not well characterized. The pre-operative requirements for achieving optimal outcomes are unclear.
Major adverse cardiovascular events (*Critical outcome*)	Odds ratio: 0.54 (95% CI 0.41 to 0.70) Crude event rates 2.4% with surgery and 4.0% without surgery Number needed to treat = 62			

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	●●○○ (*low certainty based on consistent but indirect observational studies)*		outcomes that patients and society would strongly value. However, there would still be moderate variability because of the risks and costs associated with surgery, as well as the intensive peri- and post-operative follow up.	Given the rate of complications and need for reoperation reported in the summary literature, benefit plans may wish to consider alternative payment methodologies like bundled payments or a pay-for-outcomes approach. Surgeon case volume, and to a lesser extent hospital case volume, appear to affect outcomes for patients undergoing bariatric surgery and requirements regarding surgeon or facility
Type 2 DM remission/resolution (*Important outcome*)	Odds ratio: 3.6 to 52.4 (favoring surgery) Number needed to treat: 1 to 5			
	●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			
Hypertension remission/ resolution (*Important outcome*)	Odds ratio: 2.99 to 3.12 (favoring surgery) Number needed to treat: 4			
	●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			
Change in BMI (*Important outcome*)	Mean difference at 1 year: -5.5 to - 33.35 kg/m^2 (favoring surgery) Pooled mean difference: -7.4 kg/m^2 (favoring surgery)			

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	●●●◌ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			volume may be reasonable.

Rationale: Bariatric surgery appears to lower all-cause mortality and major adverse cardiovascular events in obese adults (low certainty), and significantly reduces BMI, and results in resolution of type 2 diabetes and hypertension. The greatest benefit appears to be with BMI ≥ 40. Though bariatric surgery is costly and carries significant perioperative risks, the clear long-term positive health benefits leads to a recommendation for coverage. The strength of the recommendation is based on the fact that there is a strong benefit on critical outcomes (particularly in diabetics), and patients desiring surgery would strongly prefer this intervention. For those without diabetes, and other comorbidities are present, the evidence is less clear, leading to a weak recommendation. Though included in the original evidence review, gastric banding procedures are not included in the recommendation for coverage because they are less effective and because of reports of late complications.

Recommendation:

Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI ≥ 35 and <40) with:
  - Type 2 diabetes *(strong recommendation)* OR
  - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
- Adult obese patients (BMI ≥ 40) *(strong recommendation)*

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*	High cost (tens of thousands of dollars) but may be cost effective especially given the long time horizon if weight loss is maintained. However, uncertainty about the long-term balance of benefits and harms could significantly alter estimates of cost-effectiveness.	High variability. If conservative treatments have failed, children, adolescents and their parents would be highly motivated to find an effective alternative intervention. Children may have a significant fear of surgery, but the profound social and emotional impact of obesity may override their concerns. Parents are likely to be more	Parental involvement in weight management plans is likely necessary to assist the effectiveness of obesity treatments (based on expert opinion). Pediatric bariatric surgery is likely to be available at only a few highly specialized centers. The American Academy of Pediatrics has 10 criteria that
Major adverse cardiovascular events (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*			
Type 2 DM remission/resolution (*Important outcome*)	Rates of remission of T2DM ranged from 50 to 100% ●○○○ *(very low certainty based on mostly small observational trials with imprecise effects)*			
Hypertension remission/ resolution	Rates of remission of hypertension ranged from 50 to 100%			

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
(*Important outcome*)	●○○○ (*very low certainty based on mostly small observational trials with imprecise effects)*		concerned about the long term health impacts of obesity than children, and may be concerned about the uncertainty about the long term benefits.	pediatric bariatric surgery programs should meet.
Change in BMI (*Important outcome*)	Mean weighted difference in BMI at 1 year (from baseline): -10.5 to -17.2 kg/m^2 ●●○○ *(low certainty based on mostly small observational trials)*			
Rationale: Bariatric surgery likely results in significant reductions in BMI (low certainty) and is associated with remission of type 2 diabetes and hypertension (very low certainty). However, coverage is not recommended because of the limited evidence about overall long-term benefits and harms of bariatric surgery in this population as well as the high variability in values and preferences.				
Recommendation: Bariatric surgery is not recommended for coverage in children and adolescents *(weak recommendation).*				

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Coverage question: Should reoperative bariatric surgery for inadequate weight loss be recommended for coverage?					
Outcomes		**Estimate of Effect for Outcome** / **Confidence in Estimate of Effect**	**Resource allocation**	**Values and Preferences**	**Other considerations**
Critical outcomes	All-cause mortality	Insufficient evidence in this population	A second high cost procedure (tens of thousands of dollars), with a history of prior failure may be more costly in total and less effective, however, the cost –effectiveness in this group is unknown.	There would be high variability in patient preferences. With a prior failure of a bariatric procedure, some patients would be hesitant to try an additional procedure given the burdens of surgery and prior ineffectiveness. Others would be motivated to try a different procedure in hopes that it would work better. Patients seeking reoperation have likely no other good potential option given failure of multiple previous alternatives (e.g. clinical, pharmacological, nutritional, physical activity, and surgical).	There is evidence of greater complications rates with reoperation. There is insufficient evidence in the reoperation group to know if their outcomes would be substantially different that those undergoing their first operation. A significant proportion of these patients would be going from a band to a RYGB (from a procedure with a higher failure rate to a lower failure rate).
		Insufficient evidence			
	Major adverse cardiovascular events	Insufficient evidence in this population			
		Insufficient evidence			
Important outcomes	Type 2 DM remission / resolution	Insufficient evidence in this population			
		Insufficient evidence			
	Hypertension remission/ resolution	Insufficient evidence in this population			
		Insufficient evidence			
	Change in BMI	Mean change in BMI (from baseline): +2.4 kg/m^2 to -17.2 kg/m^2 (follow-up ranging from 8 to 48 months)			
		●○○○ *(very low certainty based on small case series)*			
Rationale: Reoperation is associated with higher complication rates but also effective weight loss (based on very low quality evidence). While there are not long term health outcomes available, there is no reason to believe that significant weight loss in the reoperation group would be associated with less future health benefits. Therefore, the subcommittee makes no recommendation that the coverage criteria should be different between					

Coverage question: Should reoperative bariatric surgery for inadequate weight loss be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome** **Confidence in Estimate of Effect**	**Resource allocation**	**Values and Preferences**	**Other considerations**
reoperation and primary surgery. Surgeons will also evaluate their patients and consider reasons for failure when deciding if the patient is a good candidate for reoperation.				
Recommendation: No recommendation that coverage criteria for re-operation should be different than for primary surgery.				

Note: GRADE framework elements are described in Appendix B GRADE evidence profile is provided in Appendix C.

EVIDENCE OVERVIEW

Clinical background

Obesity, generally defined as a body mass index (BMI) ≥ 30 kg/m^2 in adults or above the 95^{th} percentile of age- and sex-specific BMI growth charts in children and adolescents, is common. Information from the National Health and Nutrition Examination Survey published in 2014 provides estimates of obesity prevalence of 35% of adults, 17% of 2 to 19 year olds, and 8.1% of infants and toddlers (Ogden, Carroll, Kit, & Flegal, 2014). Obesity is a risk factor for several medical conditions including heart disease, type 2 diabetes mellitus (T2DM), stroke, cancer, sleep apnea, osteoarthritis and others. The Centers for Disease Control and Prevention estimates that obesity is the second leading cause of preventable death and will likely overtake tobacco use as the leading cause of preventable death within the next decade. Older estimates from 2009 found that medical spending attributable to obesity is between $147 billion and $210 billion annually with at least $60 billion of those costs accruing to Medicare and Medicaid programs (Finkelstein, Trogdon, Cohen, & Dietz, 2009).

Data from the Oregon Behavioral Risk Factor Surveillance system in 2009 found that the overall prevalence of adult obesity in Oregon is 24%, though the prevalence of obesity in adults covered by the Oregon Health Plan is greater at 38%. The Oregon Healthy Teens Survey in 2009 estimated that approximately 11% of 8^{th} graders were obese. The Oregon Department of Public Health estimated that costs of obesity related medical care in the Medicaid program alone exceeded $333 million in 2006 (State of Oregon, Department of Human Services, 2012).

There are a number of commonly used medical treatments for obesity including structured programs to promote improved nutrition and physical activity, intensive behavioral counseling for individuals or families, and medications. The Food and Drug Administration (FDA) approved pharmaceutical treatments for obesity include orlistat (Xenical®, Alli®), lorcaserin (Belviq®), phentermine/topiramate (Qsymi®), liraglutide (Victoza®, Saxenda®), and bupropion/naltrexone (Contrave®). Several other medications and herbal supplements are also promoted for weight loss. The FDA also recently approved a weight loss device called the Maestro® Rechargable System that works by blocking signals along the vagal nerve.

Bariatric surgical procedures (sometimes also referred to as metabolic surgery) are another treatment option for obesity.

Indications

Bariatric surgery (alone or in conjunction with non-surgical treatments) is indicated for the treatment of obesity. Guidelines regarding indications for bariatric surgery vary based on BMI thresholds and the presence of obesity-related comorbid conditions.

Technology description

Bariatric procedures commonly performed in the United States include adjustable gastric banding (AGB), vertical sleeve gastrectomy (VSG), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion/ duodenal switch (BPD/DS). An excellent overview of the anatomic details of these procedures is available in the executive summary of the Washington Health Technology Assessment (WA HTA) report published in April 2015 (WA HTA, 2015).

The use of bariatric surgical procedures is growing, and approximately 179,000 procedures were performed in 2013 in the United States (U.S.). The distribution of procedure types in the U.S. has shifted with greater use of vertical sleeve gastrectomy and declining use of gastric banding. The estimated number and distribution of surgical procedures in the U.S. is summarized in Table 1.

Table 1. Estimated number and distribution of bariatric surgical procedures in the United States between 2011 and 2013.

	2011	2012	2013
Total	158,000	173,000	179,000
RYGB	36.7%	37.5%	34.2%
Gastric band	35.4%	20.2%	14.0%
Sleeve gastrectomy	17.8%	33.0%	42.1%
BPD/DS	0.9%	1.0%	1.0%
Revisions	6.0%	6.0%	6.0%
Other	3.2%	2.3%	2.7%

Reproduced from the American Society of Bariatric and Metabolic Surgeons, http://connect.asmbs.org/may-2014-bariatric-surgery-growth.html.

Abbreviations: BPD/DS – Biliopancreatic diversion/duodenal switch; RYGB – Roux-en-Y gastric bypass

Adjustable gastric banding and VSG are procedures that either functionally or anatomically reduce the size of the stomach. Adjustable gastric banding, alone among the bariatric surgical procedures, is completely reversible. Roux-en-Y gastric bypass and BPD/DS are more complicated procedures that reduce the size of the stomach and connect more distal portions of the small intestine to the gastric remnant thus bypassing varying lengths of small intestine and reducing the absorption of nutrients. For this reason, these surgeries are sometimes referred to as malabsorptive procedures, with the degree of malabsorption correlating to the length of small intestine that is bypassed. Vertical sleeve gastrectomy is sometimes performed as part of a two stage procedure for patients with extremely high BMIs (the second stage of the procedure is usually a malabsorptive procedure that is more technically feasible after the initial weight loss achieved by VSG).

These procedures can be performed laparoscopically and with robotic assistance. Adjustable gastric banding is sometimes performed on an outpatient basis, but the other procedures generally require a hospital stay that varies from one to seven days after surgery depending on the procedure and patient-specific characteristics. Recovery times vary from one to four weeks. All procedures require frequent follow-up, but AGB may require a greater number of follow-up visits to make adjustments to the band (done through a port located underneath the skin of the abdomen).

All of the bariatric surgical procedures entail operative and post-operative risks, though these vary by the type of procedure. Data regarding perioperative mortality, complications, need for reoperation, and serious adverse events reported in four systematic reviews are summarized in Table 2. It should be noted that definitions of complications and adverse events varied widely across studies. Operative risks include bleeding, infection, and damage to various abdominal organs. Nausea and vomiting are common after all these procedures and the malabsorptive surgeries sometimes cause persistent diarrhea. The malabsorptive procedures are associated with an increased risk of vitamin and mineral deficiencies, and certain types of kidney stones may become more common. Gastrointestinal bleeding from ulcers occurring at the surgical anastamoses also occurs. Infections of the subcutaneous port and erosion of the gastric band into the stomach are risks unique to AGB. The overall median complication rates reported in the Washington HTA report range from 8.8% for VSG to 26.9% for BPD (WA HTA, 2015).

Table 2. Mortality, complications, reoperations, and serious adverse events reported in four systematic reviews.

