BlueCross BlueShield of Alabama

Name of Policy:
Surgical Management of Morbid Obesity

Policy #: 053
Category: Surgery
Latest Review Date: August 2011
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama 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.*

Description of Procedure or Service:

Surgery for morbid obesity, also known as bariatric surgery, falls into three general categories: gastric restrictive procedures that create a small gastric pouch, resulting in weight loss by producing early satiety and decreasing dietary intake; malabsorptive procedures, which produce weight loss due to malabsorption without necessarily requiring dietary modification. A third category is sometimes referred to as a combined procedure. A "distal" gastric bypass is determined by the length of the common channel of small bowel. This length is measured from the cecum proximally. The defined length of the common channel ranges from 50 to 150cm. This bypassed length adds to the malabsorptive portion of the gastric bypass operation.

Gastric restrictive- this procedure involves a horizontal or vertical partition of the stomach in association with a **Roux-en-Y procedure** (i.e. gastrojejunal anastomosis). Gastric bypass may be performed with either an open or laparoscopic technique. The **Vertical Banded Gastroplasty** is another gastric restrictive procedure. The stomach is segmented along its vertical axis, in which a proximal pouch of 30-60ml and a 1cm outlet are created by a vertical row of staples and a horizontally placed reinforcing band. This can also be performed either as an open or laparoscopic procedure**.** Also in this category is the **Adjustable Gastric Restrictive Device,** a surgically implanted band placed around the exterior of the stomach creating a small pouch. The system consists of a hollow silicone band, tubing, and an access port or reservoir. **Mini-gastric bypass** uses a laparoscopic approach, in which the stomach is segmented, similar to a traditional gastric bypass, and the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. **Gastric Wrapping** is a surgical procedure in which the stomach is folded over on itself and a full stomach wrap (polypropylene mesh) is applied. The outcome is to limit gastric volume. **Garren-Edwards Gastric Bubble** (aka, intra-gastric balloon) is a device made of elastomeric plastic and placed in the stomach via a gastroscope. It is a free-floating intragastric bubble used to reduce stomach capacity. The FDA withdrew its approval for the Garren-Edwards Gastric Bubble due to frequent reports of hemorrhage. **Fobi-Pouch** (FPOO), also called the Transected Vertical Banded Gastric Bypass and Silastic Ring Vertical Gastric Bypass, is a small pouch (about 2 oz. size) that has a band placed around it to control the outflow of food from the pouch into the small intestine. **Gastric Electrical Stimulation** also is a new method that uses electrodes to stimulate the stomach to enhance emptying and produces a feeling of fullness and reduces feelings of hunger. Please see Blue Cross Blue Shield of Alabama medical policy on Gastric Electrical Stimulation. **Loop Gastric Bypass** combines features of the gastric bypass with the undesirable aspects of the biliopancreatic diversion. Patients generally experience frequency of bowel movements, fat in their stools, and impaired absorption. In spite of reported good results this procedure has been abandoned by most bariatric surgeons.

Malabsorptive procedures-these are variants which differ in the lengths of the alimentary limb, the biliopancreatic limb and the common limb, where the alimentary and biliopancreatic limb are anastomosed. The degree of malabsorption is related to the length of the alimentary and common limb. A **Biliopancreatic Bypass Procedure (BPB)** (also known as the Scopinaro procedure) consists of a subtotal gastrectomy and diversion of the biliopancreatic juices in the distal ileum by a long Roux-en-Y procedure. This results in a selective malabsorption and patients may also develop iron deficiency anemia, protein malnutrition, hypocalcemia and bone demineralization (**43847**). The **Jejunoileal Bypass** is any surgical procedure that shunts

ingested food from the jejunum into the ileum thus bypassing a majority of the small intestine. **Biliopancreatic Bypass with Duodenal Switch** is a variant of BPB but is similar in that it produces selective malabsorption by limiting the food digestion and absorption to a short common ileal segment. A "sleeve" type gastrectomy is performed which is then anastomosed to a segment of the duodenum, which is then anastomosed to a segment of the ileum, to create the alimentary limb. This preserves the pyloric sphincter and tends to be more physiologic, but it still produces selective malabsorption by limiting the food digestion and absorption. (43845). The **Long Limb Gastric Bypass** (for dates of service prior to January 1, 2005, long limb defined as > 100cm; for dates of service after January 1, 2005, long limb defined as > 150cm) is a variation of the Roux-en-Y. The stomach may be bypassed in a variety of ways; however this procedure has a long alimentary limb, usually greater than 100cm now defined as greater than 150 cm, producing gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. (43847, 43645)

The **longitudinal or sleeve gastrectomy** has been introduced into the therapeutic procedures for the bariatric surgeon. Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. This procedure may be the first step in a two-stage procedure when performing the Roux-en-Y gastric bypass or the biliopancreatic bypass with duodenal switch.

A new endoscopic approach is advertised for individuals who have had previous gastric bypass surgery and are regaining the weight. It is also available for individuals desiring an alternative to invasive weight loss surgery. This procedure involves the use of an endoscope and an endoluminal fastener that gathers up or pleats the stomach tissue to re-adjust the stomach pouch of patients with previous bariatric surgery. One device is called StomaphyX, made by EndoGastric Solutions. This device received a 510(k) clearance from the FDA, March 9, 2007. The ROSE procedure (Restorative Obesity Surgery, Endolumenal) is another type of incisionless surgical option to restore gastric bypass patients' anatomy to closely match original post-surgery sizes. ROSE surgery is done under anesthesia with a four-channel tube and special Incisionless Surgery tools. The flexible tube is advanced along with a small endoscope via the patient's mouth, into the stomach pouch. Tissue anchors are used to create multiple tissue folds around the stoma to reduce the diameter. This technique is also used to place the anchors in the stomach pouch to reduce its volume.

Policy:

I. GASTRIC RESTRICTIVE PROCEDURES

Effective for dates of service on or after May 12, 2011:***
Adjustable Gastric Restrictive Device, Gastric Bypass (Roux-en-Y), Vertical Banded Gastroplasty and Sleeve Gastrectomy (as a single step procedure) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the surgical treatment of morbid obesity when the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following 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). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.
2. The condition of morbid obesity (BMI $\geq$ 40 or BMI $\geq$ 35 with presence of comorbid conditions) must be of at least 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs will be considered in lieu of recorded heights and weights. Random reviews of these patients' charts for accuracy of stated information will be conducted.
3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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.

4. A complete history and physical must be performed by the bariatric surgeon to include height and weight.
5. The patient must be at least 18 years of age.

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

If the **adjustable gastric restrictive procedure does not meet** medical criteria for coverage, or if **the patient decides to pay for the adjustable gastric restrictive procedure,** the **adjustments of the devices do not meet medical criteria for coverage.**

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***<u>**Effective for dates of service November 18, 2009 through May 11, 2011:**</u>

Adjustable Gastric Restrictive Device, Gastric Bypass (Roux-en-Y) and Vertical Banded Gastroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the surgical treatment of morbid obesity when the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following 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). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.
2. The condition of morbid obesity (BMI $\geq$ 40 or BMI $\geq$ 35 with presence of comorbid conditions) must be of at least 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs will be considered in lieu of recorded heights and weights. Random reviews of these patients' charts for accuracy of stated information will be conducted.
3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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.

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

If the **adjustable gastric restrictive procedure does not meet** medical criteria for coverage, or if **the patient decides to pay for the adjustable gastric restrictive procedure,** the **adjustments of the devices do not meet medical criteria for coverage.**

***<u>**Effective for dates of service August 1, 2009** through November 17, 2009:</u>
Adjustable Gastric Restrictive Device, Gastric Bypass (Roux-en-Y) and Vertical Banded Gastroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the surgical treatment of morbid obesity when the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following 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). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.
2. The condition of morbid obesity (BMI $\geq$ 40 or BMI $\geq$ 35 with presence of comorbid conditions) must be of at least 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs will be considered in lieu of recorded heights and weights. Random reviews of these patients' charts for accuracy of stated information will be conducted.
3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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.

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

If the **adjustable gastric restrictive procedure does not meet** medical criteria for coverage, or if **the patient decides to pay for the adjustable gastric restrictive procedure,** the **adjustments of the devices do not meet medical criteria for coverage.**

***Effective for dates of service April 10, 2007 through July 31, 2009:
Adjustable Gastric Restrictive Device, Gastric Bypass (Roux-en-Y) and Vertical Banded Gastroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the surgical treatment of morbid obesity when the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following 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). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.
2. The condition of morbid obesity (BMI ≥ 40 or BMI ≥ 35 with presence of comorbid conditions) must be of at least ~~5~~ 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs will be considered in lieu of recorded heights and weights. Random reviews of these patients' charts for accuracy of stated information will be conducted.
3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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.

