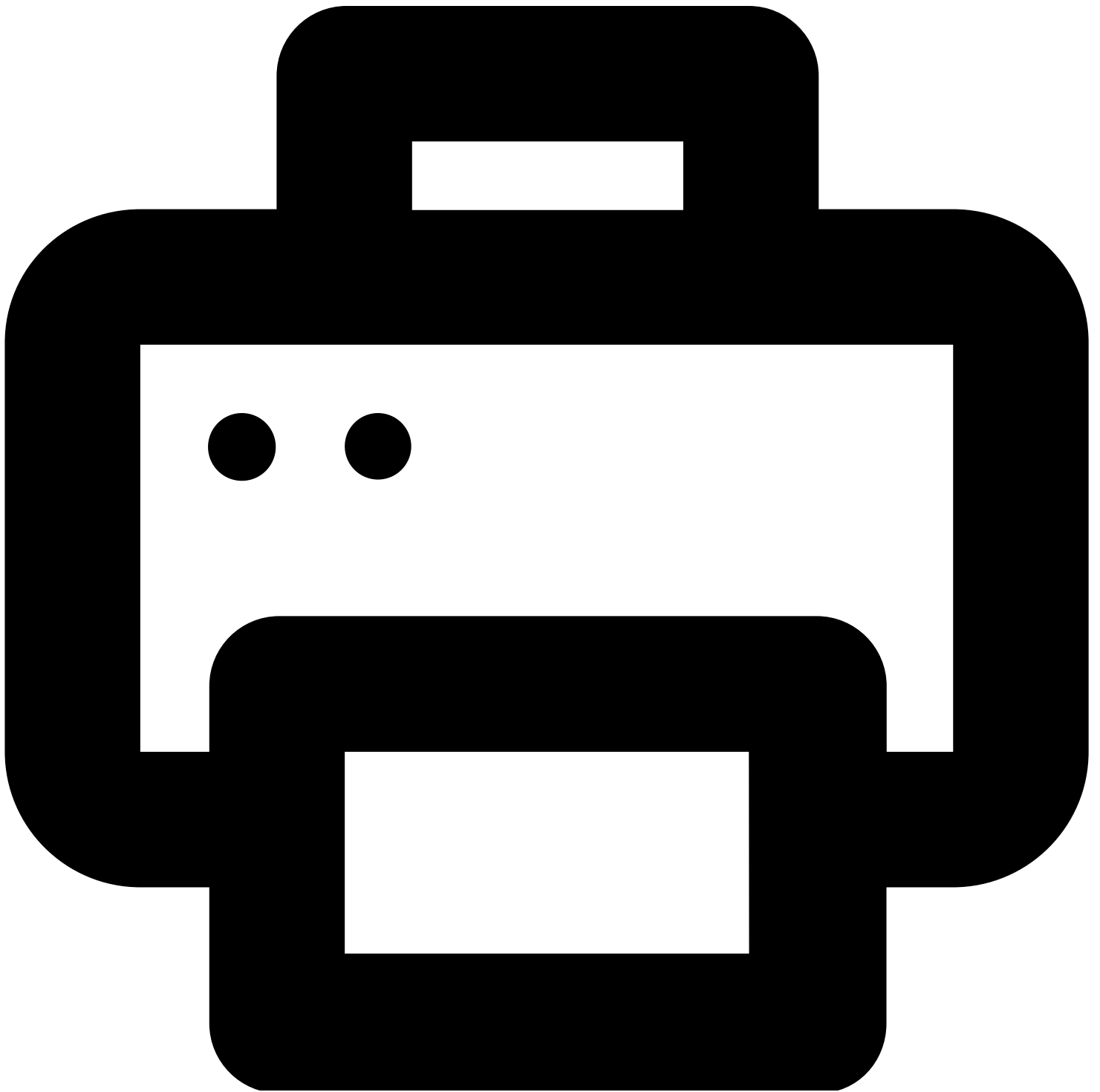


Policies & Guidelines

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Print

Bariatric Surgery for Treatment of Morbid Obesity and GERD

Policy Number: MP-053

Latest Review Date: February 2023

Category: Surgery

POLICY:

NOTE: Verify contract benefits for coverage of bariatric surgery and complications.

Effective for dates of service on and after January 15, 2023:

I. Gastric Restrictive Procedures

One of the following bariatric surgery procedures:

- Open gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic adjustable gastric banding (for patients ≥ 18 years); OR
- Sleeve gastrectomy (as a single step procedure)

May be considered medically necessary when ALL of the criteria below are present:

1. Age 16 or older with BMI of 40 or greater;

OR

Age 16 or older with BMI of 35-39.9 with one or more of the following obesity-related co-morbid conditions: HTN on optimal drug therapy, cardiovascular disease (e.g. stroke, MI), history of coronary artery disease with a surgical intervention, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, Pickwickian syndrome, obesity related cardiomyopathy, Obesity Induced Cardiomyopathy, Nonalcoholic steatohepatitis (NASH), Nonalcoholic fatty liver disease (NAFLD), Obesity-hypoventilation syndrome (OHS), or severe obstructive sleep apnea. (RDI of 50 or greater OR AHI ≥ 30);

AND

2. The condition of morbid obesity (BMI ≥ 40 ; OR BMI 35-39.9 with presence of comorbid conditions) must be of at least 3 years (36 months) duration.
 - There must be documentation in medical records by a qualified health care provider of patient height and weight. Weight must be documented at least annually, with the first weight documented at least 36 months prior to the bariatric surgical request date; or
 - If no medical record documentation is available, a letter from the primary care provider and dated photographs will be considered in lieu of recorded heights and weights;

NOTE: Random reviews of these patients' charts for accuracy of stated information will be conducted.

AND

3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision. Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.; AND

4. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND
5. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

If the adjustable gastric restrictive procedure is considered not medically necessary or if the patient decides to pay for the adjustable gastric restrictive procedure, the adjustments of the devices are considered not medically necessary.

II. Malabsorptive Procedures

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch may be considered medically necessary for treatment of the morbidly obese patients with BMI of 50 kg/m² or more when ALL of the following criteria are met:

1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties. Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:
 - Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Acceptable with medical record documentation of medical supervision are: Weight Watchers, LA Weight Loss, Jenny Craig, EatRight etc. Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.;

AND

2. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND
3. The patient must be at least 16 years of age; AND
4. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

III. Roux-en-y Gastric Bypass for Treatment of Gastroesophageal Reflux Disease in Obese Patients

Roux-en-y gastric bypass (RYGB) is highly effective in reducing refractory symptoms of GERD in obese patients, and part of this effect may be due to weight loss itself. Therefore, medical weight loss is the first line treatment of GERD in obese patients, and should be attempted before RGYB is considered.

NOTE: When performed for treatment of GERD in an obese patient without a previous gastric sleeve procedure, roux-en-y gastric bypass is still classified as bariatric surgery. Verify contract benefits for coverage of bariatric surgery and complications.

Roux-en-y gastric bypass (RYGB) may be considered medically necessary for treatment of refractory GERD in patients with a BMI > 35 kg/m² when all of the following criteria are met:

1. Age 16 or older with BMI of 40 or greater or a BMI of 35-39.9 with one or more of the following obesity-related co-morbid conditions: HTN on optimal drug therapy, atherosclerotic cardiovascular disease (e.g. stroke, MI), history of coronary artery disease with a surgical intervention, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, Pickwickian syndrome, obesity related cardiomyopathy, Obesity Induced Cardiomyopathy, Nonalcoholic steatohepatitis (NASH), Nonalcoholic fatty liver disease (NAFLD), Obesity-hypoventilation syndrome (OHS), or severe obstructive sleep apnea. (RDI of 50 or greater OR AHI >=30);

AND

2. The condition of morbid obesity (BMI ≥ 40; OR BMI 35-39.9 with presence of comorbid conditions) must be of at least 3 years (36 months) duration.
 - There must be documentation in medical records by a qualified health care provider of patient height and weight for the past 3 years (36 months); or
 - If no medical record documentation is available, a letter from the primary care provider and dated photographs will be considered in lieu of recorded heights and weights;

AND

3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision, Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.;

AND

4. A complete history and physical must be performed by the bariatric surgeon (to include their CRNP, PA, SA) to include height and weight;

AND

5. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

Roux-en-y gastric bypass (RYGB) is considered investigational for primary surgical treatment of GERD in patients with a BMI < 35 kg/m².