	Chang (2014)	Colquitt (2014)	Puzziferri (2014)	WA HTA (2015) Range, Median
Mortality <30 days	0.08% in RCTs 0.22% in OSs	NR	NR	NR
Mortality >30 days or not specified	0.31% in RCTs 0.35% in OSs	NR	1% for bypass procedures 0.2% for banding procedures	BPD: 0%-2.9%, 1.4% LAGB: 0%-2.0%, 0.15% RYGB: 0%-4.3%, 1.94% VSG: 0%-3.9%, 0.07%
Complication rate	17% in RCTs 10% in OSs	NR	NR	BPD: 8%-83%, 26.9% LAGB: 0%-53%, 10.1% RYGB: 0%-78%, 9.2% VSG: 0%- 80%, 8.8%
Reoperation rate	7% in RCTs 6% in OSs	2%-13%	NR	BPD: 0%-30%, 3.6% LAGB: 0%-44%, 7.4% RYGB: 0%-22%, 5.8%

	Chang (2014)	Colquitt (2014)	Puzziferri (2014)	WA HTA (2015) Range, Median
				VSG: 0%-17%, 3.9%
Serious adverse event rate	NR	0-37% in surgical groups 0-25% in non-surgical groups	NR	NR

Abbreviations: BPD – Biliopancreatic diversion; LAGB – Laparoscopic adjustable gastric banding; NR – Not reported; OS – Observational study; RCT – Randomized controlled trial; RYGB – Roux-en-Y gastric bypass; VSG – Vertical sleeve gastrectomy

Key Questions

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods please see Appendix A.

1. Should coverage be recommended for bariatric surgery in each of the scenarios in the table below? (Note that the "resolution of diabetes" would not be an applicable outcome in scenarios 4-9)

	BMI 30–34.9	BMI 35–39.9	BMI ≥ 40
With DM2	Scenario 1	Scenario 2	Scenario 3
W/o DM2 nor other comorbidities	Scenario 4*	Scenario 5*	Scenario 6*
W/o DM2 but with other comorbidities	Scenario 7*	Scenario 8*	Scenario 9*

*Resolution of type 2 diabetes isn't a relevant outcome for this population

2. What is the appropriate minimum age for bariatric surgery?
3. What components and systems of care are associated with improved health outcomes (e.g., centers of excellence, surgeon's experience, etc.)?
4. What preoperative assessments or requirements for preoperative weight loss should be recommended in patients being considered for bariatric surgery?

Critical outcomes selected for inclusion in the GRADE table were all-cause mortality and major adverse cardiovascular events. Important outcomes selected for inclusion in the GRADE table were weight loss (change in BMI), and remission or resolution of T2DM or hypertension.

Evidence review

General Limitations

The literature on bariatric surgery is voluminous. The search conducted by Center staff yielded more than 20 systematic reviews published in the last two years (see Appendix A for a detailed methods description). These reviews span more than 600 individual studies. It should be noted that there is little consistency in the inclusion of individual studies across reviews and that many of the systematic reviews did not perform meta-analysis, in part due to high levels of heterogeneity.

Furthermore, there are important concerns about the quality of much of the published research on bariatric surgery. As the Washington HTA report summarized:

> While the comparative evidence base for either head-to-head comparisons of bariatric procedures or comparisons of bariatric surgery to nonsurgical interventions has grown considerably over time, major challenges with the quality and applicability of available studies remains. Of the 179 comparative studies identified for this evaluation, we rated only 26 (15%) to be of good quality, based on comparable groups at baseline, comparable duration of follow-up, and limited sample attrition. An additional 74 studies (41%) were rated fair quality; issues with comparability, duration of follow-up, and/or attrition were identified in these studies, but attempts were made to control for confounding in the analytic methods (e.g., survival analysis techniques, multivariate regression). However, we considered another 79 studies (44%) to be of poor quality because at least one key quality issue was present and not adequately addressed in either study design or analysis. (WA HTA, 2015, p ES-6).

Additionally, there are at least nine ongoing trials of bariatric surgery that are expected to publish results over the next four years.

Systematic Reviews Addressing Effectiveness in Adults

Eight good quality systematic reviews address the effectiveness of bariatric surgery in adults (Chang et al., 2014; Colquitt, Pickett, Loveman, & Frampton, 2014; Hayes, 2014; Kwok et al., 2014; Muller-Stich et al., 2014; Puzziferri et al., 2014; Wang et al., 2015; WA HTA, 2015). These studies are summarized in Table 3 and discussed below by systematic review.

Table 3. Summary of Systematic Reviews: Effectiveness of Bariatric Surgery for Adults

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Chang, 2014 (Good) N = 161,756	37 RCTs 127 observational studies	Pre-surgical BMI (mean): 45 kg/m^2 T2DM: 26% Hypertension: 47%	Mortality (within 30 days of surgery) Complication rate BMI (mean change at 1 and 5 years) T2DM remission Hypertension remission
Colquitt, 2014 (Good) N ~ 600	7 RCTs	Average pre-surgical BMI (mean): 27 – 55 kg/m^2 5 out of 7 studies required participants have T2DM	BMI T2DM remission Hypertension remission Serious adverse events
Hayes, 2014 (Good) N = 1,734	18 controlled or comparative studies	Pre-surgical BMI (mean): 25 – 55 kg/m^2 T2DM	BMI T2DM remission
Kwok, 2014 (Good) N = 195,408	14 comparative cohorts	Most studies enrolled participants with BMI > 35 kg/m2	All-cause mortality Cardiovascular adverse events
Muller-Stich, 2014 (Good) N = 766	7 RCTs 6 Comparative observational studies	Pre-surgical BMI (mean): < 35 – 37 kg/m^2	BMI T2DM remission Hypertension remission
Puzziferri, 2014 (Good) N = 8,678	10 RCTs 8 cohort studies 11 case series	Pre-surgical BMI (mean): 44 – 61 kg/m^2	Weight loss T2DM remission Hypertension remission Perioperative mortality

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Wang, 2015 (Good) N = 256	4 RCTs	Pre-surgical BMI (mean): 30 – 47 kg/m^2	BMI T2DM remission
WA HTA, 2015 (Good) N = 2,083	14 RCTs 7 comparative cohort studies	Pre-surgical BMI (mean): 30 – 56 kg/m^2	BMI T2DM remission Perioperative mortality and complications

Abbreviations: BMI – body mass index; RCT – randomized controlled trial; T2DM – type 2 diabetes mellitus; WA HTA – Washington Health Technology Assessment Program

Chang (2014)

Chang et al. (2014) is a good quality systematic review and meta-analysis of 164 contemporary studies (37 randomized controlled trials [RCTs] and 127 observational studies) of bariatric surgery published between 2003 and 2012. The included studies spanned over 161,000 patients with an average age of 45 years and an average pre-surgical BMI of 45 kg/m^2. Twenty six percent of the included patients had T2DM and 47% had hypertension. More than two years of follow-up was available for 133,000 of the included patients. Results of RCTs and observational studies were reported separately in the meta-analysis.

The review and meta-analysis focused on surgical mortality and complications, change in BMI, and resolution of obesity-related comorbid conditions. The overall rate of mortality within 30 days of surgery was 0.08% (95% confidence interval [CI] 0.01% to 0.24%) in the RCTs and 0.22% (95% CI 0.14% to 0.31%) in the observational studies. The overall complication rate was 17% (95% CI 11% to 23%) in the RCTs and 9.8% (95% CI 7.4 to 13.0) in the observational studies.

The overall mean change in BMI at 1 year was -13.53 kg/m^2 in the RCTs and -11.79 kg/m^2 in the observational studies. For those studies reporting outcomes at five years of follow-up, the overall mean change in BMI was -11.40 kg/m^2 in the RCTs and -14.32 kg/m^2 in the observational studies.

In the RCTs, the T2DM remission rates in the surgical groups was 92% (95% CI 84.68 to 97.18) compared with a rate of 17.4% (95% CI 0.98 to 69.27) in the control groups. The observational studies found a T2DM remission rate of 86.5%. In the RCTs, the hypertension remission rate was 75% (95% CI 61.52 to 86.35) in the surgical groups compared with a rate of 49% (95% CI 0 to 99%). These comparisons are both indirect and imprecise because so few of the included studies compared surgical and non-surgical groups directly. Additionally, duration of follow-up for the studies examining comorbid conditions was unclear.

Colquitt (2014)

Colquitt et al. (2014) is a good quality systematic review by the Cochrane Collaboration that includes 22 RCTs, of which 7 studies, comprising approximately 600 patients, compared bariatric surgery to non-surgical controls. Because of differences in the characteristics of participants, interventions, and comparators, meta-analysis was considered inappropriate, and the results were reported narratively.

In terms of BMI, the included studies reported mean changes of -7.4 kg/m^2 to -33.3 kg/m^2 with surgery compared to -0.5 kg/m^2 to -4.7 kg/m^2 in non-surgical controls. The authors conclude that "the direction of the effect was consistently in favour of surgery" based on moderate quality of evidence.

In terms of remission of T2DM, the included studies reported rates of remission ranging from 42% to 90% at 12 to 24 months in surgical groups (73% to 90% if one study with a more stringent definition of A1c < 6 is excluded) compared to remission rates of 0% to 32% in non-surgical controls. The authors conclude that "more people experienced remission following surgery" based on moderate quality of evidence.

Three studies included in the Cochrane review also reported on hypertension outcomes. Two studies reported rates of reduction or discontinuation of antihypertensive medications ranging from 49% to 80% between 12 and 24 months in the surgical groups compared to 0% to 70% in non-surgical controls. One additional study reported that the proportion of patients with systolic blood pressure less than130 mmHg at 12 months was 84% in the surgical group and 79% in non-surgical controls. The authors did not draw any conclusions based on these data.

Hayes (2014)

Hayes (2014) is a good quality systematic review and health technology assessment based on 18 controlled or comparative studies of RYGB in adults with T2DM published between2007 and 2014. Seven of the included studies (5 RCTs and 2 non-randomized controlled trials) compared RYGB with non-surgical treatments while the remaining 11 compared RYGB with other bariatric surgical procedures. The average follow-up across the included studies was 12 months to 5 years.

In patients undergoing RYGB, BMI was reduced by 20 to 33% compared to baseline and T2DM remission was reported in 38 to 90% of patients. In the non-surgical treatment groups, BMI change ranged from -10% to 1%, and T2DM remission rates ranged from 0 to 33%. Based on this, Hayes concluded that RYGB is superior to intensive lifestyle or medical interventions for the treatment of T2DM. The authors further conclude that RYGB and sleeve gastrectomy are equally effective in the treatment of T2DM. Finally, the authors note that preliminary evidence (from a single study) suggests the RYGB may be equally effective for treatment of T2DM in patients with BMI<35 kg/m^2 and BMI>35 kg/m^2, but that additional studies are needed to establish the safety and effectiveness of RYGB in patients with lower BMIs.

Kwok (2014)

Kwok et al. (2014) is a good quality systematic review and meta-analysis of 14 comparative cohort studies reporting mortality and cardiovascular outcomes amongst 29,208 bariatric surgery patients and 166,200 non-surgical controls. The follow-up period of the included studies ranged from 2 years to 14.7 years. The surgical procedures in the studies included AGB, RYGB, SG, banded gastroplasty, as well as other unspecified bariatric surgical procedures. Most of the included studies reported enrolling patients with BMI >35 kg/m^2. Of the 14 included studies, 10 were deemed to be at low to moderate risk of bias, while four studies were deemed to be at moderate-high risk of bias due to concerns over loss to follow-up and inadequate adjustment for confounding. See Appendix D for a detailed description of the included studies.

In the 14 studies included in the meta-analysis of all-cause mortality, the crude event rate was 1059/29,208 (3.6%) in the surgical group and 18,962/166,200 (11.4%) in the non-surgical control group. The odds ratio (OR) for mortality in the surgical group compared with the non-surgical group was 0.48 (95% CI 0.35 to 0.64). Considering only the 10 studies that reported adjusted estimates, the association was consistent but more conservative with an odds ratio for mortality of 0.60 (95% CI 0.49 to 0.74) favoring the surgical group over the non-surgical controls.

In the four studies included in the meta-analysis of composite cardiovascular adverse events, the crude event rate was 407/17,262 (2.4%) in the surgical group and 1108/27,726 (4.0%) in the non-surgical control group. The odds ratio for composite cardiovascular adverse events in the surgical group compared with the non-surgical group was 0.54 (95% CI 0.41 to 0.70). The pooled estimates for the odds ratio of myocardial infarction and stroke for surgical patient compared to non-surgical controls were 0.46 (95% CI 0.30 to 0.69) and 0.49 (95% CI 0.32 to 0.75) respectively.

Overall, the authors conclude that long-term follow-up data from comparative cohort studies suggest that bariatric surgery is associated with lower rates of mortality (3.6% vs 11.4% for non-surgical controls, number needed to treat [NNT] = 13) and composite adverse cardiovascular events (2.4% vs 4.0% for non-surgical controls, NNT = 62).