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

If the **adjustable gastric restrictive procedure does not meet** medical criteria for coverage, or if **the patient decides to pay for the adjustable gastric restrictive procedure,** the **adjustments of the devices do not meet medical criteria for coverage.**

***__**Effective for dates of service November 30, 2004** and through April 9, 2007**:**__
Gastric Bypass (Roux-en-Y) and **Vertical-Banded Gastroplasty meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of morbid obesity when all of the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with co-morbid conditions including but not limited to HTN on optimal drug therapy, cardiovascular disease, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, or severe obstructive sleep apnea. (RDI of 50 or greater). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm
2. The condition of morbid obesity (BMI $\geq$ 40 or BMI $\geq$ 35 with presence of comorbid conditions) must be of at least 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs

will be considered in lieu of recorded heights and weights. Random reviews of these patients' charts for accuracy of stated information will be conducted.

3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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.

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

***<u>**Effective for dates of service prior to November 30, 2004:**</u>

Gastric Bypass-CPT code **43846** and **Vertical-Banded Gastroplasty**-CPT code **43842** **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of morbid obesity when all of the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with co-morbid conditions including but not limited to uncontrolled HTN and on optimal drug therapy, cardiovascular disease, diabetes, pulmonary hypertension, or severe obstructive sleep apnea. (RDI of 50 or greater). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see http://www.intmed.mcw.edu/clincalc/body.html.

2. The condition of morbid obesity (BMI ≥ 40 or BMI ≥ 35 with presence of comorbid condition) must be of at least 2 years duration.
3. Documentation that nonsurgical methods of weight reduction must have been attempted during the one-year prior to request for surgery
4. A personal history and physical must be performed by a practicing physician to include height and weight. If abnormal results are present, the operating physician should re-evaluate before surgery.
5. The patient must be at least 18 years of age

II. MALABSORPTIVE PROCEDURES

Effective for dates of service on or after August 1, 2009:****
Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch meets Blue Cross and Blue Shield of Alabama's medica criteria for coverage for treatment of the morbidly obese patients with **BMI of 50 kg/m^2 or more** when the following criteria are met:

1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize 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:

    a. 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

    b. 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.
2. A complete history and physical must be performed by the bariatric surgeon to include height and weight.
3. The patient must be at least 18 years of age.

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

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****<u>**Effective for dates of service prior to August 1, 2009:**</u>

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

III. PREOPERATIVE ASSESSMENTS

Blue Cross and Blue Shield of Alabama will treat the pre-operative office visit or consult as 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 V72.81-V72.84. The obesity diagnosis should be listed as the secondary diagnosis.

A pre-operative psychological evaluation is not required by Blue Cross and Blue Shield of Alabama, 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. Blue Cross and Blue Shield of Alabama will consider this medically necessary. Psychological evaluations should be reported with procedure code 90801 with type service 6 with diagnosis V72.83 or V72.84 with a secondary diagnosis as obesity.

IV. DOES NOT MEET MEDICAL CRITERIA FOR COVERAGE OR INVESTIGATIONAL

<u>Effective for dates of service on or after May 12, 2011:</u>***

The following procedures do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **either non-covered or investigational:**

<u>Investigational</u>

1. Bariatric surgery in patients under age 18 years
2. Bariatric surgery performed as a cure for type 2 diabetes
3. Biliopancreatic Bypass without Duodenal Switch

4. Endoscopic Procedures for weight gain or to remedy large gastric stoma or large gastric pouches after bariatric surgery (e.g. StomaphyX™, ROSE procedure)

5. Fobi-Pouch (FPOO) Transected Vertical Banded Gastric Bypass (Silastic Ring Vertical Gastric Bypass)
6. Garren-Edwards Gastric Bubble (Intra-Gastric Balloon)
7. Gastric Electrical Stimulation
8. Gastric Wrapping
9. Jejunoileal Bypass
10. Mini-gastric Bypass
11. Long Limb Gastric Bypass
12. Loop Gastric Bypass
13. ~~Sleeve Gastrectomy, open or laparoscopic~~

Does not meet medical criteria for coverage

1. 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.
2. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions section below)
3. Elective removal of the adjustable gastric band.
4. Revision or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions section below)

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*****Effective for dates of service August 1, 2009 through May 11, 2011**

The following procedures do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **either non-covered or investigational:**

Investigational

1. Bariatric surgery in patients under age 18 years
2. Bariatric surgery performed as a cure for type 2 diabetes
3. ~~Biliopancreatic Bypass Procedure (Scopinaro procedure)~~
4. Biliopancreatic Bypass without Duodenal Switch
5. Endoscopic Procedures for weight gain or to remedy large gastric stoma or large gastric pouches after bariatric surgery (e.g. StomaphyX™, ROSE procedure)
6. Fobi-Pouch (FPOO) Transected Vertical Banded Gastric Bypass (Silastic Ring Vertical Gastric Bypass)
7. Garren-Edwards Gastric Bubble (Intra-Gastric Balloon)
8. Gastric Electrical Stimulation
9. Gastric Wrapping
10. Jejunoileal Bypass
11. Mini-gastric Bypass
12. Long Limb Gastric Bypass
13. Loop Gastric Bypass
14. Sleeve Gastrectomy, open or laparoscopic

Does not meet medical criteria for coverage

1. 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.
2. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions section below)
3. Elective removal of the adjustable gastric band.
4. Revision or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions section below)

*****Effective for dates of service April 10, 2007 through July 31, 2009**

The following procedures do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **either non-covered or investigational:**

Investigational

1. ~~Adjustable Gastric Restrictive Device as a surgical treatment for morbid obesity~~.
2. Bariatric surgery in patients under age 18 years
3. Bariatric surgery performed as a cure for type 2 diabetes
4. Biliopancreatic Bypass Procedure (Scopinaro procedure)
5. Biliopancreatic Bypass with/without Duodenal Switch
6. Endoscopic Procedures for weight gain or to remedy large gastric stoma or large gastric pouches after bariatric surgery (e.g. StomaphyX™, ROSE procedure)
7. Fobi-Pouch (FPOO) Transected Vertical Banded Gastric Bypass (Silastic Ring Vertical Gastric Bypass)
8. Garren-Edwards Gastric Bubble (Intra-Gastric Balloon)
9. Gastric Electrical Stimulation
10. Gastric Wrapping
11. Jejunoileal Bypass
12. Mini-gastric Bypass
13. Long Limb Gastric Bypass
14. Loop Gastric Bypass
15. Sleeve Gastrectomy, open or laparoscopic

Does not meet medical criteria for coverage

1. 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.
2. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions section below)
3. Elective removal of the adjustable gastric band.
4. Revision or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions section below)

*****Effective for dates of service November 30, 2004 through April 9, 2007**

The following procedures do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **either non-covered or investigational:**

Investigational

1. Adjustable Gastric Restrictive Device as a surgical treatment for morbid obesity.
2. Bariatric surgery in patients under age 18 years
3. Bariatric surgery performed as a cure for type 2 diabetes
4. Biliopancreatic Bypass Procedure (Scopinaro procedure)
5. Biliopancreatic Bypass with/without Duodenal Switch
6. Endoscopic Procedures for weight gain or to remedy large gastric stoma or large gastric pouches after bariatric surgery (e.g. StomaphyX™, ROSE procedure)
7. Fobi-Pouch (FPOO) Transected Vertical Banded Gastric Bypass (Silastic Ring Vertical Gastric Bypass)
8. Garren-Edwards Gastric Bubble (Intra-Gastric Balloon)
9. Gastric Electrical Stimulation
10. Gastric Wrapping
11. Jejunoileal Bypass
12. Mini-gastric Bypass
13. Long Limb Gastric Bypass
14. Loop Gastric Bypass
15. Sleeve Gastrectomy, open or laparoscopic

Does not meet medical criteria for coverage

1. 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.
2. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions section below)

V. REVISIONS

Effective for dates of service on or after March 15, 2010:****

Gastric Surgery

Revision of a prior bariatric procedure (excluding adjustable gastric banding) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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**

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

AND

- The requested procedure must be a Blue Cross and Blue Shield of Alabama covered bariatric surgery/procedure

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 **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Adjustable Gastric Restrictive Devices

Revision or removal of adjustable gastric restrictive device meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the following indications:

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

Elective removal of the adjustable gastric restrictive device does not meet Blue Cross and blue Shield of Alabama's medical criteria for coverage.

Repeat surgery for morbid obesity for other than the stated surgical complications does not meet Blue Cross and Blue Shield of Alabama's criteria for coverage.

Please verify contract benefits for coverage of bariatric surgery and complications**.**

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******Effective for dates of service April 10, 2007 through March 14, 2010:

Gastric Surgery:

Revision of a prior bariatric procedure (excluding adjustable gastric banding) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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) resulting in a recurrence of morbid obesity, **OR**
- Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD) resulting in a recurrence of morbid obesity, **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**
- Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD) resulting in a recurrence of morbid obesity; **OR**
- Severe diarrhea following surgery, **OR**
- Severe dumping syndrome

AND

- The requested procedure must be a Blue Cross and Blue Shield of Alabama covered bariatric surgery/procedure

Complications (stomal dilatation, pouch dilatation, or staple line failure as verified by EGD or UGI) that have resulted in weight gain to morbid obesity (BMI ≥ 40 or BMI ≥ 35 with comorbidities) must meet coverage requirements for bariatric surgery with the exception of the 3 years of morbid obesity.

Repeat surgery for morbid obesity for other than the stated surgical complications does not meet Blue Cross and Blue Shield of Alabama's criteria for coverage.