IV. Preoperative Assessments

The pre-operative office visit or consult will be considered medically necessary when the surgery is determined to be medically necessary. Claims for a decision for surgery should be filed with modifier 57.

Many times there will be an extended lapse of time between the decision for surgery and the pre-operative visit. Pre-operative testing and a pre-operative visit will also be covered if medically necessary and if the surgery is considered medically necessary. The correct diagnoses to report pre-operative testing and evaluations are ICD-10 codes: Z01.810-Z01.811, or Z01.818. The obesity diagnosis should be listed as the secondary diagnosis.

NOTE: A pre-operative psychological evaluation is not required, but may be covered when requested by the surgeon for those patients with a history of severe psychiatric illness (schizophrenia, borderline personality disorder, suicidal ideation, severe depression), and those patients currently under the care of a psychiatrist/psychologist or on psychotropic medications. Any of the above conditions may impair the ability to give consent or be compliant post-operatively. This will be considered medically necessary. Psychological evaluations should be reported with procedure code 90791 with type service 6 with ICD-10 diagnosis of Z01.818 with a secondary diagnosis of obesity.

V. Revisions and Conversions

Gastric Surgery

Revision or conversion of a prior bariatric procedure (excluding adjustable gastric banding) may be considered medically necessary with documented evidence of ONE or MORE of the following:

- Weight loss of 20% or more below the ideal body weight following bariatric surgery; OR
- Vomiting (bilious); OR
- Stomal dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR

- Stomal stenosis after vertical gastric banding, documented by endoscopy, with vomiting or weight loss of 20% or more below the ideal body weight; OR
- Obstruction; OR
- Stricture; OR
- Severe diarrhea following surgery; OR
- Severe dumping syndrome

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and
- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

Revision or conversion of a prior bariatric procedure without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss after the prior bariatric procedure.

Treatment of complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Adjustable Gastric Restrictive Devices

Removal of the adjustable gastric restrictive device is considered medically necessary when recommended by the member's physician.

Revision (to include replacement) or, conversion of adjustable gastric restrictive device may be considered medically necessary for the following indications:

- Band erosion or slippage; OR
- Infections around the port site

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and
- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

Treatment of complications (e.g., stomal dilatation, pouch dilatation) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Revision or conversion of an adjustable gastric restrictive device without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss with the adjustable gastric restrictive device.

Concomitant Hiatal Hernia Repair With Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery may be considered medically necessary.

VI. Conversion of Sleeve Gastrectomy to Roux-en-y Gastric Bypass for Treatment of Refractory Gastroesophageal Reflux Disease

Conversion of a previous sleeve gastrectomy to Roux-en-Y gastric bypass (RYGB) may be considered medically necessary for the treatment of symptomatic gastroesophageal reflux disease (GERD) if the following criteria are met:

1. Age 16 or older; and
2. Documented evidence that symptoms persist for more than three months while receiving optimal medical therapy, which must include behavioral modification and use of maximal PPI therapy (unless there is a documented patient allergy to

PPIs); and

3. Objective evidence of reflux is documented by an abnormal 24-hour pH monitoring (performed off proton pump inhibitors) or biopsy proven moderate-to-severe esophagitis (Los Angeles Classification “B” or greater); and
4. Esophageal manometry rules out primary or secondary neuromuscular and motility disorders of the esophagus (e.g. achalasia).

Conversion of sleeve gastrectomy to RYGB for failure of weight loss or for regain of weight is considered not medically necessary.

When performed solely for the purpose of treating GERD meeting these criteria, conversion of sleeve gastrectomy to RYGB is not considered repeat bariatric surgery.

VII. The following, including but not limited to, situations and procedures is considered not medically necessary and investigational:

Situations:

1. Bariatric surgery in patients under age 16 years;
2. Bariatric surgery performed as a cure for type II diabetes;
3. Bariatric surgery revisions due to complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendation such as dietary restrictions, patient activity and/or lifestyle following the initial procedure.
4. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions and Conversions section above)
5. Revision or conversion of the adjustable gastric band for other than the stated accepted complications. (see Revisions and Conversions section above)
6. Single anastomosis duodeno-ileostomy sleeve gastrectomy (SADI-S)
7. Laparoscopic adjustable gastric banding in patients under age 18 years.

Procedures:

1. Biliopancreatic Bypass without Duodenal Switch
2. Endoscopic procedures as a primary bariatric procedure or as a revision or conversion procedure, including but not limited to endoscopic closure devices (e.g. StomaphyX™, Overstitch, Over the Scope clip[OTSC]), insertion of gastric balloon(s) (i.e., Orbera, Reshape), endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve.
3. Vertical Banded Gastric Bypass, Fobi-Pouch (FPOO) Transected (Silastic Ring Vertical Gastric Bypass)
4. Gastric Electrical Stimulation
5. Gastric Wrapping
6. Jejunoileal Bypass
7. Mini-gastric Bypass
8. Long Limb Gastric Bypass (i.e., >150cm)
9. Loop Gastric Bypass
10. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
11. Laparoscopic gastric plication
12. Balloon-in-a-Pill systems (i.e., Obalon, Elipse, etc)
13. Laparoscopic distalization
14. Weight loss stomach pumps (i.e., AspireAssist, A-tube™)

If the bariatric procedure is considered not medically necessary or if the patient decides to self-pay for the bariatric procedure, the treatment of complications that may arise from the bariatric procedure, regardless of cause is considered not medically necessary.

Any repeat surgery for morbid obesity for other than the stated surgical complications is considered not medically necessary.

Bariatric surgery in pre-adolescent children, and adolescents younger than 16 is considered not medically necessary.

Effective for dates of service February 18, 2021 through January 14, 2023:

I. Gastric Restrictive Procedures

One of the following bariatric surgery procedures:

- Open gastric bypass using a Roux-en-Y anastomosis; OR

- Laparoscopic gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic adjustable gastric banding (for patients ≥ 18 years); OR
- Sleeve gastrectomy (as a single step procedure)

May be considered medically necessary when ALL of the criteria below are present:

1. Age 16 or older with BMI of 40 or greater;

OR

Age 16 or older with BMI of 35-39.9 with one or more of the following obesity-related co-morbid conditions: HTN on optimal drug therapy, cardiovascular disease (e.g. stroke, MI), history of coronary artery disease with a surgical intervention, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, Pickwickian syndrome, obesity related cardiomyopathy, Obesity Induced Cardiomyopathy, Nonalcoholic steatohepatitis (NASH), Nonalcoholic fatty liver disease (NAFLD), Obesity-hypoventilation syndrome (OHS), or severe obstructive sleep apnea. (RDI of 50 or greater OR AHI ≥ 30);

AND

2. The condition of morbid obesity (BMI ≥ 40 ; OR BMI 35-39.9 with presence of comorbid conditions) must be of at least 3 years (36 months) duration.
 - There must be documentation in medical records by a qualified health care provider of patient height and weight. Weight must be documented at least annually, with the first weight documented at least 36 months prior to the bariatric surgical request date; or
 - If no medical record documentation is available, a letter from the primary care provider and dated photographs will be considered in lieu of recorded heights and weights;

NOTE: Random reviews of these patients' charts for accuracy of stated information will be conducted.