Muller-Stich (2014)

Muller-Stich et al. (2014) is a good quality systematic review and meta-analysis of studies comparing surgical and medical treatment of T2DM in non-severely obese patients. The systematic review included seven RCTs and six comparative observational studies comprising 818 diabetic patients. All of the studies included patients with BMI <35 kg/m^2 and eight of the studies were performed exclusively in patients with BMI <35 kg/m^2; among the remaining seven studies the highest average BMI was 37.1 kg/m^2. The surgical procedures performed in the included studies were AGB, BPD, RYGB, and SG. The follow-up periods ranged from 12 to 36 months.

In the meta-analysis of studies reporting remission of T2DM, 129 of 280 patients achieved remission in the surgical group compared with 6 of 252 patients in the medical treatment group. The combined odds ratio for T2DM resolution after surgery compared with medical treatment was 14.11 (95% CI 6.67 to 29.86).

In the meta-analysis of studies reporting change in BMI, the absolute mean difference in BMI was -5.5 kg/m^2 (95% CI -6.7 to -4.3) favoring the surgical group.

In the meta-analysis of studies reporting presence of arterial hypertension at the end of the study, the 76 of 274 patients in the surgical group and 101/189 patients in the medical treatment group had arterial hypertension. The combined odds ratio for arterial hypertension after surgery compared with medical treatment was 0.25 (95% CI 0.12 to 0.50).

The authors performed a network meta-analysis to compare the treatment effects of the different surgical procedures. Although point estimates of the odds ratio for T2DM remission compared to medical treatment ranged from 12.23 for AGB to 55.05 for RYGB, the 95% confidence intervals overlapped for all four included procedures, and all were superior to medical treatment.

Overall, the authors conclude that among non-severely obese patients with T2DM bariatric surgery results in greater short-term improvements in diabetes remission, weight loss, and arterial hypertension when compared with medical treatment.

Puzziferri (2014)

Puzziferri et al. (2014) is a good quality systematic review and meta-analysis of 29 studies with long-term follow-up and low rates of attrition. Specifically, only studies of gastric bypass, gastric band, or sleeve gastrectomy performed in patients with a BMI of >35 and that reported outcomes with a minimum of two years of follow-up and at least 80% of the original study participants were included in the review. Only 29 studies (of nearly 8,000 citations reviewed) met the inclusion criteria. Among the included studies were 10 RCTs, one matched cohort, six prospective cohorts, one retrospective cohort, and 11 case series.

Weight loss outcomes in this review were reported as percentage of mean excess weight loss (EWL). The sample size weighted mean EWL was 65.7% after gastric bypass, 64.5% after sleeve gastrectomy, and 45% after gastric banding.

Six of the included studies reported on remission of T2DM (defined as glycated hemoglobin <6.5% without medications). Sample size weighted T2DM remission rates were 66.7% after gastric bypass and 28.6% after gastric banding.

Three of the included studies reported on remission of hypertension (defined as blood pressure <140/90 without medications). The reported hypertension remission rate was 38.2% after gastric bypass and 17.4% after gastric banding.

Wang (2015)

Wang et al. (2015) is a good quality, though narrowly focused, systematic review and meta-analysis of randomized controlled trials comparing laparoscopic RYGB with sleeve gastrectomy in overweight or obese adults with T2DM. Three RCTs judged to be at low risk of bias and one RCT with an unclear risk of bias were included. The average baseline BMI in the studies ranged from 30 to 46 kg/m^2. Laparoscopic RYGB and sleeve gastrectomy resulted in similar improvements in HbA1c, fasting plasma glucose, need for any diabetic medication, and BMI. Improvements in HDL and LDL cholesterol were statistically significantly greater in the RYGB group. The absolute or relative improvements in these outcomes compared to baseline were not included. Overall, the authors conclude that RYGB and sleeve gastrectomy offer equivalent results in terms of weight loss and T2DM remission, but that RYGB affords greater improvements in lipid parameters and may thus significantly decrease cardiovascular risk.

Washington Health Technology Assessment Report (2015)

The WA HTA report (2015) is a good quality systematic review and health technology assessment summarizing results from 179 comparative studies (35 RCTs, 59 prospective cohorts, 85 retrospective cohorts). Notably, one large cohort study with long-term follow-up, the Swedish Obese Subjects study, was not included as a primary source for the Washington HTA report because most of the patients in that study received a surgical procedure (gastroplasty) that is no longer widely performed. Only 15% of the included studies were judged to be of high quality, with an additional 41% deemed fair quality. When performing meta-analysis, the authors included only good or fair quality RCTs.

Overall or cause-specific mortality was not directly addressed in the WA HTA report because none of the included comparative studies reported those outcomes. However, the WA HTA report does note that evidence from at least one recent comparative cohort study found significantly lower all-cause mortality at 1 to 14 years of follow-up in surgical subjects (hazard ratio [HR] 0.45, 95% CI 0.36 to 0.56) (Arterburn, 2015).

The comparison of bariatric surgery to non-surgical management included 21 good- or fair-quality studies (14 RCTs, 7 comparative cohorts). These studies reported on RYGB (13 studies), AGB (6 studies), VSG (4 studies) and BPD/DS (3 studies). The non-surgical comparators included diet and lifestyle interventions and/or medical interventions (some variably defined as "intensive"). Meta-analytic results were available for weight loss and resolution of T2DM. The pooled mean difference in BMI was 7.4 (95% CI 6.2 to 8.6) favoring surgery, based on 10 studies. Resolution of T2DM had a log odds ratio of 3.62 (95% CI 2.49 to 4.73) favoring surgery, based on nine studies. Meta-analysis of studies reporting resolution of HTN was not done, but the report noted that "[o]ther individual comorbidities commonly evaluated in these comparative studies included hypertension and hyperlipidemia. In studies evaluating resolution of these conditions and/or discontinuation of relevant medications as a binary variable, bariatric surgery was associated with two- to three-fold reductions in the prevalence of these comorbidities [hypertension and hyperlipidemia] at the end of follow-up, while nonsurgical management resulted in no appreciable change from baseline…" (WA HTA, 2015, p. 34).

The WA HTA report is the only systematic review staff identified that summarizes key clinical outcomes stratified by procedure and mean pre-operative BMI. Those tables are included in Appendix G. Nine good- or fair-quality RCTs and prospective cohorts comparing bariatric surgery and non-surgical management enrolled patients with BMI<35. Seven of those studies included presence of T2DM or metabolic syndrome as an entry criterion, while two did not report comorbid condition-based entry criteria. The authors conclude that for those with a mean pre-operative BMI of 30 to 35.9 “patterns of weight loss across procedures were similar to those in studies of patients at higher BMI” (WA HTA, 2015, p. ES-41). Furthermore, among studies of patients at lower BMI levels that reported on remission of T2DM at 12 to 24 months the results favored surgery (remission rates of 26% to 73%) over non-surgical treatment (remission rates of 0% to 16%).

Systematic Reviews Addressing Effectiveness in Children and Adolescents

Three fair or good quality systematic reviews address the effectiveness of bariatric surgery in children and adolescents (Aikenhead, Knai, & Lobstein, 2011; Black, White, Viner, & Simmons, 2013; Treadwell, Sun, & Schoelles, 2011). These studies are summarized in Table 4 and discussed below by systematic review.

Table 4. Summary of Systematic Reviews: Effectiveness of Bariatric Surgery for Children and Adolescents

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Aikenhead, 2011 (Fair) N = 831	1 RCT 8 cohort studies 14 observational studies 12 case series	≤ 19 years old	BMI
Black, 2013 (Fair) N = 637	1 RCT 22 observational studies	Pre-surgical BMI (mean): 46 – 52 Age: 5 – 23 years	BMI
Treadwell, 2008 (Treadwell) N = 644	18 Observational studies	Pre-surgical BMI (mean): 46 – 52 Age: 9 – 21 years	BMI

Abbreviations: BMI – body mass index; RCT – randomized controlled trial

Aikenhead (2011)

Aikenhead et al. (2011) is a fair quality narrative systematic review of 37 studies of effectiveness of bariatric surgery spanning 831 patients age 19 years old or younger. The authors note several general limitations of the pediatric bariatric surgery literature including predominately observational study designs, small sample sizes (the largest of the included trials had 68 patients), and sparse information on low frequency outcomes.

Thirteen of the included studies (all but one observational) assessed gastric banding. Twelve of these studies reported mean BMI reductions of 8.5 kg/m^2 to 43 kg/m^2, while one study (a case report of gastric banding and truncal vagotomy in an adolescent with a rare mutation in a gene implicated in regulation of appetite and energy balance) found an increase in BMI of 2.2 kg/m^2. Rates of resolution of comorbid conditions ranged from 11 to 100%.

Eight of the included studies (all observational) assessed RYGB. The studies reported mean reductions in BMI of 9 kg/m^2 to 25 kg/m^2. The authors note that four of the studies reported on comorbid conditions and three of those four studies found 100% rates of resolution for dyslipidemia, degenerative joint disease, asthma, and gastroesophageal reflux disease.

Fourteen of the included studies (all observational) reported on other bariatric procedures (sleeve gastrectomy, BPD/DS, vertical banded gastroplasty). These studies reported mean BMI reductions of 9 kg/m^2 to 24 kg/m^2. The authors note that changes in comorbid conditions were reported in 12 of the 14 studies, but additional details are not included.

The authors' overall conclusion is that "[i]n the context of a general lack of effective tools for primary prevention or behavioural treatment of obesity, surgical treatment may be advocated as a preferred and cost-effective solution for certain children and adolescents" (Aikenhead, 2011, p. 18)

Black (2013)

Black et al. (2013) is a fair quality systematic review and meta-analysis of bariatric surgery for obese children and adolescents. Twenty-three studies (22 observational and 1 RCT) comprising 637 patients undergoing RYGB, AGB, or SG were included. The mean pre-surgical BMI was 52.4 kg/m^2 in the RYGB studies, 49.6 kg/m^2 in the SG studies, and 46.1 kg/m^2 in the AGB studies. The ages of patients in the included studies ranged from 5 to 23 years old.

Overall, the average weighted BMI difference from baseline to one year postoperatively was -13.5 kg/m^2 (95% CI -15.1 to -11.9). The greatest BMI reductions were observed in patients undergoing RYGB (average weighted difference of -17.2 kg/m^2) and the smallest BMI reductions were observed in the AGB group (average weighted difference of -10.5 kg/m^2).

The authors note that they were unable to provide summary estimates of the effects on comorbidity resolution because the data were of poor quality and adequate definitions of resolution were not provided. The rates of reported resolution of T2DM from baseline to follow-up ranged from 0 to 100% in the eight studies that reported this outcome. However, excluding one study with only a single T2DM patient who did not experience resolution, the rate of resolution for T2DM would range from 50 to 100%. The rates of reported resolution of hypertension from baseline to follow-up ranged from 50 to 100% in the 10 studies that reported this outcome.

Treadwell (2008)

Treadwell et al. (2008) is a good quality systematic review and meta-analysis of bariatric surgery for pediatric obesity. This review included 18 studies of children ages 9 to 21 years (mean age 16.7 years) with mean BMI ranging from 45.8 kg/m^2 to 51.8 kg/m^2. In 14 of the 18 studies, patients must have failed a trial of non-surgical weight loss before undergoing bariatric surgery. Only one of the included studies reported a non-surgical control group and significant differences in baseline characteristics between the groups were noted including baseline BMI and comorbidities. Thus, the authors note that, in effect, the included studies were all case series.

Meta-analysis of change in BMI in six studies of AGB found a 95% CI of -13.7 kg/m^2 to -10.6 kg/m^2 at mean length of follow-up of one to three years. Two of the studies of AGB reported T2DM remission rates of 80 to 100% and three of the studies reported hypertension remission rates of 50 to 100%.

Meta-analysis of change in BMI in six studies of RYGB found a 95% CI of -17.8 kg/m^2 to -22.3 kg/m^2 at mean length of follow-up of one to six years. Only one of the studies of RYGB reported remission of T2DM. Three studies of RYGB reported rates of hypertension remission of 50 to 100%.

Because of the small number of studies and patients undergoing other procedures, summary information on weight changes or comorbidity resolution was not presented.

Overall, the authors conclude that there is weak to moderate evidence that AGB achieves weight loss at one year or longer and weak evidence of resolution of T2DM and hypertension. For RYGB, the authors conclude that there is weak to moderate evidence of weight loss at one year or longer, weak evidence of resolution of hypertension, and insufficient evidence of resolution of T2DM. There was insufficient evidence for any outcomes from other bariatric procedures.

Systematic Reviews Addressing Bariatric Reoperation Procedures

As the use of primary bariatric surgical procedures has increased, so too has the rate of bariatric reoperation. The term "bariatric reoperation" captures several types of procedures (conversion, correction, revision, or reversal) that are performed for various indications. Inadequate weight loss (commonly, but not uniformly, defined as <50% EWL) is the most common indication for revision or conversion procedures. Reoperation is also performed to address both acute complications (including anastomotic leaks, bleeding, strictures, obstruction, and perforation) and chronic complications (including protein calorie malnutrition, severe GERD, band erosion, late or recurrent leaks, late strictures, and band intolerance.) Reversal procedures are rare, but are sometimes performed to address intractable nausea and vomiting, excessive or uncontrolled weight loss, severe malnutrition, recurrent anastomotic ulcers, severe hypoglycemia, and recalcitrant hypocalcaemia.