Adjustable Gastric Restrictive Devices

Adjustable gastric restrictive devices and the revision or removal of adjustable gastric restrictive devices does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Please verify contract benefits for coverage of bariatric surgery and complications**.**

******Effective for dates of service November 9, 2005 through** April 9, 2007 **for procedure 43848:**

Revision of a gastric restrictive procedure meets Blue Cross and Blue Shield of Alabama's criteria for coverage for clinically severe obesity when there is documentation of a failure secondary to a surgical complication such as fistula, obstruction or disruption of a suture/staple line.

Revision of a gastric restrictive procedure does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure.

Requests for revision surgery for weight gain as a result of non-compliance does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Repeat surgery for morbid obesity for other than the stated surgical complications does not meet Blue Cross and Blue Shield of Alabama's criteria for coverage.

Please verify contract benefits for coverage of bariatric surgery and complications**.**

The revision code (43848) is to be filed for the procedure performed related to a previous gastric restrictive procedure.

Blue Cross and Blue Shield of Alabama 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. Blue Cross and Blue Shield of Alabama administers benefits based on the members' 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.

Key Points:

Morbid obesity, also referred to as "clinically severe obesity" or "extreme obesity" was defined as the criteria for bariatric surgery by the 1991 NIH Consensus Conference Statement on Gastrointestinal Surgery for Severe Obesity as a BMI≥ 40 kg/m2 or a BMI ≥ 35 kg/m2 in the presence of high-risk comorbid conditions. Obesity was further classified in the 1998 NIH clinical guidelines on the Identification, Evaluation, and treatment of Overweight and Obesity in adults into Class I (BMI 30 kg/m2 to 34.9 kg/m2), Class II (BMI 35 kg/m2 to 39.9 kg/m2), and Class III (BMI ≥ 40 kg/m2). Morbid obesity is estimated to afflict 20% of the obese population or over 8 million of the U.S. population. Obesity should be considered a chronic disease that has serious health consequences. Patients with obesity are at an increased risk of developing other diseases, including hypertension, heart disease, Type II diabetes, stroke, osteoarthritis, respiratory problems, sleep apnea, and certain types of cancer. Weight loss, even moderate weight loss of only 10% of body weight, has been shown to reverse many of the adverse consequences of obesity.

Weight loss surgery, also known as bariatric surgery, may be an option for carefully selected patients with clinically severe obesity (BMI ≥ 40 or ≥ 35 with co-morbid conditions) when less invasive methods of weight loss have failed and the patient is at high-risk for obesity-associated morbidity or mortality (National Institutes of Health). As the number of people with severe weight problems has increased, the number of weight loss surgeries has also risen. From 1998 to 2004, the total number of bariatric surgeries performed per year increased nine times, from 13,386 to 121,055 cases per year. Surgical patients should be well informed and motivated since they will need to be monitored for complications and major lifestyle adjustments for the remainder of their lives.

Review of Bariatric Surgical Procedures

Surgical procedures for the treatment of obesity have been available since the early 1970s. Some of the original procedures have now become outdated and have been replaced by procedures that have been improved through experience and enhancement of surgical techniques. Listed below is a review of the current bariatric surgical procedures:

Roux-en-Y gastric bypass (RYGB).
The most commonly performed weight loss surgery performed in the United States is the Roux-en-Y gastric bypass (RYGB). This procedure can be performed in a traditional or open method in which a large incision is made into the abdomen or can be performed using the laparoscopic technique. Both the open and laparoscopic techniques have sufficient data published to support that these procedures improves health outcomes for patients with morbid obesity. The Roux-en-Y bypass is currently considered the gold standard for weight loss surgery. Compared to the open procedure, when the laparoscopic approach is utilized, post-operative recovery is shorter and the patient is less likely to develop certain complications such as a hernia. The laparoscopic surgery is technically more complex and it is extremely important that a highly trained, qualified, and experienced laparoscopic weight loss surgeon performs this procedure. In addition, patient selection is critical in determining an open versus laparoscopic approach. As with all surgical procedures, there are certain risks associated with the Roux-en-Y gastric bypass. Complications may include the following: stomal obstruction, post-operative bleeding, small bowel obstruction, gastrointestinal leak, deep vein thrombosis, splenectomy, pulmonary embolism, death within 30 days, or protein-calorie malnutrition.

Vertical banded gastroplasty
Vertical banded gastroplasty is a procedure which includes gastric banding which attempts to induce weight loss by creating an intake limiting gastric pouch by segmenting the stomach along its vertical axis. The published data indicates that this procedure does improve the health outcome for patients with morbid obesity. However, many surgeons are now moving away from this procedure.

Biliopancreatic bypass with or without duodenal switch
The biliopancreatic bypass with or without duodenal switch has malabsorptive properties and multiple metabolic complications have been demonstrated. A major complication in the long-term is protein malabsorption. Patients who have this operation must have lifelong medical follow-up since the side effects can be subtle and can appear months to years after the surgery.

Long-limb gastric bypass
The long-limb gastric bypass also falls into the malabsorptive category similar to the biliopancreatic bypass or duodenal switch. The malabsorptive procedures lack data to support their safety and effectiveness.

Fobi pouch
The Fobi pouch is a procedure which has had few studies performed by anyone other than the creator of the procedure. This is a banded procedure and also has a placement of a silastic ring in the upper gastric pouch to prevent delayed stretching of the outlet stoma.

Mini-gastric bypass
The **"**mini-gastric bypass**"** is a laparoscopic procedure forming a large and elongated gastric pouch and a loop gastric bypass with distal diversion (200 cm or up to ½ of small bowel) to reduce food absorption. Currently, data is very limited on this procedure.

There are several procedures which are currently considered to be outdated and are rarely performed today. These include the **jejunoileal bypass**, **gastric wrapping**, the **Garren-Edwards gastric bubble**, and the **loop gastric bypass**.

Adjustable gastric restrictive device
Another procedure performed for morbid obesity is the adjustable gastric restrictive device procedure. Adjustable gastric restrictive device 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. Complications may include slippage of the external band or band erosion, through the gastric wall. Adjustable gastric restrictive device has been widely used in Europe. The FDA labeled indications for one of the adjustable gastric restrictive device are as follows: "The Lap-Band system is indicated for use in weight reduction for severely obese patients with a BMI of at least 40 or a BMI of 35 with one or more severe comorbid conditions. 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 the eating habits for the rest of their lives."

A 2006 TEC Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and laparoscopic adjustable gastric banding (LAGB). Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at 1 year is less for LAGB compared to gastric bypass. The percent excess weight lost at 1 year is in the range of 40%, compared to 60% or higher for gastric bypass. At time points longer than 1 year, some of the comparative studies report that the difference in weight loss between LAGB and gastric bypass lessens, but others do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that weight loss continues to increase after 1-2 years of follow-up. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

These studies also confirm that short-term (perioperative) complications are very low with LAGB, and lower than either open or laparoscopic gastric bypass. Death is extremely rare, and serious perioperative complications probably occur at rates of less than 1%. The reported rates of long-term adverse events vary considerably. Re-operations are reported in approximately 25% of patients, while in the single-arm studies the composite rate for re-operations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable, such as the range of rates for band slippage is 1%-36% and the range for port access problems is 2%-20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ration for LAGB.

In a comparison of LAGB and gastric bypass, LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay and earlier return to usual activities. There will be less weight loss for LAGB. Longer-term complications related to the presence of a foreign body in the abdomen will occur, and will result in re-operation and removal of the band in a minority of patients.

In a July 2006 article published in the Archives of Surgery, a prospective, comparative analysis between laparoscopic adjustable gastric bypass (LAGB) and laparoscopic Roux-en Y gastric bypass (LRYGB) was reported. Among 106 patients with super morbid obesity (defined as a BMI > 50), 60 underwent LAGB and 46 underwent LRYGB. Median follow-up was 16.2 months with a range of 1-40 months. The overall data revealed that LRYGB and LAGB produce satisfactory weight loss in super-morbidly obese patients. Weight loss in the LRYGB group was more pronounced. LAGB patients had shorter operative times and hospital stays but experienced a significantly greater incidence of late complications resulting in more re-operations, less weight loss and decreased overall satisfaction. LRYGB offered a significant reduction of co-morbidities after surgery. Patient satisfaction was higher in the LRYGB groups. The authors concluded that LRYGB appears superior to LAGB in super morbidly obese patients

Gastric Electrical Stimulation
The Gastric Electrical Stimulation procedure uses electrodes to stimulate the stomach. This procedure when used for the treatment of obesity is also considered investigational and is addressed in a separate medical policy.

Sleeve Gastrectomy
The Sleeve Gastrectomy is a restrictive procedure that reduces stomach capacity by 75%. This procedure has been pioneered as the new procedure for weight loss that is particularly suited to those patients at highest risk for surgery, either because of their medical co-morbidities or their weight. This procedure is offered as a bridge to other bariatric operations. Dr. Philip Schauer reported on this procedure in 2004 in a study of 75 patients. BMI ranged from 45 to 91 and many had at least one or more life threatening co-morbidity. This procedure appears to cause only short-term weight loss and thus the second stage procedure will be required to continue weight loss in the super morbidly obese. Dr. Schauer also commented that insurers have been reluctant to cover the two-stage procedure without more firm data on its ability to reduce complications. There is also inadequate data on the ability of staged procedures to reduce complications.