AND

3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:
 - Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision, Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.; AND
4. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND
 5. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

If the adjustable gastric restrictive procedure is considered not medically necessary or if the patient decides to pay for the adjustable gastric restrictive procedure, the adjustments of the devices are considered not medically necessary.

II. Malabsorptive Procedures

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch may be considered medically necessary for treatment of the morbidly obese patients with BMI of 50 kg/m² or more when ALL of the following criteria are met:

1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties. Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Acceptable with medical record documentation of medical supervision are: Weight Watchers, LA Weight Loss, Jenny Craig, EatRight etc. Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.;

AND

2. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND
3. The patient must be at least 16 years of age; AND
4. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

III. Preoperative Assessments

The pre-operative office visit or consult will be considered medically necessary when the surgery is determined to be medically necessary. Claims for a decision for surgery should be filed with modifier 57.

Many times there will be an extended lapse of time between the decision for surgery and the pre-operative visit. Pre-operative testing and a pre-operative visit will also be covered if medically necessary and if the surgery is considered medically necessary. The correct diagnoses to report pre-operative testing and evaluations are ICD-10 codes: Z01.810-Z01.811, or Z01.818. The obesity diagnosis should be listed as the secondary diagnosis.

NOTE: A pre-operative psychological evaluation is not required, but may be covered when requested by the surgeon for those patients with a history of severe psychiatric illness (schizophrenia, borderline personality disorder, suicidal ideation, severe depression), and those patients currently under the care of a psychiatrist/psychologist or on psychotropic medications. Any of the above conditions may impair the ability to give consent or be compliant post-operatively. This will be considered medically necessary. Psychological evaluations should be reported with procedure code 90791 with type service 6 with ICD-10 diagnosis of Z01.818 with a secondary diagnosis of obesity.

IV. Revisions and Conversions

Gastric Surgery

Revision or conversion of a prior bariatric procedure (excluding adjustable gastric banding) may be considered medically necessary with documented evidence of ONE or MORE of the following:

- Weight loss of 20% or more below the ideal body weight following bariatric surgery; OR
- Vomiting (bilious); OR
- Stomal dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Stomal stenosis after vertical gastric banding, documented by endoscopy, with vomiting or weight loss of 20% or more below the ideal body weight; OR
- Obstruction; OR
- Stricture; OR
- Severe diarrhea following surgery; OR
- Severe dumping syndrome

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and
- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

Revision or conversion of a prior bariatric procedure without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss after the prior bariatric procedure.

Treatment of complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Adjustable Gastric Restrictive Devices

Revision, conversion or removal of adjustable gastric restrictive device may be considered medically necessary for the following indications:

- Band erosion or slippage; OR
- Infections around the port site

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and
- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

NOTE: Smoking cessation applies to smoking of tobacco products (e.g., cigarettes, cigars, and/or pipe).

Treatment of complications (e.g., stomal dilatation, pouch dilatation) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Revision or conversion of an adjustable gastric restrictive device without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss with the adjustable gastric restrictive device.

Elective removal (i.e., removal not due to the above complications) of the adjustable gastric restrictive device is considered not medically necessary.

Concomitant Hiatal Hernia Repair With Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery may be considered medically necessary.

V. The following, including but not limited to, situations and procedures is considered not medically necessary and investigational:

Situations:

1. Bariatric surgery in patients under age 16 years;
2. Bariatric surgery performed as a cure for type II diabetes;
3. Bariatric surgery revisions due to complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendation such as dietary restrictions, patient activity and/or lifestyle following the initial procedure.
4. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions and Conversions section above)
5. Revision, conversion or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions and Conversions section above)
6. Elective removal of the adjustable gastric band.
7. Single anastomosis duodeno-ileostomy sleeve gastrectomy (SADI-S)

8. Laparoscopic adjustable gastric banding in patients under age 18 years.

Procedures:

1. Biliopancreatic Bypass without Duodenal Switch
2. Endoscopic procedures as a primary bariatric procedure or as a revision or conversion procedure, including but not limited to endoscopic closure devices (e.g. StomaphyX™, Overstitch, Over the Scope clip[OTSC]), insertion of gastric balloon(s) (i.e., Orbera, Reshape), endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve.
3. Vertical Banded Gastric Bypass, Fobi-Pouch (FPOO) Transected (Silastic Ring Vertical Gastric Bypass)
4. Gastric Electrical Stimulation
5. Gastric Wrapping
6. Jejunioileal Bypass
7. Mini-gastric Bypass
8. Long Limb Gastric Bypass (i.e., >150cm)
9. Loop Gastric Bypass
10. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
11. Laparoscopic gastric plication
12. Balloon-in-a-Pill systems (i.e., Obalon, Elipse, etc)
13. Laparoscopic distalization
14. Weight loss stomach pumps (i.e., AspireAssist, A-tube™)

If the bariatric procedure is considered not medically necessary or if the patient decides to self-pay for the bariatric procedure, the treatment of complications that may arise from the bariatric procedure, regardless of cause is considered not medically necessary.

Any repeat surgery for morbid obesity for other than the stated surgical complications is considered not medically necessary.

Bariatric surgery in pre-adolescent children, and adolescents younger than 16 is considered not medically necessary.

Effective for dates of service August 5, 2016 through February 17, 2021:

I. Gastric Restrictive Procedures

One of the following bariatric surgery procedures:

- Open gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic adjustable gastric banding; OR
- Sleeve gastrectomy (as a single step procedure)

May be considered medically necessary when ALL of the criteria below are present:

BMI of 40 or greater or a BMI of 35-39.9 with one or more of the following obesity-related co-morbid conditions: HTN on optimal drug therapy, atherosclerotic cardiovascular disease, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, or severe obstructive sleep apnea. (RDI of 50 or greater OR AHI >=30);

AND

1. The condition of morbid obesity (BMI \geq 40; OR BMI 35-39.9 with presence of comorbid conditions) must be of at least 3 years (36 months) duration.
 - There must be documentation in medical records by a qualified health care provider of patient height and weight for the past 3 years (36 months); or
 - If no medical record documentation is available, a letter from the primary care provider and dated photographs will be considered in lieu of recorded heights and weights;

NOTE: Random reviews of these patients' charts for accuracy of stated information will be conducted.

AND

2. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). Documentation provided by these health care providers will be recognized

in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision, Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.;

AND

3. A complete history and physical must be performed by the bariatric surgeon to include height and weight;

AND

4. The patient must be at least 18 years of age;

AND

5. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

If the adjustable gastric restrictive procedure is considered not medically necessary or if the patient decides to pay for the adjustable gastric restrictive procedure, the adjustments of the devices are considered not medically necessary.

II. Malabsorptive Procedures

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch may be considered medically necessary for treatment of the morbidly obese patients with BMI of 50 kg/m² or more when ALL of the following criteria are met:

1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, the plan recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties. Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

- Acceptable with medical record documentation of medical supervision are: Weight Watchers, LA Weight Loss, Jenny Craig, EatRight etc. Not acceptable are self-directed programs such as joining a gym, Atkins' diet, calorie counting, low fat, cutting back, internet programs, etc.; AND

2. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND
3. The patient must be at least 18 years of age; AND
4. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

III. Preoperative Assessments

The pre-operative office visit or consult will be considered medically necessary when the surgery is determined to be medically necessary. Claims for a decision for surgery should be filed with modifier 57.

Many times there will be an extended lapse of time between the decision for surgery and the pre-operative visit. Pre-operative testing and a pre-operative visit will also be covered if medically necessary and if the surgery is considered medically necessary. The correct diagnoses to report pre-operative testing and evaluations are ICD-10 codes: Z01.810-Z01.811, or Z01.818. The obesity diagnosis should be listed as the secondary diagnosis.