In general, bariatric reoperation is thought to be more technically challenging than primary bariatric surgery, at least in part because of the likelihood of surgical adhesions from the primary procedure. Nevertheless, many reoperative bariatric procedures can still be performed laparoscopically, though the complication rates may be higher when compared with primary bariatric procedures.

Five fair quality and one low quality systematic reviews address the effectiveness of bariatric reoperative procedures (Brethauer et al., 2014; Cheung, Switzer, Gill, Shi, & Kamali, 2014; Coblijn, Verveld, van Wagensveld, & Lagard, 2013; Elnahas, Graybiel, Farrokhyar, Gmora, Anvari, & Hong, 2013;

Mahawar, Graham, Carr, Jennings, Schroeder, Balupuri, & Small, 2015; Schouten, Japink, Meesters, Nelemans, & Greve, 2011).

These systematic reviews of bariatric reoperation provide very low certainty evidence that revisional or conversion procedures performed after an initial bariatric surgery may achieve additional weight loss (particularly those procedures that convert AGB to RYGB or BPD/DS), but at the expense of a higher rate of complications. The systematic reviews offer no evidence that bariatric reoperation improved co-morbidity resolution. Most of the studies included in the systematic reviews were not methodologically rigorous and there are concerns about publication bias in this literature. Furthermore, the indications for bariatric reoperation varied across and within individual studies.

Brethauer (2014)

Brethauer et al. (2014) is a systematic review on indications for and outcomes of reoperative bariatric surgery that was conducted by the ASMBS Bariatric Surgery Revision Taskforce. The review was supported by an unrestricted educational grant from Covidien, a company that manufactures equipment used in bariatric surgical procedures. While the review states that 175 articles were included in the systematic review, the majority of these were single center retrospective case series and the evidence tables in the review provide details on only 35 “selected studies.” Thus, the degree to which the narrative review and recommendations reflect an unbiased inclusion of studies identified in the systematic review is uncertain. Furthermore, the reporting of quantitative outcomes across indications and reoperative procedures was erratic. The conclusions of the authors, summarized here with the above caveats, are 1) reoperation for inadequate or failed weight loss generally improves weight loss, and 2) complication rates are generally higher with reoperative procedures.

Cheung (2014)

Cheung et al. (2014) is a systematic review of studies of revisional bariatric surgery following laparoscopic sleeve gastrectomy. The review includes 11 studies spanning a total of 218 patients. In most of the studies patients underwent revisional procedures because of insufficient weight loss or weight regain, although the former indication was variably defined. Intractable gastroesophageal reflux disease was an additional indication in 5 of the studies. The revisional procedures included laparoscopic butterfly gastroplasty, laparoscopic omega loop mini gastric bypass, laparoscopic re-sleeve gastrectomy, laparoscopic duodenal switch, and laparoscopic or open RYGB. Nine of the studies were cases series and two studies were case-controls. The largest single study enrolled 40 patients. The primary outcomes were change in BMI at various time points. At 24 months or greater, revisional procedures were associated with reductions in BMI. Revision of LSG to gastric bypass resulted in an average change in BMI of -6.2 kg/m^2. Revision of LSG to re-sleeve gastric bypass resulted in an average change in BMI of -3.2 kg/m^2. Revision of LSG to other surgical interventions (all other conversion procedures) resulted in an average change in BMI of -17.2 kg/m^2. In the three studies that examined the effects of revisional procedures on GERD complications, there was a 100% complete resolution rate, though it should be noted that the sample size for this outcome was very small (n=15). The authors note that their review was limited by the small number of studies and patients, the very low methodological rigor of the study designs, and the absence of postoperative complication rates after revision.

Coblijn (2013)

Coblijn et al. (2013) is a systematic review of studies of revisional bariatric surgery (LSG or LRYGB) after an initial adjustable gastric banding procedure. The review includes 15 studies of LRYGB spanning 588 patients and 8 studies of LSG spanning 286 patients. Not all studies reported the indication for revisional surgery, but in those that did the most common indication was insufficient weight loss or weight regain (approximately 65% of patients). Most of the studies were consecutive case series and there were no randomized controlled trials. The primary outcomes of interest were perioperative morbidity and mortality. In the LRYGB studies that reported this outcome there were no perioperative deaths and the overall perioperative complication rate was 8.5%. In the LSG studies that reported this outcome, there were 3 perioperative deaths and the overall perioperative complication rate was 12.2%. The rate of reoperation after the revisional procedures was 6.5% for LRYGB and 3.5% for LSG. Though weight loss was not of primary interest for this review, the authors did note that 11 of the 15 LRYGB studies reported mean EWL of 23% to 74%, though the follow-up time was not clear. Weight loss achieved with revisional LSG appeared to be nearly comparable. The authors note several limitations to their review including the very low methodological rigor of the study designs and the possibility of publication bias, particularly for studies reporting on morbidity and mortality.

Elnahas (2013)

Elnahas et al. (2013) is a systematic review of conversion bariatric procedures after failed adjustable gastric banding. The review includes 24 studies reporting outcomes of conversion to LSG (n=106 patients), LRYGB (n=514 patients), and laparoscopic BPD/DS (n=71 patients). Patients in these studies underwent the conversion procedure due to inadequate weight loss or surgical complications with AGB. All of the included studies were retrospective case series. The primary outcome of interest was weight loss measured by change in BMI or percentage EWL. The mean change in BMI at 24 to 48 months after reoperation was -2.8 kg/m^2 for LSG, -8.5 kg/m^2 for LRYGB, and -13.3 kg/m^2 for BPD/DS. The weighted mean complication rates for conversion to LSG, LRYGB, and BPD/DS were 4.1%, 10.7%, and 24.4% respectively. The authors note several limitations to their study including the very low methodological rigor of the study designs and significant heterogeneity across studies.

Mahawar (2015)

Mahawar et al. (2015) is a systematic review of studies that compare the outcomes of revisional bariatric procedures to the outcomes of the same primary procedures. The review includes 14 studies comparing revisional and primary RYGB and 7 studies comparing revisional and primary SG. The designs of the primary studies were not made explicit, but all appeared to be case-control or retrospective cohort studies. Quantitative cumulative outcomes reported in the studies comparing revisional with primary RYGB included mortality (1.3% revisional vs 0.2% primary), complications (29.5% revisional vs 13.9% primary), reoperation (8.4% revisional vs 8.6% primary), and leaks (5.8% revisional vs 1.0%

primary). Quantitative cumulative outcomes reported in the studies comparing revisional SG with primary SG included mortality (0% revisional vs 0.1% primary), complications (10.5% revisional vs 5.2% primary), reoperation (4.8% revisional vs 1.6% primary), and leaks (1.9% revisional vs 1.5% primary). Weight loss outcomes were not cumulatively analyzed because of heterogeneity in the studies, but the authors do note that most of the studies that reported on weight loss outcomes found that the weight loss achieved with revisional procedures was either inferior to (10/14 studies of RYGB, 2/5 studies of SG) or not significantly different from the weight loss achieved with primary procedures (4/14 studies of RYGB, 3/5 studies of SG). The authors do not comment on limitations of their review other than noting the absence of any level I evidence on revisional bariatric surgery.

Schouten (2011)

Schouten et al. (2011) is a systematic review of studies examining reoperation following gastric banding procedures. The review included 11 studies of re-banding, 12 studies of conversion to LRYGB, 5 studies of conversion to laparoscopic BPD/DS, and 5 studies of conversion to LSG.

Among the 11 studies that examined re-banding, the most common indications were slippage, erosion, or pouch dilation. Ten of the 11 studies presented level III or level IV evidence, while one presented level II evidence. The follow-up period varied from 8 to 48 months after reoperation. The early complication rate ranged from 0% to 11%, the late complication rate ranged from 0% to 41%, and the reoperation rate ranged from 0% to 45%. Change in BMI was reported in 6 studies and ranged from +2.4 kg/m^2 to -5.8 kg/m^2.

Among the 12 studies of conversion to LRYGB, the most common indications were insufficient weight loss, band, erosion, and pouch dilation. Ten of the 12 studies presented level III or level IV evidence, while the remaining 2 presented level II evidence. The follow-up period ranged from 8.3 to 36 months after reoperation. The early complication rate ranged from 3% to 36%, the late complication rate ranged from 2% to 23%, and the reoperation rate ranged from 0% to 20%. Change in BMI was reported in 9 studies and ranged from -6.1 kg/m^2 to -13.2 kg/m^2. Percentage EWL was reported in 2 studies and ranged from 33% to 43%.

Among the 5 studies of conversion to BPD/DS, the most common indication was insufficient weight loss. All 5 studies presented level III or level IV evidence. The follow-up period ranged from 12 to 38 months after reoperation. The early complication rate ranged from 8% to 62%, the late complication rate ranged from 20.6% to >23.5%, and the reoperation rate ranged from 0% to 20.6%. Percentage of EWL was reported in 3 studies and ranged from 44% to 70%.

Among the 5 studies of conversion to LSG, the most common indication was insufficient weight loss. Four studies presented level IV evidence while 1 study presented level II evidence. The follow-up period ranged from 12 to 24 months after reoperation. The early complication rate ranged from 0% to 13.8%, the late complication rate ranged from 0% to 10.3%, and the reoperation rate ranged from 0% to 10.3%.

Percentage of EWL was reported in 2 studies and ranged from 20% to 65.7% while change in BMI was reported in 1 study as -4.4 kg/m^2.

The authors conclude that adjustable gastric banding should remain a first line procedure with re-banding or conversion to RYGB or BPD/DS as options for managing band failure.

Systematic Reviews Addressing Patient Selection

One poor quality and two good quality systematic reviews address patient selection criteria (Ochner, Dambkowski, Teomans, Teizeira, & Xavier Pi-Sunyer, 2012; Thomas & Agrqwal, 2012; WA HTA, 2015).

Ochner (2012)

Ochner et al. (2012) is a good quality narrative systematic review of 29 studies examining the effects of preoperative weight loss requirements on postoperative outcomes. The authors note that heterogeneity in the included studies precluded formal quantitative synthesis. Overall, the included studies were mostly observations and were mixed on the effects of preoperative weight loss requirements on postoperative weight loss outcomes. As the authors note, "studies of the relation between pre- and post-operative changes in body weight range from a positive relationship (preoperative weight loss associated with greater postoperative weight loss) to a negative relationship (preoperative weight loss associated with less postoperative weight loss) and many in between (no relationship)" (Ochner et al., 2012, p. 1381). The only included RCT deemed "viable" by the authors randomized 100 patients undergoing RYGB to a group with a requirement of 10% preoperative weight loss or a group with no preoperative weigh loss requirement. At six months after surgery, patients in the preoperative weight loss group had lost 54% of excess body weight compared to 51% excess body weight loss in the in the group without a preoperative weight loss requirement, but because only 37% of the original sample was analyzed at six months there was insufficient power to detect an effect.

The review also examined studies reporting on the effects of preoperative weight loss requirements on other outcomes including resolution of comorbid conditions. One study of 90 RYGB patients found that preoperative weight loss of >5% of excess body weight was associated with shorter operative times (36 minutes on average) but no difference in complications or resolution of comorbid conditions. Another study demonstrated that patients with preoperative weight loss of >5% of excess body weight were less likely to have a postoperative length of stay of >4 days. The RCT referenced above found no difference in the complication rate or resolution of comorbid conditions at six months. A fourth study found no correlation between preoperative weight changes and remission of diabetes or hypertension.

The authors' overall conclusion is that "[g]iven the inconsistency and questionable validity of the extant research…on the question of the effect of preoperative weight loss on peri- and postoperative outcomes, it is the opinion of these authors that insufficient evidence is currently available to justify a pre-bariatric surgery weight loss mandate" (Ochner et al., 2012, p. 1386).

Thomas (2012)

Thomas & Agarwal (2012) is a poor quality systematic review of a preoperative risk stratification tool known as the obesity surgery mortality risk score (OS-MRS). The OS-MRS assigns one point each for age greater than 45 years, male gender, BMI > 50 kg/m^2, hypertension, and known risk factors for pulmonary embolism. Scores of 0 to 1 are considered class A or lowest risk, scores of 2 to 3 reflect class B or intermediate risk, and scores of 4 to 5 are class C or high risk. This review included six studies reporting on 9,382 patients evaluating the validity of OS-MRS to predict postoperative mortality risk. Overall, there were 83 death in the 9,382 patients (0.88%). There were 13 deaths among the 4,912 class A patients (0.26%), 55 deaths among the 4,124 class B patients (1.33%), and 14 deaths among the 346 class C patients (4.34%). The mortality difference between classes were statistically significant at p<0.05. The authors conclude that use of the OS-MRS can stratify mortality risk in patients undergoing bariatric surgery (particularly RYGB which was the predominately studied procedure in the included studies).