Endoscopic procedures for patients who gain weight after bariatric surgery
A new area of focus for review is endoscopic procedures for patients who gain weight after bariatric surgery. There are a number of reasons why patients who are treated with accepted forms of bariatric surgery may not lose weight or may regain weight that is initially lost. These reasons include issues of adherence (compliance) as well as technical (structural) issues. Some patients who regain weight after bariatric surgery, e.g., roux-en-Y gastric bypass (RYGB), are found to have enlarged gastric stoma and/or enlarged gastric pouches. Correction of these abnormalities has been reported to again result in successful weight loss. However, some have questioned whether the association with enlarged stoma is as important as it is for enlarged pouches. While these abnormalities can be revised using standard operative approaches, novel

endoscopic procedures are being publicized as an option for these patients. Some of these procedures use devices that are also being evaluated for endoscopic treatment of gastroesophageal reflux (see TransEndoscopic Therapies for Gastroesophageal Reflux Disease {GERD}). The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate). Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron reported on a feasibility study in animals. Thompson reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who had weight regain and dilated gastrojejunal anastomoses after RYGB. No comparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss. The StomaphyX™ device is one device used in this approach. This device was cleared by the FDA through the 510(k) process. It was determined to be equivalent to the EndoCinch™ system which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal surgery. In summary, the published scientific literature on use of these devices in patients who regain weight after bariatric surgery is very limited. No comparative studies were identified. These endoscopic procedures are considered investigational.

Bariatric Surgical Morbidity and Mortality

Complications of bariatric surgery are common and include death, bleeding, blood clots, infection, intestinal leakage with peritonitis, respiratory failure, and stomal obstruction or stenosis. Complication rates have been reported primarily from academic centers with specialized programs. These rates may not reflect those occurring in the community. Based on nationally representative data, the expected in-house clinically significant complication rate for bariatric operations is approximately 10%.

Mortality rates reported vary from 0.5% to 2.0%. Flum has reported that one gastric bypass patient in fifty dies within a month of surgery. The odds of dying within 30 days of gastric bypass are 4.4-4.7 times higher among patients of surgeons who have done less than 20 cases.

The risk of developing gallstones increases with rapid substantial weight loss. Up to 50% of patients develop gallbladder disease within 6 months after surgery.

Wound infections have been reported in up to 28% of people who have bariatric surgery. Twenty-five percent of patients who undergo non-laparoscopic bariatric surgery will need a follow-up procedure, such as abdominal hernia repair, within 3-5 years. Nearly 30% of patients develop a nutritional deficiency post-operatively, such as anemia, osteoporosis, and metabolic bone disease. Many patients do not comply with the lifelong requirement for nutritional supplements and special diet. Up to 20% of patients regain much or all of their pre-operative weight. As many as 20% of patients will lose less than their desired weight.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has established a clinical research consortium to answer key questions about the risks and benefits of the operations and their physiological effects. A spokesperson for NIDDK states “While we have seen from uncontrolled studies and case series that surgical procedures can produce larger and

more sustained weight loss than new surgical treatment, there has been little systematic research on the basic mechanisms, physiology, and outcomes."

Surgery for severe obesity should be considered only in carefully selected patients when less invasive methods of weight loss have failed. Colquitt, et al 2002, stated "There are certain circumstances where the risk of surgery may out weigh the potential benefits". Weight loss surgery may be contraindicated for individuals who have severe pulmonary disease, unstable coronary artery disease or other conditions which may seriously compromise anesthesia or wound healing. Women who are pregnant, planning to become pregnant within two years or currently breast-feeding should not be considered for surgery. Additionally, patients who are unable to understand basic principles of the procedure or to follow post-operative instructions would not be considered as suitable candidates for this type of surgery. Success of the surgical treatment depends on highly motivated patients who have realistic goals and are committed and demonstrate a thorough understanding of the procedure, possible complications, lifestyle changes and medical guidelines which must be followed for the rest of their lives. Patients should be active participants in their own care and in their own education.

The NIH Consensus Conference for surgical treatment of morbid obesity which was issued in 1998 states that obesity surgery should be reserved only for patients who have had first attempted medical therapy: "weight loss surgery should be reserved for patients and whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity". The following criteria have been adapted from the NIH consensus conference.

Presurgical Preparatory Regimen

- The patient should be committed to the appropriate work up for consideration for a surgical procedure and also for the continuing long-term post-operative medical management.
- The patient is willing to lose weight prior to surgery to make surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restrictions which will occur post-surgery.
- An individual's understanding with the procedure and the ability to comply with lifelong follow-up and lifestyle changes, "e.g., as exemplified by compliance with previous medical care" are necessary for the success of the procedure.
- Modifications to improve dietary and exercise habits may reduce surgical risks and improve surgical outcomes.

Obesity makes many types of surgery more technically difficult to perform. Weight loss prior to surgery makes the procedure easier to perform. In addition, weight reduction may reduce the size of the liver making surgical access to the stomach easier. In contrast, the liver enlarges and becomes increasingly infiltrated with fat when weight is gained prior to surgery. A fatty liver is more likely to suffer injury during the surgical procedure. The patient who is able to comply with pre-surgical interventions is likely to show a better compliance with the post-operative care and severe dietary restrictions which will be imposed post-operatively.

In an article published in October 2005, Flum et al reported on a study on early mortality among Medicare beneficiaries undergoing bariatric surgery. Over 16,000 patients underwent bariatric

surgery in a period from 1997-2002. There was a mean age of 47.7 years and just over 75% were female. Rates were calculated at 30-day, 90-day and 1-year mortality and were 2.0%, 2.8%, and 4.6%, respectively. Males had the higher rates of early death 3.7%, 4.8% and 7.7%, respectively compared to females were 1.5%, 2.1%, and 3.7%. Rates were higher for those aged 65 years or older compared to younger patients. Flum et al concluded in this study that the risk of early postsurgical death among Medicare beneficiaries undergoing bariatric surgery was considerably higher than prior case series have suggested and was strongly associated with advancing age, male sex, and lower surgeon volume.

Rationale for Nutrition and Exercise Program Prior to Surgery

Effective weight control involves multiple techniques and strategies including dietary therapy, physical activity, behavioral therapy, pharmacotherapy, and surgery as well as combinations of these strategies. Physical activity should be an integral part of weight loss therapy and weight maintenance. The NIH Consensus Conference (1998) has stated the patient should begin a nutrition and exercise program prior to surgery: "An integrated program must be in place to provide guidance on diet, physical activity and behavioral and social support both prior to and after surgery". This statement documents that the initial goal of medical therapy is a 10% reduction in weight and that a reasonable duration for medical therapy is six months. The rationale for this initial goal is that a moderate weight loss, i.e., 10% of the initial body weight, can significantly decrease the severity of obesity associated risk factors.

The combination of a reduced calorie diet and increased physical activity can result in substantial improvements in blood pressure, glucose tolerance, lipid profile and cardiorespiratory fitness. The purpose of the pre-operative nutrition program prior to obesity surgery is to test patient motivation, to reduce perioperative morbidity, to accustom patients to the restriction of food intake after surgery, and to increase total weight loss (van de Weijgert, et al, 1999; Jung and Cusciheri, 2000; Pekkarinen, et al, 1997; Martin, et al, 1995). The medical literature indicates that even super obese patients with a BMI >50 may benefit from initiating a nutritional and exercise program prior to surgery. Obesity in and of itself increases the likelihood of pulmonary complications and wound infections. Even relatively moderate weight loss prior to surgery can result in substantial improvements in pulmonary function, glucose tolerance, blood pressure and other physiological parameters (Anderson, et al, 1992; Hakala, et al, 1995; Kansanen, et al, 1998 and Pekkarinen, et al, 1998).

Requirement that Morbid Obesity be Present for a Defined Period of Time Prior to Surgery

According to the guidelines of the American Association of Clinical Endocrinologists and the American College of Endocrinology (1998), "Surgical treatment of obesity may be considered only in carefully selected patients where…obesity has been present for at least five years". Obesity surgery should not be indicated for persons with transient increases in weight (Collazo-Clavell, 1999). Patients who gain weight to meet certain criteria or who are unwilling to participate in serious, medically supervised nutritional attempts at weight loss should not be considered surgical candidates.

Requirement for Physician Supervision
Physicians should document their assessment of the patient, what health interventions are prescribed and their assessment of the patient's progress. There is established evidence that medical supervision of a nutrition and exercise program increases the likelihood of success (Blackburn, 1993). It is recommended by the American Medical Association Council on Scientific Affairs, "Any person considering a weight loss program first consult a physician for a physical exam and objective evaluation of the proposed weight loss program as it relates to the individual's physical condition"… Various health organizations recommend that physicians assess their patients for overweight and patients receive appropriate counseling about safe weight management and the benefits of physical activity and a healthy diet. (NHLBI, AACE/ACE, U.S. Preventive Services Task Force, The American Obesity Association, The American Medical Association Guidelines). (Lyznicki 2001).