NOTE: A pre-operative psychological evaluation is not required, but may be covered when requested by the surgeon for those patients with a history of severe psychiatric illness (schizophrenia, borderline personality disorder, suicidal ideation, severe depression), and those patients currently under the care of a psychiatrist/psychologist or on psychotropic medications. Any of the above conditions may impair the ability to give consent or be compliant post-operatively. This will be considered medically necessary. Psychological evaluations should be reported with procedure code 90791 with type service 6 with ICD-10 diagnosis of Z01.818 with a secondary diagnosis of obesity.

IV. Revisions and Conversions

Gastric Surgery

Revision or conversion of a prior bariatric procedure (excluding adjustable gastric banding) may be considered medically necessary with documented evidence of ONE or MORE of the following:

- Weight loss of 20% or more below the ideal body weight following bariatric surgery; OR
- Vomiting (bilious); OR
- Stomal dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); OR
- Stomal stenosis after vertical gastric banding, documented by endoscopy, with vomiting or weight loss of 20% or more below the ideal body weight; OR
- Obstruction; OR
- Stricture; OR
- Severe diarrhea following surgery; OR
- Severe dumping syndrome

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and
- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

Revision or conversion of a prior bariatric procedure without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss after the prior bariatric procedure.

Treatment of complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Adjustable Gastric Restrictive Devices

Revision, conversion or removal of adjustable gastric restrictive device may be considered medically necessary for the following indications:

- Band erosion or slippage; OR
- Infections around the port site

AND

- The requested procedure must be a covered bariatric surgery/procedure; and
- The patient must be at least 18 years of age; and

- Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

Treatment of complications (e.g., stomal dilatation, pouch dilatation) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure is considered not medically necessary.

Revision or conversion of an adjustable gastric restrictive device without complicating factors to another bariatric procedure is considered not medically necessary when requested due to lack of weight loss or less than anticipated weight loss with the adjustable gastric restrictive device.

Elective removal (i.e., removal not due to the above complications) of the adjustable gastric restrictive device is considered not medically necessary.

Concomitant Hiatal Hernia Repair With Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery may be considered medically necessary.

V. Does not meet medical criteria for coverage & Investigational

The following, including but not limited to, situations and procedures is considered not medically necessary and investigational:

Situations:

1. Bariatric surgery in patients under age 18 years;
2. Bariatric surgery performed as a cure for type II diabetes;
3. Bariatric surgery revisions due to complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendation such as dietary restrictions, patient activity and/or lifestyle following the initial procedure.
4. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions and Conversions section above)
5. Revision, conversion or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions and Conversions section above)
6. Elective removal of the adjustable gastric band.

Procedures:

1. Biliopancreatic Bypass without Duodenal Switch
2. Endoscopic procedures as a primary bariatric procedure or as a revision or conversion procedure, including but not limited to endoscopic closure devices (e.g. StomaphyX™, Overstitch, Over the Scope clip[OTSC]), insertion of gastric balloon(s) (i.e., Orbera, Reshape), endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve.
3. Vertical Banded Gastric Bypass, Fobi-Pouch (FPOO) Transected (Silastic Ring Vertical Gastric Bypass)
4. Gastric Electrical Stimulation
5. Gastric Wrapping
6. Jejunioileal Bypass
7. Mini-gastric Bypass
8. Long Limb Gastric Bypass (i.e., >150cm)
9. Loop Gastric Bypass
10. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
11. Laparoscopic gastric plication
12. Balloon-in-a-Pill systems (i.e., Obalon, Elipse, etc)
13. Laparoscopic distalization
14. Weight loss stomach pumps (i.e., AspireAssist, A-tube™)

If the bariatric procedure is considered not medically necessary or if the patient decides to self-pay for the bariatric procedure, the treatment of complications that may arise from the bariatric procedure, regardless of cause is considered not medically necessary.

Any repeat surgery for morbid obesity for other than the stated surgical complications is considered not medically necessary.

DESCRIPTION OF PROCEDURE OR SERVICE:

General Information

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these different techniques have heterogeneous mechanisms of action, the result is a smaller gastric pouch that leads to restricted eating. However, these surgeries may lead to malabsorption of nutrients, or eventually to metabolic changes.

Bariatric surgery is performed for the treatment of morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m² or a BMI greater than 35 kg/m² with weight related complications. BMI is calculated by dividing a patient's weight (in kilograms) by height (in meters) squared.

- To convert pounds to kilograms, multiply pounds by 0.45
- To convert inches to meters, multiply inches by 0.0254

Morbid obesity results in a very high risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectum, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. The majority of patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

Documented failure of attempts to respond to conservative measures for weight reduction should be reviewed by the practitioner prior to seeking approval for the surgical procedure. Active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise may be used not only for documentation of structured attempts using conservative measures for weight reduction, but also for pre-procedure educational purposes and for gauging commitment to the lifestyle changes necessary following bariatric surgery.

Resolution (cure) or improvement of Type 2 diabetes mellitus (T2D) after bariatric surgery and observations that glycemic control may improve immediately after surgery, before a significant amount of weight is lost, have promoted interest in a surgical approach to treatment of T2D. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (1GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

Patients with a BMI greater than or equal to 50 kg/m² need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m². Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

Types of Bariatric Surgery Procedures

The following summarizes the different types of bariatric surgery procedures.

Open Gastric Bypass (CPT code 43846—gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb [150cm or less] Roux-en-Y gastroenterostomy)

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications

compared to other gastric restrictive procedures, including iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

Note: In 2005, the CPT code 43846 was revised to indicate that the short limb must be 150cm or less, compared to the previous 100cm. This change reflects the common practice in which the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150cm. This length also serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

Laparoscopic Gastric Bypass (CPT code 43644—laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy [roux limb 150cm or less])

CPT code 43644 was introduced in 2005 and essentially described the same procedure as code 43846, but performed laparoscopically.

Adjustable Gastric Banding (CPT code 43770—laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device [e.g., gastric band and subcutaneous port components])

Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two such devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States. The first such device that received FDA approval was the Lap-Band (original applicant, Allergan Inc, BioEnterics, Carpinteria, CA; sold to Apollo Endosurgery, Inc., Austin, TX, in 2013; sold to ReShape Lifesciences in 2018). The labeled indications for this device are as follows:

"The Lap-Band® system is indicated for use in weight reduction for severely obese patients with a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 pounds or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives."

In 2011, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 with at least one obesity-related comorbid condition.

A second adjustable gastric banding device was approved by the FDA through the Premarket Approval (PMA) process in September 2007, the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are as listed below:

"The [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m², or a BMI of at least 35 kg/m² with one or more comorbid conditions. The band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs."

Sleeve Gastrectomy (CPT code 43775 – laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy [i.e., sleeve gastrectomy])

A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status and thus, reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure) (CPT code 43847— gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

Biliopancreatic bypass (BPB) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPB consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components.

1.
 1. A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
 2. A 200-cm long “alimentary tract” consists of 200cm of ileum connecting the stomach to a common distal segment.
 3. A 300- to 400-cm “biliary tract” connects the duodenum, jejunum, and remaining ileum to the common distal segment.
 4. A 50- to 100-cm “common tract” is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.

Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to biliopancreatic bypass, including most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, there have been several case reports of liver failure resulting in death or liver transplant.

Biliopancreatic Bypass (Scopinaro procedure) with Duodenal Switch (CPT code 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])

CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is essentially a variant of the biliopancreatic bypass described above. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the biliopancreatic bypass, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

Vertical-Banded Gastroplasty (CPT code 43842)

Vertical-banded gastroplasty was formerly one of the most common gastric restrictive procedures performed in the U.S. but has now been essentially replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

Long-Limb Gastric Bypass (i.e., >150cm) (CPT code 43847—Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

Endoluminal (also called endosurgical, endoscopic, or natural orifice) Bariatric Procedures (no specific CPT code)

With these procedures, access to the relevant anatomical structures is gained through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce the risks associated with open and laparoscopic interventions.