WA HTA (2015)

The WA HTA report included a single retrospective comparative cohort study that stratified outcomes by patient adherence to preoperative program recommendations. In the laparoscopic AGB group, patients who did not attend >75% of their pre-procedure appointments had attenuated weight loss at 12 months of follow-up (23% EWL vs 32% EWL in patients with fewer missed appointment, p=0.01). There were no differences in RYGB performance related to pre-procedure appointment adherence.

A single study included in the WA HTA report concluded that patients with congestive heart failure and cardiac arrhythmias had a significantly increased risk of post-surgical complications compared with the overall cohort (40% vs 13.4% for open RYGB, 21.1% vs 8.6% for laparoscopic RYGB, and 17.4% vs 3.1% for laparoscopic AGB, all p-values <0.001). The same study reported that patients with peripheral vascular disease undergoing RYGB had significantly increased complication rates compared to those without peripheral vascular disease (32.0% vs 8.4%, p<0.001).

The WA HTA report also notes that it did not find studies that stratified outcomes by smoking status or psychosocial health that met inclusion criteria.

Systematic Reviews Addressing Systems of Care

One good quality systematic review addresses the effect of systems of care on bariatric surgery outcomes (Zevin, Aggarwal, & Grantcharov, 2012).

Zevin (2012)

Zevin et al. (2012) is a good quality systematic review of volume-outcome associations in bariatric surgery. The article reviews 24 observational studies comprising almost 460,000 patients. Meta-analysis was not performed due to a high level of heterogeneity that resulted, in part, from differences in duration of follow-up and risk-adjustment.

Thirteen studies addressed the relationship between annual surgeon case volume and patient outcomes. Across the five cohort studies that were included, there was consistent evidence of improved outcomes with increasing surgeon volume. The results of lower quality studies (primarily retrospective cohorts) were mixed, but six of the eight studies supported an association between surgeon volume and outcomes.

Seventeen studies addressed the association between hospital volume and outcomes. While the two case-control studies that were included did not support an association between facility volume and outcomes, the preponderance of retrospective case series (14/15 studies) that were included found an association between facility volume and outcomes.

The authors conclude that there is strong evidence to support the association between surgeon volume and patient outcomes, and that weaker evidence supports the association between hospital volume and outcomes. Overall, they conclude that the literature "supports the BSCOE accreditation and the bariatric surgery fellowship training programs" (Zevin et al., 2012, p. 70).

WA HTA (2015)

The WA HTA report notes that pre-procedure support groups have shown little benefit, but that there is some evidence that patients in postoperative support groups experience improvements in psychological comorbidities and achieve greater weight loss. The WA HTA report cites one RCT of 144 Hispanic-American RYGB patients randomized to "comprehensive nutrition and lifestyle support or brief, printed healthy lifestyle guidelines…" At one year after surgery, patients in the comprehensive support group had greater reductions in BMI (6.48 kg/m^2 vs 3.63 kg/m^2, $p<0.001$).

Systematic Reviews Addressing Cost-effectiveness

WA HTA (2015)

The WA HTA report (2015) performed a cost-effectiveness analysis based on a model constructed by the authors. This analysis assumed a public payer perspective. The base-case analysis compared RYGB with standard care over a 10 year time horizon; other base-case assumptions included a procedural cost of $24,277, 20% worsening in BMI after 12 months, mean BMI at baseline of 40 kg/m^2, and a discounting rate of 3%. In the base-case analysis, the incremental cost-effectiveness of RYGB compared to standard care was $37,423 per quality-adjusted life year (QALY) gained. In the deterministic sensitivity analyses, the incremental cost-effectiveness estimates ranged from $5,444 per QALY to $84,971 per QALY. The estimates were most sensitive to changes in the time horizon, the cost of the bariatric surgical procedure, maintenance of weight loss after surgery, and baseline BMI. The WA HTA cost-effectiveness estimates, stratified by procedure and baseline BMI, are included in Appendix H.

There is very sparse evidence on the cost-effectiveness of bariatric surgery in children and adolescents. The only included systematic review which addresses this question is Aikenhead et al. (2011). The conclusions of this review are limited by the small number of studies, use of economic models that are not directly applicable to the U.S., and inferences from cost-effectiveness studies of bariatric surgery in adults.

EVIDENCE SUMMARY

Despite the existence of a large number of studies and systematic reviews, there remain substantial limitations to the evidence regarding bariatric surgery. Differences in patient characteristics, choice of surgical procedure, and individual components and intensity of non-surgical management arms make it difficult to summarize effects across studies. Variable measures of weight loss and wide variation in definitions of remission or resolution of comorbid conditions pose additional problems. Many of the studies included in the reviews were non-comparative, and the comparative observational studies suffer from risk of bias related to patient selection and residual confounding. The data from RCTs is limited by questions regarding proper allocation concealment and the universal absence of blinding. Perhaps the greatest concern is the limited long term follow-up of patients from RCTs and incomplete outcomes data due to high rates of attrition in most studies.

Overall, the following conclusions can be drawn based on review of the summary literature:

1. Bariatric surgery is associated with lower rates of all-cause mortality and major adverse cardiovascular events in adults, despite a short term increased risk of perioperative mortality and complications (based on low certainty evidence from cohort studies with long term follow-up, with study populations consisting predominantly of patients with BMI ≥35).
2. Bariatric surgery is associated with significant reductions in BMI in adults, despite a short term increased risk of perioperative mortality and complications (based on moderate certainty evidence from a mix of observational and randomized trials). The effects on weight loss appear to be greatest in patients with baseline BMI ≥40 based on the BMI stratification provided in the WA HTA report.
3. Bariatric surgery is associated with remission or resolution of T2DM and hypertension in adults with BMI ≥ 35, despite a short term increased risk of perioperative mortality and complications (based on moderate certainty evidence from a mix of observational and randomized trials).
    - The effects on remission of T2DM appear to be greatest in patients with baseline BMI ≥40 based on the BMI stratification provided in the WA HTA report.
    - Preliminary evidence suggests that adults with BMI < 35 may also achieve significant reductions in BMI and improvement in comorbid T2DM and hypertension, though the long term effects are not yet clear.
4. Bariatric surgery is associated with significant reductions in BMI in children and adolescents, despite a short term increased risk of perioperative mortality and complications (based on low certainty evidence primarily from small, non-comparative observational trials of bariatric surgery for pediatric obesity).

5. Bariatric surgery is associated with remission or resolution of T2DM and hypertension in children or adolescents, despite a short term increased risk of perioperative mortality and complications (based on very low certainty evidence from a small number of trials).
6. There is no evidence-based minimum age recommendation for pediatric bariatric surgery. Patients as young as five years old were included in the studies reported in the summary literature.
7. There is low certainty conflicting evidence on the effects of preoperative weight loss requirements.
8. The obesity surgery mortality risk score (OR-MRS) is a validated preoperative assessment of perioperative mortality risk (particularly for RYGB procedures) and may be useful in selecting patients for surgery or counseling them on surgical risks.
9. Harms of bariatric surgery include a perioperative mortality rate that probably ranges from 0.10 to 2%, and an overall complication rate that is probably on the order of 8 to 25%. The estimated reoperation rate is likely between 2 and 13%. There is limited evidence from a single study that comorbid congestive heart failure, cardiac arrhythmias, and peripheral vascular disease are associated with higher rates of complications after bariatric surgery.
10. There is low certainty evidence that surgeon experience is associated with improved outcomes and very low certainty evidence that hospital bariatric surgical volume is associated with improved outcomes.
11. There is very low certainty evidence that revisional or conversion procedures performed after an initial bariatric surgery may achieve additional weight loss (particularly those procedures that convert AGB to RYGB or BPD/DS), but at the expense of a higher rate of complications. Systematic reviews offer no evidence that bariatric reoperation improved co-morbidity resolution.

Other Decision factors

Resource allocation

Bariatric surgery for adults is costly, but improved outcomes compared with non-surgical management may offset these costs. The WA HTA report cites total costs of bariatric surgical procedures as ranging from $17,483 for gastric banding to $36,160 for biliopancreatic diversion. By comparison, standard non-surgical care has a reported total cost of $3,746. Accounting for reductions in BMI, resolution of comorbid conditions, and complications of surgery and projecting costs and effectiveness over a 10-year horizon, bariatric surgical procedures are uniformly cost-effective at a willingness-to-pay threshold of $100,000 per QALY gained. This was true across BMI thresholds and surgical procedures. Excerpts from the economic analysis in the WA HTA report are provided in Appendix H.

Bariatric surgery for children is also costly, but improved outcomes may offset these costs, and the beneficial effects could accrue over the longer time horizon afforded by earlier intervention in children and adolescents. However, there is very limited evidence of cost-effectiveness of pediatric bariatric surgery. The pediatric cost-effectiveness information included in the review by Aikenhead et al. in 2011 used assumptions from Australia that are likely too indirect to influence deliberations on resource allocation.

Reoperations for additional weight loss are sometimes requested; a second high cost procedure (tens of thousands of dollars), with a history of prior failure is unlikely to show a favorable cost-effectiveness ratio.

Values and preferences

Adults

Most people would prefer to avoid surgery and its attendant risks if similar results could be attained through safer and less invasive interventions. However, patients who have failed to achieve adequate weight loss with less invasive interventions may decide that the superior outcomes of bariatric surgery (including long term improvements in all-cause mortality, complete remission of diabetes, and significant weight loss) outweigh the upfront risks of surgery. Overall, there would be a moderate variability given these considerations.

Children and adolescents

Similar to adults, most children and their parents would prefer to avoid surgery and its attendant risks if similar results could be attained through safer and less invasive interventions. However, patients who may have failed to achieve adequate weight loss with less invasive interventions may decide that bariatric surgery offers the best chance at weight reduction. The significant social pressures of obesity at a young age may also push children and their parents to have strong interest in an effective treatment. Children though would likely have a great fear of surgery and the associated procedures and loss of social/academic participation. However, additional uncertainties related to malnutrition in this age group and its effects on growth, development, and reproductive capacity may make surgery less appealing in children and adolescents (to their caregivers). Long term remission rates of morbid obesity and recurrence of the comorbidities are unknown; most studies report outcomes at one year, although a few studies report outcomes at up to three years. Given these considerations, there would be high variability in children's and parents preferences.

Re-operations for inadequate weight loss

There would be high variability in patient preferences regarding reoperation. With a prior failure of the procedure, some patients would be hesitant to try an additional procedure given the burdens of surgery and prior ineffectiveness, but others would be motivated to try a different procedure in hopes that it would work. Patients seeking reoperation likely have no other good option given failure of multiple previous alternatives (e.g. clinical, pharmacological, nutritional, physical activity, surgical).

Other factors

Adults

The greatest health benefits may be with BMI ≥ 40 but otherwise specific subpopulations which would benefit the most from bariatric surgery are not well characterized.

The pre-operative requirements for achieving optimal outcomes are unclear.

Given the rate of complications and need for reoperation reported in the summary literature, benefit plans may wish to consider alternative payment methodologies like bundled payments or a pay-for-outcomes approach.

Surgeon case volume, and to a lesser extent hospital case volume, appear to affect outcomes for patients undergoing bariatric surgery and requirements regarding surgeon or facility volume may be reasonable.

Children and adolescents

Parental involvement in weight management plans is likely necessary to assist the effectiveness of obesity treatments (based on expert opinion).

Pediatric bariatric surgery is likely to be available at only a few highly specialized centers. The American Academy of Pediatrics has 10 criteria that pediatric bariatric surgery programs should meet.

Re-operations for inadequate weight loss

It is unclear from the evidence which modifiable patient factors that resulted in surgical failure would predict a high likelihood of success or failure of a second procedure.

Policy landscape Sources

Quality measures

One bariatric surgery-specific quality measure was identified when searching the National Quality Measures Clearinghouse:

- Prevention and management of obesity for adults: percentage of patients with a BMI greater than or equal to 40 who have been provided with a referral to a bariatric specialist (Institute for Clinical Systems Improvement)

Payer coverage policies

Medicare (National Coverage Determination [NCD] 100.1), Washington Medicaid, Aetna, Cigna, Regence Blue Cross Blue Shield, and Moda all provide coverage of bariatric surgery. Each coverage policy outlines specific coverage criteria that must be met prior to bariatric surgery being approved. These criteria are described below and provided in more detail in Appendix E.

Age

All six payers provide coverage of bariatric surgery for adults (defined as at least 18 years), and Aetna and Cigna additionally provides coverage for adolescents (defined as an individual with completed skeletal growth). Washington limits the procedure type to LAGB only for individuals aged 18 to 20 years.

Body Mass Index

For adults, Aetna, Cigna and Moda require individuals have a BMI of greater than or equal to 40 kg/m^2, or greater than or equal to 35 kg/m^2 with specific comorbidities. Washington and NCD 100.1 cover individuals with a BMI of greater than or equal to 35 kg/m^2 with comorbidities, and Regence BCBS requires that an individual have a BMI of greater than or equal to 40 kg/m^2 or a BMI of greater than, or equal to 35 kg/m^2 with type 2 diabetes or at least two other specified comorbidities. Washington is the only identified payer that explicitly requires individuals not be pregnant at the time of the surgery.