Smoking
The NIH also recommends all smokers should quit smoking due to the high risk smoking adds to all patients. It is of particular importance for high-risk management in obese patients since these patients already have reduced pulmonary capacity. These patients become a high priority for risk reduction by smoking cessation. Smoking and obesity together apparently compounds cardiovascular risks. Smoking is a risk factor for post-operative pulmonary complications as has been demonstrated repeatedly since the first report in 1944. Smoking increases risks even among those without chronic lung disease. The relative risk of pulmonary complications among smokers as compared with non-smokers ranges from 1.4 to 4.3. The risk declines only after 8 weeks of pre-operative cessation (Smetana, et al, New England Journal of Medicine). Warner, et al, prospectively studied 200 smokers preparing for coronary bypass surgery and found a lower risk of pulmonary complications among those who have stopped smoking at least eight weeks before surgery than among current smokers.

Criterion of Body Mass Index
Surgery is indicated for persons with severe obesity, i.e., BMI of 40 kg/m2 or more or for persons with a BMI of 35 kg/m2 or more and serious co-morbidities. According to the American Society for Bariatric Surgery, *Rationale for the Surgical Treatment of Morbid Obesity,* (2001), in certain situations, patients less severely obese may also be considered for surgery. These patients must still have a BMI of between 35 and 40 and have high-risk co-morbid conditions such as life threatening cardiopulmonary problems (e.g. severe sleep apnea, Pickwickian syndrome, obesity related cardiomyopathy, or severe diabetes mellitus). Barthel and Strome consider obstructive sleep apnea mild if the respiratory distress index (RDI) is 6 to 20, moderate if 21 to 50, and severe if more than 50.

2009 Update
<u>Mini-Gastric Bypass</u>
Although largely abandoned because of concerns about biliary regurgitation with bile gastritis and esophagitis, the mini-gastric bypass procedure continues to have its proponents, mainly outside the United States. An RCT compared mini-gastric bypass with LRYGP in 80 patients randomized to 40 patients in each group. At two years, the EWL was not significantly different (64% vs. 60%, respectively). The rate of major early postoperative complications was 5% in the LRYGP group and none in the mini-gastric bypass group, but the incidence of marginal ulcer

was 5% in the mini-gastric bypass group and 3% in the LRYGP group. A number of case series with short outcomes are reported in the recent literature. Wang et al report results in 423 patients. Mean preoperative BMI was 44.2 and decreased to 29.2 and 28.4 at one- and two-year follow-up. Mean EWL at 1 and 2 years was 69% and 72%, respectively. Seven major and 18 minor complications occurred. Marginal ulcers were noted in 34 patients and anemia in 41 during follow-up. Two case series had 100 or more patients but report only six-month or one-year outcomes. Johnson et al identified 32 mini-gastric bypass patients who require or required surgical revision after the procedure. Complications requiring surgery included gastrojejunostomy leak, bile reflux, intractable marginal ulcer, malabsorption/malnutrition, and weight gain. Twenty-one patients underwent conversion to RYGB, and five more have planned revisions in the future. The authors propose a national registry to record complications and revisions performed after non-traditional bariatric procedures. This evidence does not prompt reconsideration of the policy statement.

Biliopancreatic Diversion (BD)

Superobese patients with body mass index >50 kg/m^2 generally show insufficient long-term weight loss following restrictive procedures and it is generally accepted that malabsorptive procedures are more effective for the super-obese patients.

Three comparative studies were identified on BD versus gastric bypass, one of which was randomized, and a retrospective comparison of BD with distal gastrectomy versus BD with duodenal switch. A fourth study compared the impact of BD (with or without duodenal switch), gastric bypass, and adjustable gastric band on diabetes. In addition, several case series of BD that included at least 100 patients were found.

Skroubis et al randomized 130 patients with a BMI of 35–50 to either RYGB or BD (without duodenal switch) using a variant of BPD that included Roux-en-Y gastrectomy in place of sleeve gastrectomy. The purpose of the study was to look at the results of the BPD in the non-super-obese population. All patients were followed up for at least two years. Weight loss outcomes were superior for the BD group at every time period examined up to two years. The EWL at one year was 73.7% for RYGB and 83.1% for BD (p=0.0001); at three years, the EWL was 72.6% for RYGB and 83.1% for BD (p=0.00003). There were more early complications in the RYGB group, but this difference did not reach statistical significance (six complications vs. one, p=0.12). Late complications also did not differ significantly between the RYGB and BD groups (16 complications vs. 22, p=0.46).

Prachand et al published the largest comparative series of 350 super-obese patients with BMI >50 who underwent either RYGB (n=152) or Scopinaro BD combined with the DeMeester duodenal switch (DS-BPD) (n=198). In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The DS- BPD patients differed from RYGB patients on weight and BMI; mean weight in pounds was 368.2 +/- 52.3 (range, 267.4–596.5) in DS-BPD patients vs. 346.3 +/- 55.2 (range, 239.8–504.9) in the RYGB group and mean BMI was 58.8 +/- 6.7 (range, 50–96) in DS-BPD patients vs. 56.4 +/- 6.8 (range, 49.5–84.2) in the RYGB group. At one year, data were reported for 143 DS-BPD patients and 81 RYGB patients. The EWL was greater for BPD versus RYGB (64.1% vs. 55.9%, p<0.01), and the reduction in BMI was also greater for BPD versus RYGB (23.6 vs. 19.4, p<0.001). Complications and data on

resolution of comorbidities were not reported in this study. Strain et al published a smaller comparative study of 72 patients who underwent either RYGB (n=50) or BPD (n=22). Choice of surgery was per surgeon and/or patient and the patient populations differed in age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 23.3 for BPD compared to 16.5 for RYGB ($p<0.001$).

Marceau et al conducted a retrospective study comparing results of BPD with distal gastrectomy (DG, Scopinaro method) vs. BPD with duodenal switch (DS) at 10 years after surgery. Between 1984 and 1990, 248 patients underwent BPD-DG and, between 1992 and 1997, 438 had BPD with DS. The BPD-DS patients were significantly more obese preoperatively than the BPD-DG patients (49.5 +/- 9.6 vs. 46.4 +/- 8.7). At ten years, EWL in the BPD-DG group (n=140) was 60.2 +/- 20.7 kg vs. 69.6 +/- 21 kg in the BPD-DS group (n=251) (p=.001). Ten percent more patients in the BPD-DS group than in the BPD-DG group had lost >50% of the initial excess weight. During ten-year follow-up, 46 of 248 BPD-DG patients required revision surgery versus six of 431 BPD-DS patients. Most revisions after BPD-DG were for malnutrition and diarrhea and consisted of lengthening the common channel. Information regarding side effects was collected in questionnaires; 90 of 178 BPD-DG and 44 of 185 BPD-DS responders reported vomiting during the last month, and diarrhea was reported by 14% of BPD-DG versus 20% of BPD-DS responders. Heartburn was reported more frequently by BPD-DS patients (67 of 185 vs. 32 of 178) and was manageable without revision. One ulcer was documented by gastroscopy and cured with medical treatment. Long-term complications (fractures, urolithiasis) and rates of reoperation for obstruction were not significantly different between groups. At ten years, albumin levels were comparable; however, the common channel had been lengthened in 20% of BPD-DG patients for hypoalbuminemia. Mortality at ten years was 4.8% in the BPD-DG group and 8.4% in the BPD-DS group, although the difference was mainly attributed to causes unrelated to operative technique (trauma and suicide).

Parikh et al compared three types of bariatric surgery for outcomes on resolution of diabetes: LAGB, n=218; RYGB, n=53; and BPD (with or without DS), n=11. Outcomes with and without DS were not reported separately. Patient preference played a large part in choice of surgery type. Data on the 282 diabetic patients came from a registry of 1,293 patients collected from July 2001 through December 2004 at a U.S. center. Diabetes diagnosis was based on requirement for diabetes medication or diagnosis of diagnosis or glucose intolerance by the primary physician. Resolution was defined as discontinuation of oral hypoglycemic agents or insulin. Preoperative BMIs were LAGB, 49.8 +/- 11; RYGB, 46.1 +/- 9.6; and BPD with or without DS, 46 +/- 10.6. The EWL at one year was 43% for LAGB (87% follow-up), 66% for RYGB (72% follow-up), and 68% for BPD with or without DS (55% follow-up). At three years, the EWL was 45% (65% follow-up), 66% (65% follow-up), and 82% (56% follow-up). At one year, 39% of LAGB patients, 22% of RYGB patients, and 11% of BPD patients required oral hypoglycemics, and at two years 34%, 13%, and 13%, respectively, did. At one year, 14% of LAGB patients, 7% of RYGB patients, and 11% of BPD patients required insulin, and at two years, 18%, 13%, and 13%, respectively, did. A subgroup analysis revealed that LAGB patients who still required medications at two years had longer duration of diabetes before surgery and a lower EWL.