Examples of endoluminal bariatric procedures studies include gastroplasty using a transoral endoscopically guided stapler and placement of devices such as a duodenal-jejunal sleeve and gastric balloon.

Laparoscopic Malabsorptive Procedure (CPT code 43645—Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)

CPT code 43645 was introduced in 2005 to describe a laparoscopic malabsorptive procedure. However, the code is not specific for the type of malabsorptive procedure.

Mini-Gastric Bypass (no specific CPT code)

Recently, a variant of the gastric bypass, called the mini-gastric bypass, has been popularized. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. This unique aspect of this procedure is not based on its laparoscopic approach but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

Laparoscopic Gastric Plication (no specific CPT code)

Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.

KEY POINTS:

The most recent update with literature review covers the period through January 3, 2023.

Summary of Evidence

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous different surgical techniques available. These different techniques have heterogenous mechanisms of action, with varying degrees of gastric restriction that creates a small gastric pouch, malabsorption of nutrients, and metabolic changes that result from gastric and intestinal surgery.

Adults with Morbid Obesity

For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass. There is less weight loss with LAGB compared with gastric bypass, but LAGB is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies (evaluating SG alone and comparing SG with gastric bypass), and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG compared with gastric bypass. Long-term weight loss was greater after gastric bypass but SG is associated with fewer AEs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive biliopancreatic diversion (BPD) with duodenal switch (DS), the evidence includes nonrandomized comparative studies, observational studies and a systematic review. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Non-randomized comparative studies found significantly higher weight loss after BPD with duodenal

switch compared with gastric bypass at one year. A large case series found sustained weight loss after seven years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive BPD without DS, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without duodenal switch or gastric bypass. However, there are concerns about complications associated with BPD without duodenal switch, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive two-stage bariatric surgery procedures, the evidence includes a small RCT and observational studies. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that two-stage bariatric procedures improve outcomes compared with one-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at six months post-surgery. Case series have shown relatively high complication rates in two-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes two RCT, observational studies and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2021 systematic review demonstrated that laparoscopic SG is superior to laparoscopic greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One additional RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive single anastomosis duodeno-ileal bypass with SG (SADI-S), the evidence includes a systematic review of observational studies and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of 12 observational studies concluded that SADI-S was associated with promising weight loss and comorbidity resolution. A comparative chart review found that patients without diabetes experienced significantly better weight loss and lipid profiles with SADI-S than with Roux-en-y gastric bypass (RYGB) and patients who had diabetes experienced significantly higher rates of remission with SADI-S than with RYGB. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of SADI-S. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive a duodenojejunal sleeve, the evidence includes RCTs, systematic reviews, and an observational study. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of duodenojejunal sleeves included five RCTs and found significantly greater short-term weight loss (12-24 weeks) with the sleeves compared with medical therapy. There was no significant difference in symptoms associated with diabetes. All RCTs were small and judged by systematic reviewers to be at high risk of bias. High-quality comparative studies are needed to permit conclusions on the safety and efficacy of the procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive intragastric balloon (IGB) devices, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. RCTs assessing the two IGB devices approved by the Food and Drug Administration have found significantly better weight loss with IGB compared with sham treatment or lifestyle therapy alone after six months (maximum length of device use). There are some adverse events, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how six months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive an aspiration therapy (AT) device, the evidence includes one RCT and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at one year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial aspiration therapy patients completed the study through 4 years. In addition to a high degree of missing data, the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study noted a potentially large number of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. One small case series reported on 15 patients at two years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism, safety, nutrition, and long-term durability of treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Revision Bariatric Surgery

For individuals who are adults with morbid obesity and failed bariatric surgery who receive revision bariatric surgery, the evidence includes systematic reviews, case series, and registry data. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with Type 2 Diabetes

For individuals who are diabetic and not morbidly obese who receive gastric bypass, SG, BPD, or LAGB, the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for type 2 diabetes in obese patients, including those with a body mass index (BMI) between 30 and 34.9 kg/m². The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 3 years of follow-up; with a few having 5-year follow-up data. There are clinical concerns about durability and long-term outcomes at 5 to 10 years as well as potential variation in observed outcomes in community practice versus clinical trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Nondiabetic and Nonobese Adults

For individuals who are not diabetic and not morbidly obese who receive any bariatric surgery procedure, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population. The evidence is insufficient to determine the effects of the technology on health outcomes.

Adolescent Children with Morbid Obesity Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

For individuals who are adolescent children with morbid obesity who receive gastric bypass, or LAGB, or SG, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents are similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m². Also, greater consideration should be placed on the patient developmental stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

For individuals who are adolescent children with morbid obesity who receive bariatric surgery other than gastric bypass, or LAGB, or SG, the evidence includes systematic reviews and a cohort study. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Studies using bariatric surgery other than gastric bypass, LAGB, or SG, have small sample sizes. Results from a meta-analysis including patients using other procedures have shown significant improvements in BMI reduction, fasting blood insulin, and total cholesterol, although the estimates have wide confidence intervals, limiting interpretation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Preadolescent Children with Morbid Obesity

For individuals who are preadolescent children with morbid obesity who receive bariatric surgery, there are no studies focused solely on this population. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old. A recent (2021) cohort study included 801 children ages 5 to 14 years in their total cohort of children and adolescents, and excess weight loss and comorbidity resolution were substantial and long-lasting without safety concerns across all age groups. However, comparative studies are still lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Hiatal Hernia Repair with Bariatric Surgery

For individuals with morbid obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes a systematic review, cohort studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review found that hiatal hernia repair during SG was superior to SG alone for gastroesophageal reflux disease (GERD) remission, but not de novo GERD. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Association of Clinical Endocrinologists et al

In 2020, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm. Updates were made in 2022 and recommendations for bariatric surgery are presented in Table 1.

Table 1. Recommendations for Bariatric Surgery in Diabetes

Recommendation	GOE	BEL
Persons with a BMI 35 kg/m ² and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, NAFLD/NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure	C	3
Persons with BMI 30 to 34.9 kg/m ² and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure	B	2

BEL: best evidence level; BMI: body mass index; GOE: grade of evidence; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; OSA: obstructive sleep apnea; T2D: type 2 diabetes.

In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity. The guidelines addressed nine broad clinical questions with 123 recommendations. With regard to bariatric surgery, the following recommendations were added:

- Recommendation 35: “Patients with obesity (BMI ≥30 kg/m²) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion.” (Grade B; BEL1 [best evidence level], downgraded due to evidence gaps)
- Recommendation 121. “Patients with a BMI of ≥35 kg/m² and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life

may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m² with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.

- BMI ≥ 35 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD [cardiovascular disease] risk (Grade A; BEL 1).
- "BMI ≥ 30 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk (Grade B; BEL 2).
- BMI ≥ 30 kg/m² and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk (Grade C; BEL 3)."
- Recommendation 122. "Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone (Grade D)."
- Recommendation 62: "Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett's esophagus." (intermediate recommendation, intermediate evidence). This recommendation also states, "Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux" (strong recommendation; strong evidence).

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists. Recommendations on the following questions are summarized below.

"Which patients should be offered bariatric surgery?"

- Patients with a BMI [body mass index] ≥ 40 kg/m² without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure.
- Patients with a BMI ≥ 35 kg/m² and one or more severe obesity-related complications remediable by weight loss, including T2D [type 2 diabetes], high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
- "Patients with the following comorbidities and BMI ≥ 35 kg/m² may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; GERD [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
- Patients with BMI of 30 to 34.9 kg/m² with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
- "The BMI criterion for bariatric procedures should be adjusted for ethnicity (eg, 18.5 to 22.9 kg/m² is normal range, 23 to 24.9 kg/m² overweight, and ≥ 25 kg/m² obesity for Asians)."
- "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related complications cannot be obtained using only structured lifestyle change with medical therapy."