For adolescents, Aetna covers individuals with a BMI of greater than 40 kg/m^2 who have serious comorbidities, or individuals with a BMI of greater than 50 kg/m^2 with less serious comorbidities. Cigna uses the same BMI criteria as the adult population.

Comorbidities

Diabetes is the only comorbidity specified by all five payers. Payers specify various combinations of other comorbid conditions including coronary heart disease, dyslipidemia, hypertension, lower extremity lymphatic or venous obstruction, mechanical arthopathy in major weight bearing joint, rare comorbid conditions (e.g., pseudo tumor cerebri), and obstructive sleep apnea. Aetna specifies several less severe comorbidities for adolescents with a BMI of over 50 including gastroesphageal reflux disease, intertriginous soft-tissue infection, nonalcoholic steatohepatitis, obesity-related psychosocial distress, significant impairments in daily living, and stress urinary incontinence.

Pre-Surgical Requirements

Five payers require individuals to undergo a comprehensive psychosocial evaluation and participate in a formal weight loss program prior to being approved for bariatric surgery (Aetna, Cigna, Moda, Regence BCBS, and Washington). Three payers require a separate medical evaluation (Washington, Cigna, Moda), surgical evaluation (Washington, Cigna), and nutritional evaluation (Cigna, Moda) prior to surgery. The NCD 100.1 requires that individuals have been previously unsuccessful with medical treatment for obesity.

Payers require an individual attend a formal weight loss program within six months (Washington) to two years of surgery (Aetna, Regence BCBS, Moda). The weight loss program must be greater than or equal to three (Cigna) to six months in duration (Washington, Aetna, Regence BCBS, Moda). Both Washington and Moda require that individuals lose 5% of their initial body weight as part of the weight loss program prior to surgery. Aetna's policy states that there can be no net weight gain during weight loss program attendance. Payer coverage policies include a variety of additional required program components including counseling by a registered dietitian, patient journal of participation, regular face-to-face provider visits, behavior modification, supervised exercise regimen, and hypocaloric diet changes.

Provider Requirements

Washington Medicaid and Moda state that bariatric surgery is only covered if provided by an approved facility, defined by Moda as a Center of Excellence and by Washington with specific criteria. Bariatric surgery facilities approved by Washington Medicaid must have performed a minimum of 100 bariatric surgical procedures, be under the direction of an experienced board-certified surgeon, been in operation for at least five years, have a 2% or less mortality rate, have a 15% or less morbidity rate, have at least five years of patient follow-up data, have an average of at least 50% patient weight loss at five years, and have a reoperation/revision rate of 5% or less.

The Centers for Medicaid and Medicare have approved six facilities in Oregon to perform bariatric surgery: Bay Area Hospital, Legacy Good Samaritan Hospital and Medical Center, Oregon Health & Science University, Sacred Heart Medical Center, Salem Hospital, St. Charles Medical Center – Bend.

Repeat Surgery Coverage

Aetna, Cigna and Regence BCBS address repeat bariatric surgery and outline specific circumstances under which it is covered. All three payers provide coverage to correct complication from the initial surgery, and conversion from gastric banding to sleeve gastrectomy, RYGB or BPD/DS. Aetna and Cigna specify that conversion surgery is covered for individuals who have not lost more than 50% of their body weight two years following the primary bariatric surgery. Cigna will cover the adjustment of the silicone gastric band and repeat surgery for a failed dilation of a gastric pouch. Aetna will additionally cover removal of a gastric band, replacement of adjustable band, and repeat surgery for a failed dilation of a gastric pouch.

Non-Covered Procedures

Aetna, Cigna, and Regence BCBS outline specific conditions and procedures that are not in the coverage of bariatric surgery. Across all three payers, gastroplasty ("stomach stapling"), laparoscopic gastric plication, mini gastric bypass, transoral endoscopic surgery (e.g., OverStich suturing device, StomaphX™, TOGA®), are not covered. In addition, Aetna and Cigna do not cover gastrointestinal liners (e.g., EndoBarrier™), intragastric balloon, loop gastric bypass, silastic ring vertical gastric bypass (e.g., Fobi pouch), or vagus nerve blocking. Aetna and Regence BCBS do not cover band over bypass surgeries, band or sleeve gastrectomy surgeries, sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery, or for gastroesophageal reflux disease in non-obese individuals. Cigna and Regence BCBS do not cover intestinal bypass (jejunoileal bypass) or restorative obesity surgery (e.g., ROSE). Regence BCBS specifically does not cover vertical banded gastroplasty; Aetna covers this procedure for members who are at increased risk of adverse consequences from Roux-en-Y gastric bypass due to certain gastrointestinal conditions (see Appendix E).

The NCD 100.1 does not provide coverage for open adjustable gastric banding, open sleeve gastrectomy, open and laparoscopic vertical banded gastroplasty, intestinal bypass surgery, and gastric balloon for treatment of obesity.

Professional society guidelines

Adults

The Institute for Clinical Systems Improvement (ICSI) (Fitch et al., 2013a) (good quality), Veterans Administration (VA) (Management of Overweight and Obesity Working Group, 2014) (good quality), the American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic & Bariatric Surgery (Mechanick et al., 2013) (poor quality primarily), the Australian National Health and Medical Research Council (NHMRC) (NHMRC, 2013) (good quality), and the National Institute for Health and Care Excellence (NICE) (NICE, 2014) (good quality) provide recommendations on the use of bariatric surgery in adults. The guideline from the American Heart Association/American College of Cardiology/The Obesity Society (Jensen et al., 2014) (good quality) provides a summary of the evidence related to the long-term effectiveness of bariatric surgeries and the long-term effects of these procedures on varying BMI levels with and without comorbidities. The guideline does not provide clinical practice recommendations.

All identified guidelines consistently recommend bariatric surgery for individuals with a BMI of greater than 40 kg/m^2, or greater than 35 kg/m^2 with significant comorbidities. There is some variance between guidelines in what comorbidities are considered significant. For example, only two of the five guidelines list gastroesophageal reflux disease as a significant comorbidity. Four guidelines (AACD/OS/ASMBS, ICSI, NHMRC, NICE) recommend bariatric surgery be considered for individuals with a BMI of greater than 30 kg/m^2 who have severe comorbidities such as diabetes, and NICE recommends bariatric surgery for individuals of Asian descent with recent-onset diabetes who may have a lower BMI than other populations. The VA determined that there was insufficient evidence to recommend the use of bariatric surgery for individuals with a BMI less than 35 kg/m^2.

The AACD/OS/ASMBS and NICE guidelines recommend individuals have pre-surgical comprehensive medical and psychological evaluations. The use of multidisciplinary teams consisting of surgical, medical, nutrition, and psychological expertise is recommended by NICE and NHMRC.

Children

The ICSI (Fitch et al., 2013b) (good quality), the Australian NHMRC (NHMRC, 2013), and NICE (NICE, 2014) provide recommendations on indications for bariatric surgery in the pediatric population. Both the ICSI and NHMRC guidelines recommend bariatric surgery as an option for adolescents with a BMI greater than 40, or greater than 35 with severe comorbidities. The NHMRC specifies that only laparoscopic gastric banding performed by a specialist bariatric/pediatric surgical team is recommended for adolescents. The guideline from ICSI is the most comprehensive and recommends detailed pre-surgical evaluations, failed attempts at weight loss through formal weight loss programs, and the use of multidisciplinary team at regional bariatric centers of excellence. ICSI further recommends that children have attained Tanner stage 4 or 5 or have bone age of ≥13 years in girls or ≥15 years in boys before considering bariatric surgery. Pediatric bariatric surgery is not recommended by NICE except in the case of exceptional circumstances.

Assessment of congruence between guidelines and evidence

In general, the clinical practice guideline recommendations for adults are supported by the available evidence. Patients with BMI ≥40 kg/m^2 or with BMI 35 to 39.9 with obesity-related comorbid conditions have been well studied in the literature, and the clinical practice guidelines reflect this stronger evidence base. The divergence in the recommendations for patients with BMI 30 to 34.9 probably reflects the smaller number of studies that specifically address this population and the shorter follow-up periods reported in these studies. Recommendations regarding pre-surgical evaluations may reflect expert practice tips, but are not directly supported by the summary literature. Similarly, recommendations regarding preoperative weight loss are based on expert opinion and are not directly supported by the summary literature.

The wider variation in the recommendations for bariatric surgery in children reflects greater uncertainty about both the effectiveness and the adverse effects of surgery. When surgery is recommended for children, there is general agreement based on expert opinion that this should be performed at regional centers of excellence.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Appendix A. Methods

Scope Statement

Populations

Obese individuals who are being considered for bariatric or metabolic surgery

Population scoping notes: *Include <18. Exclude overweight (BMI<30)*

Interventions

Bariatric or metabolic surgery (Adjustable gastric banding, Roux-en-y gastric bypass, biliopancreatic diversion, duodenal switch, vertical sleeve gastrectomy)

Intervention exclusions: *Gastric balloon (not FDA approved)*

Comparators

Nonsurgical treatment (medical management, pharmacotherapy, intensive multicomponent behavioral interventions, behavioral counseling, structured weight management programs (e.g. Weight Watchers)

Outcomes

<u>Critical:</u> All-cause mortality, Major Cardiac Events (MACE)

<u>Important</u>**:** Resolution of hypertension, weight loss, resolution of type 2 diabetes

Considered but not selected for the GRADE table: Hyperlipidemia, arthritis, sleep apnea, CPAP use, medication use

Key Questions

1. Should coverage be recommended for bariatric surgery in each of the scenarios in the table below? (Note that the "resolution of diabetes" would not be an applicable outcome in scenarios 4-9)

	BMI 30-34.9	BMI 35-39.9	BMI>=40
With DM2	Scenario 1	Scenario 2	Scenario 3
W/o DM2 nor other comorbidities	Scenario 4*	Scenario 5*	Scenario 6*
W/o DM2 but with other comorbidities	Scenario 7*	Scenario 8*	Scenario 9*

*Resolution of type 2 diabetes isn't a relevant outcome for this population

2. What is the appropriate minimum age for bariatric surgery?

3. What components and systems of care are associated with improved health outcomes? (e.g., centers of excellence, surgeon's experience, etc.)

4. What preoperative assessments or requirements for preoperative weight loss should be recommended in patients being considered for bariatric surgery?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms "bariatric." Searches of core sources were limited to citations published after 2004 with one exception (see inclusion criteria).

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program (WA HTA)

A recent technology assessment from the WA HTA program was identified as the most comprehensive review identified (WA HTA, 2015). A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of the WA HTA report. The search was limited to publications in English published after 2014 (the end search date for the WA HTA systematic review).

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)

United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria

Due to the volume of available literature related to the effectiveness of bariatric surgery in adults (Key Question #1), reviews were limited to those published after 2013. Center staff dual quality assessed the identified reviews and only included those that were rated as good quality.

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines. The following systematic review was excluded because it only included studies that were found in the other systematic reviews:

Ashrafian, H., Toma, T., Rowland, S. P., Harling, L., Tan, A., Efthimiou, E., … Athanasiou, T. (2014). Bariatric surgery or non-surgical weight loss for obstructive sleep apnoea? A systematic review and comparison of meta-analyses. *Obesity Surgery, 25*(7), 1239-50. DOI: 10.1007/s11695-014-1533-2.

Appendix B. GRADE Informed Framework - element descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issue about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.
Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.
Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[1]

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.
Moderate: The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

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[1] Includes risk of bias, precision, directness, consistency and publication bias

Low: The subcommittee's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.
Very low: The subcommittee has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

APPENDIX C. GRADE EVIDENCE PROFILE

Quality Assessment (Confidence in Estimate of Effect) – Adults							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
All-cause Mortality[1]							
14	Cohort	Moderate	Consistent	Direct	No serious imprecision	Large effect size	Low confidence in estimate of effect ●●○○
Major Adverse Cardiovascular Events[1]							
4	Cohort	Moderate	Consistent	Direct	No serious imprecision	Large effect size	Low confidence in estimate of effect ●●○○
Type 2 DM Remission/Resolution[2]							
60	15 RCTs; 45 observational studies	Moderate to High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
Hypertension Remission/Resolution[2]							
52	13 RCTs; 39 observational studies	Moderate	Consistent	Direct	Imprecise	None	Moderate confidence in

Quality Assessment (Confidence in Estimate of Effect) – Adults							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
							estimate of effect ●●●○
Change in BMI[2]							
101	28 RCTs; 73 observational studies	Moderate to High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○

[1] Studies from Tables 1 and 2(Kwok, 2014). Strength of evidence assessment based on Table 2 in Kwok (2014).