One single-arm case series provided further evidence on long-term outcomes from BPD. In this study, 343 consecutive patients who underwent the Larrad variation of BPD were followed for up to ten years (n=65). (The Larrad 50-50 BPD consists of lengthening the alimentary channel preserving most of the jejunum-ileum, by creating a short biliopancreatic limb (50 cm) and maintaining 50 cm of common limb.) Weight loss was maintained for up to ten years, with a 77.8% EWL reported at ten years. Diarrhea was reported in 10.8% of patients, with severe diarrhea in 2.5%. Anemia or iron deficiency was experienced by 30% of patients, and vitamin D deficiency was experienced by 30% of patients.

Marceau et al reported their 15-year experience with DS in 1,423 patients from 1992–2005. Follow-up evaluation was available for 97% of patients. Survival rate was 92%. After a mean of seven years (2–15), 92% of patients with an initial BMI < 50 obtained BMI <35, and 83% of patients with BMI >50 achieved a BMI <40. Diabetes medication was discontinued in 92% and decreased in others. The use of continuous positive airway pressure was discontinued in 92% of patients and the prevalence of cardiac risk index >5 was decreased by 86%. Operative mortality was 1%; the revision rate was 0.7%, and the reversal rate was 0.2%. Revision for failure to lose sufficient weight was needed in only 1.5%. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage.

In a 2009 evidence-based review of literature, Farrell et al summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at mean of one-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (four studies, aggregate n=896), 67% for RYGB (seven studies, n=1,627), and 42% for AGB (11 studies, n=4,456). At mean follow-up of five years, EWL for BPD with or without DS was 73% (three studies, aggregate n=174), 58% for RYGB (three studies, n=176), and 55% for AGB (five studies, n=640). The authors note that "given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another.

In their 2008 review article, Smith et al discuss the various methods of bariatric surgery including biliopancreatic diversion and duodenal switch and conclude the following:
This operation (BPD) is considerably more complex and technically more challenging than bariatric restrictive procedures. The role of malabsorptive procedures for treating morbid obesity should be limited to selected centers. These procedures may have a role in treating patients who are extremely obese (BMI $\geq$60 kg/m^2).

Needleman and Happel note that malabsorptive procedures such as the BPD/DS have the advantage of providing excellent weight loss with fewer patient-related factors influencing the weight loss. Despite the decreased absorption, the gastric reservoir is large enough to eventually allow the patient to consume larger amounts of foods that may be detrimental to weight loss, especially those high in fat content. This consumption carries an increased risk and frequency of abdominal bloating and foul-smelling stool and gas which may ultimately alter patient satisfactions. Long-term complications are mostly related to the short common channel and absorption and include the potential for protein malnutrition and deficiency of fat soluble vitamins and minerals, and may place the patient at risk for metabolic bone disease. Other

common complications include risk of anemia, decreased vitamin A, increased vitamin D, and decreased calcium levels, with 20% of patients having below normal levels and 1.3% having serious calcium deficiencies. The incidence of kidney stones is also higher in BPD/DS patients.

These authors conclude that, "despite a lack of studies prospectively comparing BPD/DS with other weight loss operations, BPD/DS appears to be a considerably effective operation for patients who are super obese (BMI >50) when compared with the other procedures and is associated with a signification reduction in comorbidities related to obesity, especially diabetes".

The American Society for Bariatric States that BPD/DS have some of the highest reported weight loss in ling-term studies, but also have the highest rate of nutritional complications compared to the RYGBP and the purely restrictive procedures. These operations are some of the most complex in bariatric surgery. However, as with most studies of weight loss surgery, there is wide variability in long-term results between different weight loss centers. Only multi-center comparative studies can establish definitively the true difference between all bariatric surgeries.

The incidence of perioperative mortality for BPD/DS has been published at 1.1% compared to 0.2% for Roux-en-Y.

In summary, the comparative studies provide evidence that weight loss at one year following BPD is superior to RYGB. The difference in EWL at one year is approximately 10% in favor of BPD. Evidence of long-term weight loss is limited, and comparisons between techniques are more difficult. Long-term nutritional complications such as protein, iron, or vitamin D deficiency are common after malabsorptive procedures, and careful monitoring and compliance with dietary advice and supplementation are required. The impact of these and other long-term nutritional/metabolic complications of BPD cannot be determined from the current evidence. Some studies combine data for BPD with and without DS so that the outcomes of one or the other technique cannot be directly compared. The more recent literature describes BPD with DS. Though RCTs with mid- to long-term outcomes are lacking, BD with DS appears to produce weight loss at least comparable to that with RYGB in the super obese.

Limb-Length

Interest in improving weight loss outcomes, increasing control of comorbidities, and minimizing complications, particularly long-term nutritional deficiencies, has resulted in continuous evolution of bariatric surgical procedures including modification of limb lengths. Two comparative studies that evaluated long-limb gastric bypass were identified. Christou et al reported the results of a study comparing long-term weight loss between short-limb (standard) and long-limb gastric bypass. This retrospective study obtained data on 228 of 272 (83.8%) consecutive patients undergoing one of the two procedures at one institution. Short-limb gastric bypass was performed on 140 patients (61%), and 69 (39%) underwent long-limb bypass; the mean follow-up for all patients was 11.4 years. The decision on which operation to perform was made according to time as this institution used the short-limb bypass until 1993 and then switched to the long-limb bypass afterward. The results of this study showed no difference between groups in weight loss or percent of patients categorized as 'failures'.

In a study by Pinheiro et al, 105 patients with BMI of 50 or greater who were diabetic or had insulin resistance were randomly assigned to RYGB with a biliary limb of 50 cm and a Roux limb of 150 cm (group 1, n=57) or RYGB with a biliary limb of 100 cm and a Roux limb of 250 cm (group 2, n=48). Co-morbidities were considered controlled if patients required no medications and had normal blood test results during follow-up and improved if they required less medication or had improved blood test results. Mean follow-up was 48 months (range, 6–56 months). Preoperatively, 55 patients in group one had a mean fasting glucose of 154 mg/dL and a mean hemoglobin A1c of 7.7%; 34 used oral hypoglycemic drugs, 11 used oral drugs and insulin, and 10 used only insulin. In group 2, 45 patients had a mean fasting glucose of 174 mg/dL and a mean hemoglobin A1c of 8.3%; 23 used only oral agents, 14 used oral agents and insulin, and eight used only insulin. In group 1, 32 of 55 (58%) patients achieved control of diabetes (mean fasting glucose 104 mg/dL), 22 improved (mean fasting glucose 118 mg/dL), and one had no response. In group 2, 42 of 45 (93%) patients achieved control, one improved, and two had no improvement ($p<.05$). Control was achieved within one–twelve weeks in both groups. With respect to lipid disorders (present in 52 of the 57 group 1 patients and in 41 of the 48 group 2 patients), 30 (57%) in group 1 and 29 (70%) in group 2 improved ($p<.05$). Rates of improvement in hypertension, sleep apnea, and gastroesophageal reflux disease were not significantly different between groups. Excess weight loss was faster in group 2, but not significantly different at 48 months. The authors cite total and subgroup sample size as limitations of their study and note that larger studies are needed to better assess the differences between the techniques.

One case series was identified in the recent literature. Hamoui et al divided their series of 1,001 patients with mean BMI of 52 +/- 9 who underwent BBP with DS into two groups according to the ratio of the biliopancreatic limb length to the total small bowel length: a biliopancreatic limb length 45% or less of the small bowel length versus a biliopancreatic limb length more than 45% of the small bowel length. They compared nutritional parameters and EWL at one, two, and three years' follow-up. In patients with a BMI of 60 or less, EWL was not clinically significant at any time point. For patients with BMI greater than 60, the EWL was 56.8% in patients with a biliopancreatic limb length 45% or less of the small bowel length versus 61.4% in those with a biliopancreatic limb length more than 45% of the small bowel length ($p=.07$). At two years, the EWL was 62.2% versus 77.5% ($p=.04$), and at three years, it was 59.8% versus 77.5% ($p=.05$).

Sleeve Gastrectomy

Two trials and a large number of reports of case series were identified in the literature search, most from centers outside the United States. Sleeve gastrectomy as a stand-alone procedure dominates the recent literature. Himpens et al report on a randomized study comparing LAGB and laparoscopic isolated sleeve gastrectomy (SG). Eighty subjects received surgery over a period of one year. Median BMI was 37 (range, 30–47) in the LAGB group versus 39 in the SG group. Outcomes of weight loss, feeling of hunger, sweet eating, gastroesophageal reflux disease, complications, and reoperations were recorded at one and three years' follow-up. Median decrease in BMI in the GB group was 15.5 (range, 5–39) after one year and 18 (range, 0–39) at three years after LAGB. One year after SG, decrease in BMI was 25 (range, 0–45) after one year and 27.5 (range, 0–48) after three years. Median EWL in the LAGB group was

41.4% after one year and 48% at three years. Median EWL after SG was 58% and 66% at one and three years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the differences were not significant; gastroesophageal reflux disease appeared de novo in more SG than LAGB patients at one year, and the relationship reversed at three years; between group differences were not significant at either time point. Two SG patients required reoperation for complications. Late complications requiring reoperation after LAGB included pouch dilations treated by band removal (n=2) or conversion to RYGB (n=1), one gastric erosion treated by conversion to RYGB, and three disconnections of the system were reconnected. Four patients had reoperations for inefficacy; two GB patients underwent conversion to RYGB, and two SG patients had conversion to duodenal switch. The authors note that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group. Karamanakos et al carried out a double-blind study to compare outcomes of LRYGB and laparoscopic SG (LSG) on body weight, appetite, and fasting and postprandial ghrelin and peptide-YY (PYY) levels at one, three, six, and 12 months after surgery. Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI was marked and comparable in each group. Excess weight loss was greater after LSG at six months (55.5% vs. 50.2%, p=0.04) and 12 months (69.7% vs. 60.5%, p=0.05). Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but was greater after LSG.