"Which bariatric surgical procedure should be offered?"

- Selecting a bariatric procedure should be based on individualized goals of therapy depends on the individualized goals of therapy (e.g., weight loss target and/or improvement in specific obesity-related complications), available local-regional expertise (obesity specialists, bariatric surgeon, and institution), patient preferences, and personalized risk stratification, and other nuances as they become apparent. Notwithstanding technical surgical reasons, laparoscopic bariatric procedures should be preferred over open bariatric procedures due to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding, sleeve gastrectomy, RYGB [Roux-en-y gastric bypass], and LBPD/DS [laparoscopic biliopancreatic diversion/duodenal switch], or related procedures should be considered as primary bariatric and metabolic procedures performed in patients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD [biliopancreatic diversion], BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (ie, about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy."

American College of Cardiology et al.

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published guidelines on the management of obesity and overweight in adults. The guidelines make the following recommendations related to bariatric surgery:

- "Advise adults with a BMI 40kg/m² or BMI 35 kg/m² with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer

referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI [National heart, lung, and blood Institute] Grade A (Strong); AHA/ACC COR [class of recommendation]: IIa; AHA/ACC LOE [level of evidence]: A.”

- “For individuals with a BMI <35 kg/m², there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation).”

Institute for Clinical Systems Improvement

In 2013, the Institute for Clinical Systems Improvement (ICSI) published health care guidelines on the prevention and management of obesity in adults. The following were current indications for bariatric surgery:

- BMI >40 kg/m²
- BMI >35 kg/m² with significant comorbidity (diabetes, hypertension, dyslipidemia, sleep apnea, cardiovascular disease, gastroesophageal reflux, and pseudotumor cerebri)
- Need for significant weight loss prior to solid organ transplantation, abdominal wall hernia repair, or joint replacement
- Medical management to exclude untreated endocrinopathies, stabilize hypertension or type 2 DM, and demonstrate patient compliance
- Psychological stability, as determined by an experienced practitioner

American Society for Metabolic & Bariatric Surgery

In 2016, ASBMS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES]). The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

- There is level 1 data from RCTs on the “efficacy [and] safety of intragastric balloon therapy for obesity ... [and] lower-level evidence [suggesting] that weight loss can be maintained ... for some finite time into the future.”
- It is difficult to separate the effect from the intragastric “balloon alone from those of supervised diet and lifestyle changes...” This has been addressed in recent FDA pivotal trials. “In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team...”
- “...serious complications are rare. Early postoperative tolerance challenges ... can be managed with pharmacotherapy in the majority of patients...”

In 2017, the ASMBS published a position statement on sleeve gastrectomy. This updated statement provided the following conclusions:

- “Substantial long-term outcome data published in the peer-reviewed literature, including studies comparing outcomes of various surgical procedures, confirm that sleeve gastrectomy [SG] provides significant and durable weight loss, improvements in medical comorbidities, improved quality of life, and low complication and mortality rates for obesity treatment.”The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach.
- “In terms of initial early weight loss and improvement of most weight-related comorbid conditions, SG and RYGB appear similar. The effect of SG on GERD, however, is less clear, because GERD improvement is less predictable and GERD may worsen or develop de novo.”
- The ASMBS recognizes SG as an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned staged approach.”Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature.

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery.⁹ The guideline contained the following conclusions and summary recommendations:

- “There is a significant link between obesity and hernia formation both after abdominal surgery and de novo. There is also evidence that abdominal wall hernia can more commonly present with obstruction or strangulation in patients with obesity.”
- “There is a higher risk for complications and recurrence after hernia repair in patients with obesity.”
- “In patients with severe obesity and ventral hernia, and both being amenable to laparoscopic repair, combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection. There is a relative lack of evidence, however, about the use of synthetic mesh in this setting.”
- “In patients with severe obesity and abdominal wall hernia that is not amenable to laparoscopic repair, a staged approach is recommended. Weight loss prior to hernia repair is likely to improve hernia repair outcomes. Metabolic/bariatric surgery appears to provide far more significant and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia.”

In 2018, ASBMS published an update to the 2012 guideline. Summary of major changes in the guideline included:

- “Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron

absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."

- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m² or 120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m² or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI <45 kg/m²) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."
- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children, these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."
- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI >120% of the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."
- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."
- "Routine screening of alcohol use is imperative across all procedures. Conservative clinical care guidelines, which strongly advocate abstinence, while appropriate, must also include information for this age group on harm reduction (i.e., lower consumption levels, how to avoid or manage situations related to alcohol-related harm) to mitigate clinical and safety risks. Risks of nicotine should be discussed and smoking or vaping nicotine should be discouraged."
- "The recognition of obesity as a chronic disease that requires multimodal therapies justifies the treatment of such a disease in a multidisciplinary team that can provide surgical, pharmacologic, behavioral, nutritional, and activity interventions. Pharmacologic therapies as adjuncts to surgical therapies may provide improved outcomes long term in the pediatric population; more studies are needed."

In 2020, ASMBS published an updated statement on single-anastomosis duodenal switch (SADI-S) "in response to numerous inquiries made...by patients, physicians, society members, hospitals, and others regarding [this procedure] as a treatment for obesity and metabolic diseases."¹⁶⁶ The following recommendations were endorsed regarding SADI-S for the primary treatment of obesity or metabolic disease:

- "SADI-S, a modification of classic Roux-en-Y duodenal switch, is an appropriate metabolic bariatric surgical procedure."
- "Publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged, particularly with published details on sleeve gastrectomy size and common channel length."
- "There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for duodenal switch patients."

In 2022, ASMBS, along with the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), updated their guideline on indications for metabolic and bariatric surgery. Historically, class III obesity was the threshold for bariatric surgery; however, ASMBS now recommends metabolic and bariatric surgery in individuals with a BMI greater than or equal to 35 kg/m², regardless of the presence, absence, or severity of comorbidities. Studies referenced by the guideline to support this recommendation generally demonstrated weight loss and remission in both T2D and hypertension in the bariatric surgery groups compared to the nonsurgical groups. However, there were no subgroup analyses performed on individuals without metabolic disorders, so it is difficult to determine if this benefit extends to all patient populations with BMI greater than or equal to 35 kg/m², regardless of the presence, absence, or severity of comorbidities. Additionally, only 1 systematic review referenced by the guidelines included RCTs, and heterogeneity of these RCTs was considered high; all other trials referenced were nonrandomized.

The ASMBS/IFSO guideline also states that metabolic and bariatric surgery can be considered for individuals with metabolic disease and class I obesity, defined as BMI of 30 to 34.9 kg/m², who do not achieve substantial or durable weight loss or

comorbidity improvement with nonsurgical methods. Additionally, they state that BMI thresholds should be adjusted in the Asian population, as the prevalence of diabetes and cardiovascular disease is higher at a lower BMI than in the non-Asian population. Thus, a BMI greater than or equal to 25 kg/m² suggests clinical obesity, and individuals with BMI greater than or equal to 27.5 kg/m² should be offered bariatric surgery.

Importantly, these recommendation from the 2022 ASMBS/IFSO guideline do not appear to be informed by a separately conducted systematic review, include strength of evidence ratings, or include a description of management of conflict of interest.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery. These guidelines state, "During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired" (moderate quality evidence, weak recommendation).