[2]Studies and strength of evidence assessment based on Figure 2 of Colquitt (2014), Supplemental Table 1 of Muller-Stich (2015), and the description of study quality from the WA HTA review (2015, p.27-28). Chang (2014) does not provide individual study risk of bias assessments.

Quality Assessment (Confidence in Estimate of Effect) – Children and Adolescents							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
All-cause Mortality							
0	NA	NA	NA	NA	NA	NA	Insufficient evidence
Major Adverse Cardiovascular Events							
0	NA	NA	NA	NA	NA	NA	Insufficient evidence

Quality Assessment (Confidence in Estimate of Effect) – Children and Adolescents							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Type 2 DM Remission/Resolution[1]							
13	13 observational studies	High	Consistent	Direct	Imprecise	None	Very low confidence in estimate of effect ●○○○
Hypertension Remission/Resolution[1]							
15	15 observational studies	High	Consistent	Direct	Imprecise	None	Very low confidence in estimate of effect ●○○○
Change in BMI[1]							
28	1 RCT; 27 observational studies	High	Consistent	Direct	Imprecise	None	Low confidence in estimate of effect ●●○○

[1] Studies from Black (2013) and Treadwell (2008).

Appendix D. Mortality Benefit Outcomes from Kwok (2014) Systematic Review and Meta-Analysis

Several large cohort studies with long-term follow-up comparing bariatric surgery patients to non-surgical controls have demonstrated a consistent reduction in all-cause mortality (as summarized in the meta-analysis in Kwok 2014). In the included cohort studies that performed direct subgroup analysis by BMI, the effects of bariatric surgery appear to be stronger in patients with higher BMI, though other cohorts that report proportional hazard ratios using BMI of 35-40 kg/m2 as the reference find increasing mortality in BMI groups >40. Only two of the cohorts reported outcomes by baseline comorbidities. In the Swedish Obese Subjects study (Sjostorm, 2012), patients with T2DM may have benefited more than those without T2DM, while patients with SBP <140 may have benefited more than hypertensive patients; however, in both scenarios the 95% confidence intervals overlap. It should be noted that Sjostrom reported on the incidence of cardiovascular events rather than mortality and that 70% of the patients received vertical banded gastroplasty, a procedure that is no longer used in the United States. Scott (2013) reports on a cohort of bariatric patients compared to matched controls undergoing either orthopedic or gastrointestinal procedures. There were no significant differences based on the presence of HTN in either group or T2DM in the bariatric-orthopedic comparison; among T2DM patients in the bariatric-GI comparison, there was a slight increase in the proportional hazard of mortality. Two other cohort studies (Arterburn, 2013 and Johnson, 2013) only included patients with T2DM at baseline.

Caution should be exercised in interpreting subgroup analyses from these cohorts given the potentially small number of patients involved. Individual studies with pre-specified inclusion criteria based on comorbidities are more likely to provide accurate estimates of the effects in these groups. On balance, there is insufficient evidence from these cohort studies to conclude that the effects of bariatric surgery on long-term mortality vary based on pre-operative BMI or the presence of comorbid conditions.

Studies in the table below were reviewed in the following article: Kwok, C. S., Pradhan, A., Khan, M. A., Anderson, S. G., Keavney, B. D., Myint, P. K., … Loke, Y. K. (2014). Bariatric surgery and its impact on cardiovascular disease and mortality: a systematic review and meta-analysis. International Journal of Cardiology, 173(1), 20-28. DOI: 10.1016/j.ijcard.2014.02.026

Study	Population (surgical group)	Overall effect of surgery on mortality (95% CI)	Effect of surgery on mortality by BMI (95% CI)	Mortality effect by comorbidities (95% CI)
Adams (2007) Matched retrospective cohort	9,949 adults RYGB Avg BMI 44.9	HR 0.63 (0.53 to 0.74) (all subjects) HR 0.60 (0.45 to 0.67) (matched subjects)	BMI<45 HR 0.72 (0.53 to 0.99) BMI >45 HR 0.56 (0.43 to 0.74)	NR
Arterburn (2013) Retrospective cohort	1,395 adults 80% RYGB BMI>35 and T2DM	HR 0.54 (0.22 to 1.30)	NR	NR
Busetto (2007) Matched cohort	821 adults LAGB BMI>40	RR 0.36 (0.16 to 0.79)	BMI 40-49 RR 0.67 (0.23 to 1.94) BMI>50 RR 0.21 (0.21 to 0.75)	NR
Christou (2004) Retrospective cohort	1,035 adults RYGB Mean BMI 50.0	RR 0.11 (0.04 to 0.27)	NR	NR
Flum (2004) Retrospective cohort	3,328 adults Any gastric bypass “Morbidly obese” (by ICD codes) 13% T2DM	HR 0.67 (0.54 to 0.85)	NR	NR
Gentileschi (2012) Prospective cohort	208 adults RYGB, VSG, AGB Avg BMI 46.6 31% T2DM, 48% HTN	1/208[i] (surgical group) 4/81 (non-surgical group)	NR	NR

Johnson (2013) Retrospective cohort	2,580 adults with T2DM Any bariatric surgery Avg BMI 47 82% HTN, 8.6% CAD	41/2580[ii] (surgical group) 985/13,371 (non-surgical group)	NR	NR
Maciejewski (2011) Retrospective cohort	850 adults (Vets) RYGB Avg BMI 47	HR 0.64[iii] (0.51 to 0.80)	BMI 35-39 HR 1.0 (reference)[iv] BMI 40-49 HR 1.22 (1.16 to 1.27) BMI >50 HR 1.71 (1.59 to 1.85)	NR
Miranda (2012) Retrospective cohort	2,020 adults 95% RYGB Avg BMI 49	HR 0.76 (0.60 to 0.96)	NR	NR
Peeters (2007) Prospective cohort	966 adults LAGB Avg BMI 45	HR 0.28 (0.10 to 0.85)	BMI <40 HR 0.89 BMI >40 HR 0.16	NR
Scott (2013) Retrospective Cohort	4,747 adults Any bariatric surgery "Morbid obesity" (by ICD codes) 41% T2DM, 71% HTN, 5% CAD	HR 0.72 compared to matched ortho surgery pts (0.58 to 0.89) HR 0.48 compared to matched GI surgery pts (0.39 to 0.61)	NR	Bariatric-ortho[v] HTN HR 1.02 (0.8 to 1.4) T2DM HR 1.14 (0.9 to 1.5) Bariatric-GI HTN HR 0.79 (0.6 to 1.1) T2DM HR 1.49 (1.1 to 2.0)

Sjostrom (2012) Prospective cohort	2,010 adults 70% gastroplasty	HR 0.83[vi] (0.69 to 1.00)	BMI <40.8 HR 0.91 (0.70 to 1.18) BMI >40.8 HR 0.8 (0.60 to 1.06)	T2DM HR 0.63 (0.45 to 0.90) No TD2M HR 0.84 (0.67 to 1.06) SBP<140 HR 0.63 (0.46 to 0.86) SBP>140 HR 0.82 (0.64 to 1.04)
Sowemimo (2007) Retrospective cohort	908 adults Nearly all RYGB BMI>40 or >35 with comorbidities Mean BMI 54	HR 0.18 (0.09 to 0.35)	NR	NR

BMI=Body mass index (reported in kg/m^2), CAD=Coronary artery disease, HR=Hazard ratio, HTN=Hypertension, LAGB=Laparoscopic Adjustable gastric banding, NR=Not reported, RR=Relative risk, RYGB=Roux-en-Y gastric bypass, SBP=Systolic blood pressure (reported in mmHg), T2DM=Type 2 diabetes mellitus, VSG=Vertical sleeve gastrectomy

[i] Reported as crude event rates

[ii] Reported as crude event rates

[iii] Reported after unadjusted Cox regression; after adjustment for covariates, the HR was 0.80 (95% CI 0.63 to 0.995). An analysis of propensity matched patients resulted in a HR of 0.83 (95% CI 0.61 to 1.14).

[iv] Reported as adjusted Cox proportional hazards

[v] Reported as Cox proportional hazards

[vi] Primary outcome in Sjostrom was not mortality but incidence of CV events (included here because of its analysis by comorbidity)

[vii] Reported as adjusted Cox proportional hazards

APPENDIX E. BARIATRIC SURGERY COVERAGE

Table E1. Bariatric Surgery Coverage – Adults

Coverage criteria	Payer				
	Washington Medicaid	Aetna[1]	Cigna[2]	Regence BCBS[3]	Moda
Patient Characteristics					
Age	18 – 20 yrs (LAGB obly) 21 – 59 yrs (all procedures)	≥ 18 yrs	≥ 18 yrs	≥ 18 yrs	≥ 18 yrs
BMI	≥ 35 with comorbidities 30-34.9 with DM2 (*see below*)	> 40 > 35 with comorbidities (*see below*)	≥ 40 ≥ 35 with comorbidities (*see below*)	≥ 40 ≥ 35 with DM2 or at least two other comorbidities (*see below*)	≥ 40 ≥ 35 with comorbidities (*see below*)
Not pregnant	√	---	---	---	---
Comorbidities					
Coronary heart disease	---	√	√	√	√
Diabetes	√	√	√	√	√
Dyslipidemia	---	---	√	√	---
Hypertension	---	√	√ (poorly controlled or pulmonary)	√	√
Lower extremity lymphatic or venous obstruction	---	---	√	---	---
Mechanical arthopathy in major weight bearing joint	√	---	√	---	√
Rare comorbid conditions (e.g., pseudo tumor cerebri)	√[4]	---	---	---	---
Sleep apnea	---	√	√	√	√
Absence of other medical conditions (e.g., multiple sclerosis)	√	---	---	---	√

Key: √ – required; --- – not in policy description

Abbreviations: BCBS – Blue Cross Blue Shield; BMI – body mass index; LAGB – laparoscopic adjustable gastric banding; yrs – years

Notes:

1. Specific to open or laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS).
2. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch (BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty
3. Roux-en-Y with an alimentary limb of 150 cm or less, sleeve gastrectomy as a stand-alone procedure, or adjustable gastric banding
4. Must be medical evidence that bariatric surgery is medically necessary and that the benefits of bariatric surgery outweigh the risk of surgical mortality

Table E2. Bariatric Surgery Coverage – Children

Coverage criteria	Payer	
	Aetna[1]	Cigna[2]
Patient Characteristics		
Age	Adolescents who have completed bone growth (~13 yrs in girls, ~15 yrs in boys)	Reached full expected skeletal growth
BMI	> 40 with serious comorbidities > 50 with less serious comorbidities	≥ 40 ≥ 35 with comorbidities
Comorbidities		
Coronary artery disease	---	√
Diabetes	√ (>40 BMI)	√
Dislipidemias	√ (> 50 BMI)	√
Gastroesophageal reflux disease	√ (> 50 BMI)	---
Hypertension	√ (> 50 BMI)	√ (poorly controlled or pulmonary)
Intertriginous soft-tissue infection	√ (> 50 BMI)	---
Mechanical arthropathy in a major weight bearing joint	√ (> 50 BMI)	√
Nonalcoholic steatohepatitis	√ (> 50 BMI)	---
Obesity-related psychosocial distress	√ (> 50 BMI)	---
Rare comorbid conditions (e.g., pseudo tumor cerebri)	√ (>40 BMI)	---
Significant impairments in daily living	√ (> 50 BMI)	---
Sleep apnea	√ (>40 BMI)	√
Stress urinary incontinence	√ (> 50 BMI)	---
Venous stasis disease	√ (> 50 BMI)	√

Key: √ – required; --- – not in policy description   Abbreviations; BMI – body mass index; yrs - years

Notes:

1. Specific to open or laparoscopic Roun-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS)
2. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch (BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty

Table E3. Pre-Surgical Requirements

Coverage criteria	Payer				
	Washington Medicaid	**Aetna[1]**	**Cigna[4]**	**Regence BCBS**	**Moda**
Patient Evaluation					
Comprehensive psychosocial evaluation	√[2]	√[3]	√	√	√
Internal medicine evaluation	√	---	√	---	√
Surgical evaluation	√	---	√	---	---
Nutrition evaluation	---	---	√	---	√
Weight Loss Program					
Required	√	√ (physician-supervised *or* multi-disciplinary surgical prep regimen)	√ (physician- or registered dietician-supervised)	√ (physician-supervised)	√
Timing	Within 180 days of surgery	Within 2 years of surgery (physician-supervised) Within 6 months of surgery (surgical prep regimen)	Within 1 year of surgery	Within 2 years of surgery	Within 2 years of surgery
Duration	≥ 6 months	Cumulative total ≥ 6 months, one program ≥ 3 months (physician-supervised) ≥ 3 months (surgical prep regimen)	≥ 3 months	≥ 6 months	≥ 6 months
Required weight loss	5% of initial body weight	No net weight gain during program	---	----	5% of initial body weight over 6 months