Case series with at least 100 subjects and at least one-year follow-up are summarized here. All report on LSG as a stand-alone procedure. Lee et al report on a comparison of outcomes of four different laparoscopic bariatric procedures, RYGB (303 patients), adjustable gastric band (AGB, 271 patients), vertical banded gastrectomy also known as sleeve gastrectomy) (VG, 216 patients), Hess' BPD and DS (56 patients) performed between November 2002 and August 2005. Choice of operation was based on a combination of insurance coverage, patient preference, and physician recommendations. Preoperative and one-year outcomes are shown below:

	VG	**AGB**	**RYGB**	**BPD-DS**
	n=216	n=271	n=303	n=56
Preop BMI	49+/-11	42+/-5	46+/-6	47+/-6
1-yr BMI	37+/-9	32+/-5	28+/-5	27+/-4
1-yr EWL, %	59+/-17	47+/-20	75+/-16	79+/-12
BMI at 2 years (from graph)	27.7	31.4	27.8	25.1

Complication rates are as follows:

	VG	AGB	RYGB	BPD-DS
Nonoperative readmissions (%)	5 (2.3)	4 (1.5)	12 (4.0)	4 (7.1)
Reoperations (%)	6 (2.8)	13 (4.8)	26 (8.6)	18 (32.1)
Deaths (%)	0 (0)	0 (0)	0 (0)	0 (0)
Major complications (%)	10 (4.6)	13 (4.8)	32 (10.6)	22 (39.3)
Total complications (%)	6 (7.4)	18 (6.6)	69 (22.8)	27 (48.2)

The authors conclude that while long-term efficacy of sleeve gastrectomy is not clear, the data are promising. Nocca et al report EWL, mortality, and morbidity for 163 patients who underwent LSG. The EWL was 48.97% at 6 months, 59.45% at one year (120 patients), 62.02% at 18 months, and 61.52% at 2 years (98 patients). No statistical difference was noticed in EWL between obese and extremely obese patients. There was no operative mortality. Perioperative complications occurred in 12 cases (7.4%). The reoperation rate was 4.90%, and the postoperative morbidity was 6.74% due to six gastric fistulas (3.66%), in which four patients (2.44%) had a previous LAGB. Long-term morbidity was caused by esophageal reflux symptoms (11.80%). The authors noted that LSG may be proposed for volume-eater patients; however, weight regained, quality of life, and obesity-related morbidities need to be evaluated in longer-term studies. Fuks et al reviewed experience with 135 patients who had stand-alone LSG. Mean preoperative BMI was 48.8 (range, 37–72) and decreased to 39.8 at 6 months ($p < .001$). Average excess body weight loss was 38.6% and 49.4% at 6 months and 1 year, respectively. There was no mortality, and the major complication rate, corresponding to gastric fistula in every case, was 5.1% ($n = 7$).

Hamoui et al reported on 118 high-risk patients undergoing sleeve gastrectomy by the open approach. There was 1 perioperative death (0.85%) and 18 postoperative complications (15.3%). Median EWL was 49.4% at 12 months and 47.3% at 24 months. Cottam et al, 2006, reported on 126 high-risk patients (ASA class III or IV) who underwent LSG as the first stage of a two-stage operation. There was one death that occurred after the immediate postoperative period (0.8%), and major postoperative complications occurred in 16 patients (13%). Mean EWL at one year was 46%; 36 patients proceeded to the second stage operation, LRYGP, after a mean interval of 12.6 months.

Two papers report on complications of sleeve gastrectomy. Lalor et al retrospectively reviewed data from 164 patients who underwent LSG as a primary or revision bariatric surgery. The major complication rate was 2.9% in the 148 patients who had LSG as a primary procedure. Complications were one leak and one case of hemorrhage requiring reoperation, one postoperative abscess, one sleeve stricture requiring endoscopic dilation, and late

choledocholololithiasis and bile duct stricture requiring a Whipple procedure. Of the 16 patients undergoing revision surgery, one developed a leak and an abscess requiring reoperation, one case was aborted, and two were converted to an open procedure due to dense adhesions. No patient in either group died. Frezza et al reported their patients' complications after LSG and compared them to 17 other published series. The mean complication rate for the 17 articles was 4.5%, the most common being reoperation, which occurred after 3.6% of procedures.

The additional evidence on sleeve gastrectomy indicates that this procedure is associated with early mortality of <1% and a risk of postoperative complications in the range of 13%–15%. The RCT suggests that weight loss at one year may be greater than for LAGB, while the case series report weight loss at one year that may be less than that reported for RYGP. This new evidence does not prompt reconsideration of the policy statement, which remains unchanged.

Bariatric Surgery for Treatment of Type 2 Diabetes

Current indications for bariatric surgery view poorly or uncontrolled diabetes mellitus as a comorbidity whose presence supports the medical necessity of surgery for patients with BMI of 35 to 40. There also is growing interest in gastrointestinal surgery to treat patients with type 2 diabetes with a BMI in this range whose disease is under control and in patients with lower BMI. Dixon et al performed an RCT designed to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI of >30 and <40. (Results were not reported separately for patients with BMI < or >35.) Sixty patients were enrolled and 30 were randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the two-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and four (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was <6.2% at baseline in two surgically and four conventionally treated patients versus 24 and six patients, respectively, at two years. At baseline, two surgically treated and four conventionally treated patients were using no pharmacotherapy versus 26 and eight, respectively, at two years. One surgical patient developed a wound infection, two developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band.

The remaining evidence at the present time consists of small case series and case reports with short follow-up from non-U.S. centers employing procedures considered investigational in this policy. Lee et al retrospectively identified 44 patients with type 2 diabetes and BMI <35, 114 patients with BMI between 35 and 45, and 43 patients with BMI >45 in a large series (820) of patients who underwent laparoscopic mini-gastric bypass. One year after surgery, fasting plasma glucose levels returned to normal in 89.5% of patients with BMI <35 and in 98% of those with BMI >35. The treatment goal of hemoglobin A1c <7%, LDL<150 mg/dl, and triglyceride <150 mg/dl was met in 76.5% of patients with BMI <35 and in 92.4% of those with BMI >35. DePaula et al report on 39 patients with BMI <35 who underwent one of two laparoscopic procedures comprising different combinations of ileal interposition into the proximal jejunum via a sleeve or diverted sleeve gastrectomy. Mean BMI was 30.1 (range, 23.4–34.9). All participants had type 2 diabetes for at least three years (mean duration, 9.3 years, range 3–22 years) and evidence of stable treatment with oral hypoglycemic agents or insulin for at least 12 months. Mean follow-up was seven months (range, 4–16 months). Mean

postoperative BMI was 24.9 (range, 18.9–31.7). Adequate glycemic control was achieved for 86.9% of patients, and 13.1% had important improvement. Four major complications occurred within 30 days of surgery, and mortality was 2.6%. Scopinaro reported outcomes at mean follow-up of 13 years (range, 10–18 yrs) on seven patients with BMI < 35 who underwent BPD. In all patients serum glucose levels were normalized at one, two, and three years. In five patients, a slight increase above 123 mg/dl was observed at or around five years. The values were maintained at all subsequent times with no one value higher than 160 mg being recorded. The other two patients had full resolution of diabetes at all follow-up times. Serum cholesterol and triglyceride values fell to normal one year after BPD and remained within the normal range. Blood pressure normalized in 6 cases and improved in one. No patient had excessive weight loss at any postoperative time. Kakoulidis et al investigated the role of sleeve gastrectomy for patients with BMI 30–35. Fifteen of the 79 patients in the study had type 2 diabetes. At a follow-up of six months or more, diabetes was resolved in two patients and improved in one patient. Ramos et al reported preliminary results for 20 patients with BMI <30 who underwent duodenal-jejunal exclusion for treatment of type 2 diabetes. Outcomes measured preoperatively and at three and six months were BMI and fasting glycemia, glycosylated hemoglobin, and C-peptide levels. BMI decreased to the third month and stabilized between three and six months. Fasting glycemia was reduced by 43.8% (mean preoperative value, 171.3 [127–242], 107.1 [82–145] at three months, and 96.3 [78–118]) at six months, and hemoglobin A1c was lowered by 22.8% up to the sixth month (mean preoperative level, 8.8% [7.5–10.2], 7.8% [6.7–9.6] at three months, and 6.8% [5.8–7.9] at six months). C-peptide levels decreased 25% between the third and sixth months. ($p<0.001$). Two (20%) patients remained on oral medication after the sixth month. Longer follow-up of a larger number of patients is required before conclusions can be drawn regarding a potential role for this procedure. Clinical trials are underway in South America.