International Federation for the Surgery of Obesity and Metabolic Disorders

In 2019, members of societies affiliated with the IFSO established an expert consensus statement on revisional bariatric surgery (RBS). Consensus agreement was established for the following recommendation statements:

- "RYGB is an acceptable RBS option after gastric banding."
- "OAGB is an acceptable RBS option after gastric banding."
- "SADI-S is an acceptable RBS option after gastric banding."
- "RBS after gastric banding can be carried out in either 1 or 2-stage."
- "OAGB is an acceptable RBS option after SG."
- "BPD-DS is an acceptable RBS option after SG."
- "SADI-S is an acceptable RBS option after SG."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after RYGB."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after OAGB."

BPD-DS: bilio-pancreatic diversion duodenal switch; OAGB: one anastomosis gastric bypass; RBS: revisional bariatric surgery; RYGB: Roux-en-Y gastric bypass; SADI: single anastomosis duodeno-ileal bypass with sleeve gastrectomy; SG: sleeve gastrectomy.

Consensus achieved in second round of voting.

In 2020, members of societies affiliated with the IFSO established a position statement on Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS). The following recommendations were made based on available data:

- "SADI-S/OADS offers substantial weight loss that is maintained into the medium term."
- "SADI-S/OADS provides an improvement in metabolic health that is maintained into the medium term."
- "Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure and patients undergoing this procedure need to be aware of this, and counseled to stay in long-term multidisciplinary care."
- "Surgeons performing the SADI-/OADS, as well as other bariatric/metabolic procedures, are encouraged to participate in a national or international registry so that data may be more effectively identified."
- "IFSO supports the SADI-S/OADS as a recognized bariatric/metabolic procedure, but highly encourages RCT's in the near future."

Guidelines for Children and Adolescents

Childerhose et al (2017) conducted a systematic review of adolescent bariatric surgery recommendation documents published in the United States and provided recommendations based on their review. The literature search was conducted from 1999 through 2013 and identified 16 recommendations for inclusion: 10 clinical practice guidelines, 4 position statements, and 2 consensus statements. Fifteen of the 16 publications recommended bariatric surgery for adolescents. The main reasons for recommending bariatric surgery for adolescents included: (1) surgery is effective in producing short- and long-term weight loss; (2) surgery is appropriate when the patient does not respond to behavioral or medical interventions; (3) surgery is appropriate when serious comorbidities threaten the health of the patient; and (4) surgery can improve long-term health and/or emotional problems. Body mass index thresholds ranged from 35 kg/m² or more to 50 kg/m² or more, with lower thresholds usually requiring the presence of at least 1 serious comorbidity. The minimum age was specified in 10 publications, with most using physiologic maturity (Tanner stage IV and/or 95% of adult height based on bone age, corresponding to ≥13 years for females and to ≥15 years for males) rather than years.

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) published a report outlining the current evidence regarding adolescent bariatric surgery that provided recommendations for practitioners and policy makers. Within this report, AAP listed indications for adolescent metabolic and bariatric surgery that reflected 2018 ASMBS recommendations. Additionally, the AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2023, the AAP published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity. The recommendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is below:

- "Pediatricians and other PHCPs [pediatric health care providers] should offer referral for adolescents 13 years and older with severe obesity (BMI \geq 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

American Society for Metabolic and Bariatric Surgery

In 2012, the ASMBS best practice guidelines found that current evidence was insufficient to discriminate among specific bariatric procedures, but allowed that there was an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population. Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

- Strong indications: Type 2 diabetes, Moderate or severe obstructive sleep apnea (apnea-hypopnea index >15), Nonalcoholic steatohepatitis, Pseudotumor cerebri.
- Less strong indications: Cardiovascular disease, Metabolic syndrome.

The guidelines stated that depression and eating disorders should not be considered exclusion criteria for bariatric surgery. The guidelines also noted that depression should be monitored following the procedure and that eating disorders should be treated and the patient stabilized before the procedure.

In 2018, ASMBS published an update to the 2012 guideline. Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m² or 120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m² or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI <45 kg/m²) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."
- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children, these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."
- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI $>120\%$ of the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."

- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."

In 2022, the ASMBS updated their guideline on indications for metabolic and bariatric surgery. They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as 5 years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that syndromic obesity, developmental delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents.

Endocrine Society

In 2008, the Endocrine Society published recommendations on the prevention and treatment of pediatric obesity. In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology. These guidelines recommended the following:

“We suggest that bariatric surgery be considered only under the following conditions:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI > 40 kg/m2 or has BMI above 35 kg/m2 and significant, extreme comorbidities.
- Extreme obesity and comorbidities persist, despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents (and those planning to become pregnant within 2 yr of surgery) and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder.”

U.S. Preventive Services Task Force Recommendations

Bariatric surgery is not a preventive service.

KEY WORDS:

Roux-en-Y procedure, Vertical Banded Gastroplasty, Adjustable Gastric Banding, Gastric Wrapping, Garren-Edwards Gastric Bubble, Fobi Pouch, Biliopancreatic Bypass Procedure, Jejunioleal Bypass, Biliopancreatic Bypass with Duodenal Switch, Long Limb Gastric Bypass, Sleeve gastrectomy, Longitudinal gastrectomy, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, Lap Band, REALIZE™, adjustable gastric restrictive device, StomaphyX™, ROSE procedure, revision, conversion, gastric balloon, Reshape, Orbera, distalization, Obalon, Elipse, balloon-in-a-pill, gastric plication, mini gastric bypass, weight loss stomach pump, gastric drainage tube, AspirationAssist, AspireAssist, Aspire Bariatrics, A-tube™, Overstitch, Obalon™ intragastric balloon system

APPROVED BY GOVERNING BODIES:

Forms of bariatric surgery performed without specific implantable devices are surgical procedures that are not regulated by FDA.

Table 2 shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

Table 2: FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 mo treatment period.
AspireAssist	Aspire	Jun	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in

SystemÖ	Bariatrics	2016	obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m ² and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy
ORBERAÖ intra-gastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30-40 kg/m ²) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
REALIZEÖ Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m ² , or a BMI of at least 35 kg/m ² with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).
LAP- BANDÖ Adjustable Gastric Banding System	ReShape Lifesciences	May 2019	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m ² or a BMI of at least 30 kg/m ² with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).

BMI: body mass index; FDA: Food and Drug Administration; PMA: premarket approval.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intra-gastric balloons in response to reports of two types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. The second set of adverse event reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape (no longer marketed in the US) and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of five unanticipated deaths occurring from 2016 through the time of the letter, due to intra-gastric balloons. The FDA recommended close monitoring of patients receiving these devices. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intra-gastric balloons worldwide; 7 of these deaths were in patients in the U.S.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers "instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications."

BENEFIT APPLICATION:

Coverage for bariatric surgery is subject to member's specific benefits and to the bariatric procedures covered by this medical policy. Group specific policy will supersede this policy when applicable.

Benefits will only be provided for one surgical procedure in a lifetime. Benefits will not be provided for subsequent surgery for complications related to a covered surgical procedure for obesity (morbid) if the complications arise from noncompliance with medical recommendations regarding patient activity and lifestyle following the procedure. Once per lifetime coverage limits on bariatric surgical procedure(s) may cause a repeat procedure such as a conversion of a laparoscopic adjustable band to a Roux-en-Y to be non-covered.

ITS: Home Policy provisions apply

FEP: Special benefit consideration may apply. Refer to member's benefit plan.

CURRENT CODING:

CPT codes:

43290	Esophagogastroduodenoscopy, with deployment of balloon (Effective 1/1/23)
43291	Esophagogastroduodenoscopy, with removal of balloon (Effective 1/1/23)
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
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
43659	Unlisted laparoscopy procedure, stomach
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 (less than 100cm) 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)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	;removal of subcutaneous port component only
43888	;removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach
90791	Psychiatric diagnostic evaluation
90792	; with medical services
96156	Health behavior assessment, or re-assessment (Effective 01/01/20)

NOTE: Hiatal hernia repair performed at the time of bariatric surgery would not be reported with the hiatal hernia repair code. There is no code for this specific surgery, therefore it should be reported with code 43289 -Unlisted laparoscopy procedure, esophagus.