Coverage criteria	Payer				
	Washington Medicaid	Aetna[1]	Cigna[4]	Regence BCBS	Moda
Program Components	Supervised by licensed provider; monthly provider visits; 2x/month counseling by a registered dietitian; patient journal of participation	Physician-supervised: medical record documentation with program compliance record; supervised nutrition and exercise program must have face-to-face component Surgical Prep Regimen: Behavior modification program; dietician or nutritionist consultation; medical record documentation; supervised exercise regimen; substantial face-to-face component; reduced-calorie diet supervised by a dietitian or nutritionist	---	Three visits for medical supervision (no more than 4 months apart); provided by MD, DO, NP, PA, or RD under supervision of MD, DO, NP or PA; assessment and counseling on weight, diet, exercise and behavior modification; clinical documentation of willingness to comply with pre- and post-operative treatment plan	Hypocaloric diet changes, nutritional education, physical activity, behavior change strategies; three or more primary care visits; completion of a 8-week health education, weight management program

Key: √ – required; --- – not in policy description

Abbreviations: DO – doctor of osteopathy; MD – medical doctor; NP – nurse practitioner; PA – physician assistant; RD – registered dietician

Notes:

1. Specific to open or laparoscopic Roun-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS)
2. Provider must be a psychiatrist, licensed psychiatric ARNP, or licensed independent social worker with a minimum of two years postmasters' experience in a mental health setting
3. For members who have a history of severe psychiatric disturbance (schizophrenia, borderline personality disorder, suicidal ideation, severe depression) or who are currently under the care of a psychologist/psychiatrist or who are on psychotropic medications
4. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch

(BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty

Table E4. Facility Requirements

Approved Facility Requirements	Payers
	Washington Medicaid
Minimum number of bariatric surgical procedures performed	100
Direction	Experience board-certified surgeon
Time in operation	≥ 5 years
Mortality rate	≤ 2%
Morbidity rate	≤ 15%
Patient follow-up	≥ 5 years
Average patient weight loss at 5 years	≥ 50%
Reoperation/revision rate	≤ 5%

Table E5. Repeat Surgery Coverage

Circumstances	Payers		
	Aetna	Cigna	Regence BCBS
Adjustment of silicone gastric band	---	√	---
Removal of gastric band	√	---	---
Correct complications	√	√	√
Conversion to sleeve gastrectomy, RYGB or BPD/DS	√[1, 2, 3]	√[2]	√
Failed dilation of gastric pouch after primary surgery	√[1] (if primary surgery was successful in inducing weight loss)	√	---
Replacement of adjustable band	√ (for complications)	---	---

Key: √ – covered; --- – not in policy description

Abbreviations: BPD – biliopancreatic diversion; DS – duodenal switch RYGB – Roux-en-Y gastric bypass;

Notes:

1. If patient has been compliant with a prescribed nutrition and exercise program following the procedure
2. For members who have not lost > 50% of body weight 2 years following primary surgery
3. Conversion from adjustable band to sleeve gastrectomy, RYGB or BPD/DS, for complications that cannot be corrected with band manipulation, adjustments or replacement

Table E6. Non-Covered Conditions and Procedures

	Payers		
	Aetna	Cigna	Regence BCBS
Conditions			
Idiopathic intracranial hypertension	X	---	---
Infertility	X	---	---
DM2 w/BMI <35	X	X[1]	
Gastroesophageal reflux in non-obese persons	X	---	X
Gastroparesis	X	---	---
Procedures			
Band over bypass	X	---	X
Band over sleeve	X	---	X
Roux-en-Y gastric bypass combined with simultaneous BPD without DS	---	X	---
Gastrointestinal liners (EndoBarrier™)	X	X	---
Gastroplasty (“stomach stapling”)	X	X	X
Intragastric balloon	X	X	
Laparoscopic gastric plication	X	X	X
Loop gastric bypass	X	X	
Mini gastric bypass	X	X	X
Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery	X	---	X
Silastic ring vertical gastric bypass (Fobi pouch)	X	X	---
Transoral endoscopic surgery (OverStitch suturing device or StomaphyX™ device)	X	X (including TOGA®)	X
Vagus nerve blocking	X	X	---
Gastric electrical stimulation or gastric pacing	---	X	---
Intestinal bypass (jejunoileal bypass)	---	X	X
restorative obesity surgery, endoluminal (ROSE)	---	X	X
Vagus nerve stimulation	---	X	---

Distal gastric bypass (long limb gastric bypass, >150 cm)	---	---	X
Biliopancreatic bypass (Scopinaro procedure)	---	---	X
Biliopancreatic bypass with duodenal switch	---	---	X
Two-stage procedures	---	---	X
Vertical banded gastroplasty	---	---	X
EndoCinch™	---	---	X

Key: √ – covered; X – not covered; --- – not in policy description

Notes:

1. Not covered when performed solely for treatment of diabetes mellitus
2. Specific requirements for vertical banded gastroplasty (members who are at increased risk of adverse consequences from Roux-en-Y Gastric bypass due to the presence of:
    - Demonstrated complications from extensive adhesions involving the intestines from prior major abdominal surgery, multiple minor surgeries, or major trauma
    - Hepatic cirrhosis with elevated liver function tests
    - Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
    - Poorly controlled systemic disease
    - Radiation enteritis.

APPENDIX F. APPLICABLE CODES

CODES	DESCRIPTION
ICD-10	
E11.0 – E11.9	Diabetes, type 2
E66.01-E66.9	Overweight, Obesity and Morbid Obesity
G47.30 – G47.39	Sleep apnea
I10	Essential hypertension
ICD-9-CM Volume I Codes	
250.00, 250.02; 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92	Diabetes, Type II
278.00 – 278.03	Overweight, Obesity, and Morbid Obesity
327.20 – 327.29; 780.57	Sleep apnea
401.0 – 401.9	Hypertension
ICD-9-CM Volume III Codes	
43.82	Laparoscopic vertical (sleeve) gastrectomy
43.89	Open and other partial gastrectomy
44.31	High gastric bypass
44.38	Laparoscopic gastroenterostomy
44.5	Revision of gastric anastomosis
44.68	Laparoscopic gastroplasty
44.69	Other repair of stomach
44.95	Laparoscopic gastric restrictive procedure
44.96	Laparoscopic revision of gastric restrictive procedure
44.97	Laparoscopic removal of gastric restrictive device(s)
44.98	Laparoscopic) adjustment of size of adjustable gastric restrictive device

45.51	Isolation of segment of small intestine
45.91	Small-to-small intestinal anastomosis
CPT Codes	
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 Level II Codes	
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Note: Inclusion on this list does not guarantee coverage

APPENDIX G. OUTCOMES BY BASELINE MEAN BMI FROM THE WA HTA REPORT (P. 64-65)

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Decrease BMI	RYGB	25.4	(19.6-34.3)	26.0	(24.1-33.1)	32.2	(7.5-52.3)	34	(10.1-46.7)
	VSG	21.3	(21.3-21.3)	22.0	(19.1-22.5)	28.4	(15.0-37.1)	30.1	(11.0-39.4)
	LAGB	16.8	(11.8-21.7)	16.8	(13.0-17.5)	20.4	(6.0-46.8)	17.7	(1.0-31.8)
	BPD/DS	31.8	(17.3-46.3)			32.6	(15.9-50.8)	43.4	(39.2-47.7)
	Follow-up (months)	12.0	(3.0-45.2)	15.3	(12.0-60.0)	12.0	(0.5-120.0)	22.6	(1.2-84.0)
	No. Studies	7		6		79		22	
	Good/Fair/Poor	2/3/2		3/1/2		9/34/36		4/10/8	
% EWL	RYGB	70.0		77.0	(61.0-92.9)	67.0	(27.1-88.0)	61.8	(43.8-72.3)
	VSG			58.5	(51.0-66.0)	59.2	(30.7-83.0)	47.5	(25.4-75.0)
	LAGB	87.2		50.1	(34.0-62.5)	43.5	(18.2-78.8)	45.9	(31.0-73.0)
	BPD/DS					52.7	(34.9-70.4)	73.4	63.0-84.0)
	Follow-up (months)	18.0	(12.0-24.0)	30.0	(18.7-60.0)	24.0	(0.47-120)	24.0	(12.0-84.0)
	No. Studies	2		4		57		15	
	Good/Fair/Poor	1/0/1		1/1/2		6/27/24		1/8/6	
% Improvement Hypertension	RYGB			90.0		71.0	(22.0-100.0)	62.6	(60.7-69.2)
	VSG					64.3	(23.5-100.0)		
	LAGB			40.0		57.5	(18.0-100.0)	54.3	(33.3-66.7)
	BPD/DS	67.0				81.4	(68.6-87.0)	68.3	(66.7-69.9)
	Follow-up (months)	36.0		60.0		21.0	(3.5-84.0)	24.0	(12.0-50.4)
	No. Studies	1		1		29		5	
	Good/Fair/Poor	0/1/0		0/0/1		4/12/13		1/3/1	

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Improvement T2DM	RYGB	51.1	(33.0-92.3)	73.4	(66.7-80.0)	79.0	(33.0-100.0)	77.1	(40.0-100.0)
	VSG	50.0	(50.0-50.0)			77.3	(36.0-100.0)	88.9	(88.9-88.9)
	LAGB	33.0	(21.1-100.0)	50.0	(25.0-73.0)	50.0	(17.0-100.0)	52.3	(36.4-66.7)
	BPD/DS	84.8	(83.0-84.8)			87.1	(81.5-92.7)	91.4	(82.7-100.0)
	Follow-up (months)	12.0	(3.0-45.2)	24.0	(12.0-60.0)	16.0	(1.0-62.7)	24.0	(1.5-50.4)
	No. Studies	6		3		35		7	
	Good/Fair/Poor	0/3/3		2/0/1		3/14/18		1/4/2	
% Improvement Sleep Apnea	RYGB	89.0				70.5	(10.0-100.0)	56.7	(49.3-88.0)
	VSG					62.0	(6.0-99.0)		
	LAGB					29.0	(3.0-55.0)	46.2	(39.3-66.7)
	BPD/DS	90.0						79.5	(78.9-80.0)
	Follow-up (months)	45.15				21.6	(12.0-36.0)	20.1	(12.0-20.1)
	No. Studies	1		0		11		4	
	Good/Fair/Poor	0/0/1				2/5/4		1/3/0	
% Improvement Dyslipidemia	RYGB			100.0		64.5	(6.0-100.0)	52.9	(27.3-58.8)
	VSG					67.5	(35.0-67.5)		
	LAGB			38.0		36.5	(0.0-36.5)	34.4	(23.3-45.5)
	BPD/DS					90.0	(90.0-90.0)		
	Follow-up (months)			60.0		24.0	(12.0-62.7)	16.2	(12.0-50.4)
	No. Studies	0		1		18		3	
	Good/Fair/Poor	0		0/0/1		2/9/7		1/1/1	

APPENDIX H. COST-EFFECTIVENESS ESTIMATES FROM THE WA HTA REPORT (P. 80)

BMI Level/ Procedure	Cost ($)	Effectiveness (QALYs)	Cost-effectiveness ($/QALY gained)	
			Vs. SC	Vs. RYGB
BMI≥30				
Standard care	$34,923	7.5680	NA	NA
RYGB	$54,110	8.0807	$37,423	NA
VSG	$48,702	8.0417	$29,087	Less expensive & less effective
LAGB	$47,668	7.9252	$35,680	Less expensive & less effective
BPD/DS	$65,741	8.2307	$46,508	$77,574
BMI 30-34.9				
Standard care	$27,943	7.9418	NA	NA
RYGB	$49,735	8.3529	$53,021	NA
VSG	$44,298	8.3211	$43,122	Less expensive & less effective
LAGB	$42,738	8.2273	$51,826	Less expensive & less effective
BPD/DS	$61,410	8.4730	$63,011	$97,194
BMI 35-39.9				
Standard care	$32,538	7.6567	NA	NA
RYGB	$52,886	8.1351	$42,534	NA
VSG	$47,468	8.0986	$33,789	Less expensive & less effective
LAGB	$46,217	7.9898	$41,073	Less expensive & less effective
BPD/DS	$64,533	8.2751	$51,743	$83,224
BMI≥40				
Standard care	$40,329	7.2846	NA	NA
RYGB	$58,257	7.8630	$30,995	NA
VSG	$53,047	7.8194	$23,784	Less expensive & less effective
LAGB	$52,255	7.6882	$29,552	Less expensive & less effective
BPD/DS	$69,329	8.0322	$38,790	$65,431

BPD = biliopancreatic diversion; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

NOTE: Because of rounding, performing calculations may not produce the exact results shown.

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[i] Reported as crude event rates
[ii] Reported as crude event rates
[iii] Reported after unadjusted Cox regression; after adjustment for covariates, the HR was 0.80 (95% CI 0.63 to 0.995). An analysis of propensity matched patients resulted in a HR of 0.83 (95% CI 0.61 to 1.14).
[iv] Reported as adjusted Cox proportional hazards
[v] Reported as Cox proportional hazards
[vi] Primary outcome in Sjostrom was not mortality but incidence of CV events (included here because of its analysis by comorbidity)