HCPCS:

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

PREVIOUS CODING:

96150 Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment (Deleted 12/31/19)

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POLICY HISTORY:

Medical Policy Administration Committee, June 2002

Available for comment June 17-July 31, 2002

Medical Policy Group, November 2003 (1)

Medical Review Committee, December 2003

Medical Policy Administration Committee, December 2003

Available for comment October 12-November 29, 2004

Medical Policy Group, November 2005 (1)

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Available for comment December 16, 2005-January 30, 2006

Medical Policy Group, May 2006 (1)

Medical Policy Administration Committee, May 2006

Available for comment May 5-June 19, 2006

Medical Policy Group, June 2006 (1)

Medical Policy Administration Committee, June 2006

Available for comment July 7-August 21, 2006

Medical Policy Group, April 2007 (1)

Medical Policy Administration Committee, April 2007

Available for comment April 13-May 28, 2007

Medical Policy Group, February 2008 (1)

Medical Policy Administration Committee, February 2008

Available for comment March 5-April 18, 2008

Medical Policy Group, September 2008 (1)

Medical Policy Administration Committee, October 2008 (1)

Available for comment September 24-November 7, 2008

Medical Policy Panel, March 2009

Medical Policy Group, July 2009 (2)

Medical Policy Administration Committee, August 2009

Available for comment August 7-September 21, 2009

Medical Policy Group, September 2009 (1)

Medical Policy Administration Committee, October 2009

Available for comment October 3-November 17, 2009

Medical Policy Group, April 2010 (1)

Medical Policy Administration Committee, April 2010

Available for comment April 15-May 29, 2010

Medical Policy Group, June 2010 (1) Rose procedure added to policy as non-covered

Medical Policy Administration Committee, June 2010

Available for comment June 18-August 2, 2010

Medical Policy Group, February 2011; Removed ICD9 code

Medical Policy Group, May 2011 (1) Updated Policy, Key Points and References for coverage for sleeve gastrectomy; Entire policy reformatted

Medical Policy Administration Committee, June 2011

Available for comment June 23 – August 8, 2011

Medical Policy Group, July 2011 (1) Clarification that medically supervised weight loss programs not generally a covered benefit added to Policy section

Medical Policy Group, August 2011 (1) Clarification of physician documentation of medically supervised weight loss program as referenced from previous bariatric Q&A document

Medical Policy Administration Committee, August 2011

Medical Policy Group, April 2012 (1) Reformatted Coding section

Medical Policy Group, November 2012: 2013 Coding Update – Added 90791 & 90792, deleted 90801; all effective 1/1/2013

Medical Policy Panel, October 2013

Medical Policy Panel, October 2014

Medical Policy Group, January 2016: Added ICD-10 Diagnosis under preoperative assessments

Medical Policy Panel, February 2016

Medical Policy Group, May 2016 (3): Updated Description, Policy Statements, Key Points, Governing Bodies, Current Coding, Key Words & References; removed policy statements with through dates prior to May 12, 2011 (all currently effective policy statements remained with updating and new effective date added)

Medical Policy Administration Committee, July 2016

Available for comment June 21 through August 4, 2016

Medical Policy Group, June 2016 (3): Added AspireAssist device to procedures considered investigational; updated Key Words

Medical Policy Group, August 2016 (3): in response to comments, clarified the policy statement related to concomitant hiatal hernia repair to read as follows: Repair of a hiatal hernia at the time of bariatric surgery is considered medically necessary. No other changes made.

Medical Policy Panel, April 2017

Medical Policy Group, May 2017 (3): 2017 Updates to Key Points & References; no changes in policy statements

Medical Policy Group, February 2018(4): Added “endoscopic closure devices” to policy statement to encompass other devices. Added CPT code 43999 to current coding.

Medical Policy Panel, February 2018

Medical Policy Group, March 2018 (3): 2018 Update to Description, Key Points, Governing Bodies, Key Words & References; removed Previous Coding section due to outdated information; no change in policy statements

Medical Policy Group, December 2019 (5): 2020 Annual Coding Update. Moved CPT code 96150 from Current coding section. Created Previous coding section to include code 96150. Added CPT code 96156 to the Current coding section. No change in Policy Statement.

Medical Policy Panel, February 2020

Medical Policy Group, February 2020 (5): Updates to Description, Key Points, Practice Guidelines and Position Statements, and References. No change to Policy Statement.

Medical Policy Group, July 2020 (5): Updates to Description and Approved by Governing Bodies to reflect the change in the LAP-BAND manufacturer from Apollo Endosurgery to ReShape Lifesciences. No change to Policy Statement.

Medical Policy Panel, February 2021

Medical Policy Group, February 2021 (5): Updates to Description, Key Points, Practice Guidelines and Position Statements, Approved by Governing Bodies, and References. Policy Statement updated to include adolescents age 16-17, and preadolescents. Clarifying verbiage added to weight documentation requirements with no change in policy intent. Additional comorbidities added to policy statement coverage criteria. Available for comment February 18, 2021 through April 4, 2021.

Medical Policy Group, May 2021 (5): Update to References. No change to Policy Statement.

Medical Policy Panel, February 2022

Medical Policy Group, March 2022 (5): Updates to Description, Key Points, Practice Guidelines and Position Statements, Key Words: Obalon™ intragastric balloon system, Approved by Governing Bodies, and References. No changes to Policy Statement.

Medical Policy Group, November 2022 (5): 2023 Annual Coding Update. Added CPT codes 43290 and 43291 to the Current Coding section. No change to Policy Statement.

Medical Policy Group, November 2022 (5): Updated Title: Bariatric Surgery for Treatment of Morbid Obesity and GERD. Update to Current Coding to include CPT codes 43860 and 43865. Update to References. Update to Policy Statement to include criteria for Conversion of Sleeve Gastrectomy to Roux-en-y Gastric Bypass for Treatment of Refractory Gastroesophageal Reflux Disease and Roux-en-y Gastric Bypass for Treatment of Gastroesophageal Reflux Disease in Obese Patients. Update to policy statement to include: Removal of the adjustable gastric restrictive device is considered medically necessary when recommended by the member's physician.

Medical Policy Administration Committee, December 2022

Available for comment December 1, 2022- January 15, 2023.

Medical Policy Group, December 2022 (5): Clarification made to section IV Conversion of Sleeve Gastrectomy to Roux-en-y Gastric Bypass for Treatment of Refractory Gastroesophageal Reflux Disease policy statement to include the following: Esophageal manometry rules out primary or secondary neuromuscular and motility disorders of the esophagus (e.g. achalasia).

Medical Policy Group, January 2023 (5): Current Coding section updated to add CPT code 43633. No change to Policy Statement or intent.

Medical Policy Panel, February 2023

Medical Policy Group, February 2023 (5): Updates to Description, Key Points, Practice Guidelines and Position Statements, Benefit Application, and References. Policy Statement updated to replace the word "patients" with the word "individuals." No change to policy intent. Policy statement updated to include "primary surgical" for clarity to the following statement: Roux-en-y gastric bypass (RYGB) is considered investigational for primary surgical treatment of GERD in patients with a BMI < 35 kg/m². No change to policy intent.

Medical Policy Group, March 2023 (5): Policy section updated to include a note for clarity in section III. Roux-en-y Gastric Bypass for Treatment of Gastroesophageal Reflux Disease in Obese Patients. No change to policy intent.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.

The plan does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. The plan administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

As a general rule, benefits are payable under health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*

3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Body Mass Index Table

To use the table, find the appropriate height in the left-hand column labeled Height. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.

BMI	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Height (inches)	Body Weight (pounds)																		
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Body Mass Index Table adapted from the National Heart, Blood and Lung Institute, available at: www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl2.htm. Accessed March 12, 2018