The data are insufficient to allow conclusions regarding the efficacy of expanding the surgical approach in the treatment or cure of type 2 diabetes.

June 2010 Update

ROSE procedure is an endoscopic procedure to restore gastric bypass patients' anatomy to closely match original post-surgery sizes. This is an incisionless procedure and is marketed that there is less risk than traditional open or laparoscopic surgery, minimal post-operative pain, fast recovery time and no scarring. Those eligible are patients who originally lost significant weight following gastric bypass but who now find themselves regaining weight may be ideal candidates. Due to the novelty of this procedure, there is no long-term data available on this procedure and therefore is considered investigational.

2011 Update

Sleeve Gastrectomy

Additional data are now available related to sleeve gastrectomy. These data include both long-term follow-up (to six years) as well as comparative studies. The long-term studies show extensive weight loss; although, as with other procedures, weight gain often recurs over time. For example, in a study from Europe, Himpens et al reported on 4- to 6-year follow-up results in a series of patients who had sleeve gastrectomy performed in 2001 and 2002. This study evaluated 53 consecutive morbidly obese patients who (according to the authors' algorithm)

qualified for restrictive surgery and were selected for laparoscopic sleeve gastrectomy. Of the 53 patients, 11 received an additional malabsorptive procedure at a later stage because of weight regain. At six years, follow-up was obtained in 41 patients (78%). After 3 years, a mean excess weight loss (EWL) of 72.8% was documented, after 6 years EWL had dropped to 57.3%. These results included 11 patients who had benefited from an additional malabsorptive procedure (duodenal switch) and 2 patients who underwent a "resleeve" between the third and sixth postoperative year. In analyzing the results for the 30 patients receiving only sleeve gastrectomy, the authors found a 3-year %EWL of 77.5% and 6+ year %EWL of 53.3%. In addition, new gastroesophageal reflux complaints appeared in 21% of patients. In another study from Europe, D'Hondt reported on long-term follow-up (median of 49 months) from review of 102 patients who underwent laparoscopic sleeve gastrectomy. A total of 83 patients (81.4%) were eligible for follow-up evaluation. The mean initial BMI was 39.3 kg/m2. At a median follow-up point of 49 months (range, 17-80 months), the mean %EWL was 72.3% ± 29.3%. For the 23 patients who reached the 6-year follow-up point, the mean %EWL was 55.9% ± 25.55%.

Three publications report findings for obese patients who had sleeve gastrectomy compared to other bariatric procedures. In a comparative study from France, Chouillard performed a comparative analysis with 200 patients who had undergone either SG or RYGB (Roux-en-Y gastric bypass) between 2005 and 2008. Patients in each group were matched for age, gender, and body mass index. The postoperative complications, percentage of excess weight loss, and the resolution of co-morbidities in each group were compared at 6, 12, and 18 months postoperatively. The overall mortality rates were similar in both groups. However, the morbidity rate was significantly greater in the RYGB group (20.5%) as compared to the SG group (6.5%; P <.05). The overall remission of type 2 diabetes was significantly better in the RYGB group. However, the percentage of excess weight loss at 6, 12, and 18 months as well as the resolution of non-diabetic comorbidities were comparable in both groups. The authors concluded that in this study, compared with SG, RYGB was associated with a greater short-term morbidity rate and RYGB could be associated with better diabetes control. They also note that additional studies are needed to evaluate the comparative efficacy of SG and RYGB for the treatment of morbid obesity and its co-morbidities. Lebya et al reported on a series of 117 patients from Venezuela who were treated with either SG or RYGB. From January 2008 to December 2008, 117 obese patients who met criteria for bariatric surgery were assigned by patient choice after informed consent to either a laparoscopic RYGB procedure (n = 75) or a LSG procedure. Both groups were comparable in age, sex, body mass index, and co-morbidities. Mean operative time of LSG was 82 minutes while LRYGB was 98 minutes ($p < 0.05$). Differences in length of stay, major complications, improvement in co-morbidities, and excess weight loss were not significant ($p > 0.05$). One year after surgery, average excess weight loss (EWL) was 86% in LRYGB and 78.8% in LSG ($p > 0.05$). The authors concluded that in the short term, both techniques are comparable regarding safety and effectiveness. In a comparative study from India, Lakdawala et al compared 50 patients who underwent LSG and LRYGB from 2007 to 2008. Groups were matched for age, sex, and body mass index. Patients were evaluated at 6 months and 1 year post-operatively. Resolution of most comorbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, joint pain, and percentage of EWL in both groups was comparable at the end of 6 months and 1 year. Early resolution of type 2 diabetes was better in the LRYGB group, the results were comparable at 1 year. There was increased incidence of gastroesophageal reflux disease in LSG patients. Chiu reported a

systematic review on the effect of sleeve gastrectomy on symptoms of gastroesophageal reflux (GERD). A total of 15 reports were retrieved; two reports analyzed GERD as a primary outcome, and 13 included GERD as a secondary study outcome. Of the 15 studies, 4 showed an increase in GERD after SG, 7 found reduced GERD prevalence after SG, 3 included only the postoperative prevalence of GERD, and 1 did not include data on prevalence of GERD. The authors concluded that the studies showed differing outcomes and that studies that objectively evaluate GERD after SG are needed.

In summary, given the outcome data about sleeve gastrectomy, both for long-term outcomes as well as short-term comparative data, this technique may be considered medically necessary in the treatment of morbid obesity. (The policy statement is changed.)

Other Issues
Benotti et al evaluated the impact of preoperative weight loss on surgical complications in a series of 881 patients undergoing open or laparoscopic gastric bypass from 2002 to 2006. Of the 881 patients, 592 (67.2%) lost 5% or more EBW and 423 (48.0%) lost more than 10% EBW. Controlling for age, sex, baseline body mass index, and type of surgery in a multiple logistic regression model, increased preoperative weight loss was a predictor of reduced complications for any (P =0.004) and major (P =0.03) complications.

O'Brien reported on a prospective, randomized trial from Australia of 50 adolescents between the ages of 14 and 18 with BMI above 35 who received either a lifestyle intervention or gastric banding, and were followed up for 2 years. Twenty-four of 25 patients in the gastric-banding group and 18 of 25 in the lifestyle group completed the study. Twenty-one (84%) in the gastric banding group and 3 (12%) in the lifestyle group lost more than 50% of excess weight. Overall, the mean changes in the gastric-banding group were a weight loss of 34.6 kg (95% confidence interval [CI], 30.2-39.0), representing an excess weight loss of 78.8% (95% CI, 66.6%-91.0%). The mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1-8.1), representing excess weight loss of 13.2% (95% CI, 2.6%-21.0). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 operations (33%) were required in 7 patients for revisional procedures either for proximal pouch dilatation or tubing injury during follow-up. The authors concluded that among obese adolescent participants, use of gastric banding compared with lifestyle intervention resulted in a greater percentage achieving a loss of 50% of excess weigh

Key Words:

Roux-en-Y procedure, Vertical Banded Gastroplasty, Adjustable Gastric Banding, Gastric Wrapping, Garren-Edwards Gastric Bubble, Fobi Pouch, Biliopancreatic Bypass Procedure, Jejunoileal 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

Approved by Governing Bodies:

Lap-Band Adjustable Gastric Banding System made by BioEnterics Corporation received FDA approval on June 5, 2001.
REALIZE™ Adjustable Gastric Band marketed by Ethicon Endo-Surgery, Inc. received FDA approval on September 28, 2007.

Benefit Application:

Coverage for bariatric surgery is subject to member's specific benefits and to the bariatric procedures covered by Blue Cross and Blue Shield of Alabama 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 contracts: Per FEP, gastric restrictive procedures, gastric malabsorptive procedures, and combination restrictive and malabsorptive procedures to treat morbid obesity, a condition in which an individual has a body mass index (BMI) of 40 or more, or an individual with a BMI of 35 or more with comorbidities who has failed conservative treatment. Eligible members must be 18 years of age or over. Benefits are also available for diagnostic studies and a psychological examination performed prior to the procedure to determine if the patient is a candidate for the procedure.

International Paper, for select groups, will cover the biliopancreatic diversion (Bypass) with Duodenal Switch when diagnosed as morbidly obese and criteria for gastric restrictive surgery are met. Please verify benefits.

Tyco International has special benefit consideration. Please verify benefits.
Effective for dates of service on or after July 1, 2008, only the Regence Blue Shield Medical Policy #58 will be used in making benefit determinations for **Boeing TMP** members.

LGB Groups please verify benefits for special language.

XO Communications, LLC, please verify benefits for special language effective January 1, 2009.

Current Coding:

CPT codes:

43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
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) **(effective on and after 01/01/2010)**
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)
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
90791	Psychiatric diagnostic evaluation **(effective on and after 01/01/2013)**
90792	; with medical services **(effective on and after 01/01/2013)**
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

HCPCS:

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

Previous Codes:

90801 Psychiatric diagnostic interview examination **(deleted effective 01/01/2013)**

96100 Psychological testing (includes psychodiagnostic assessment of personality, psychopathology, emotionality, intellectual abilities, eg, Wais-r, Rorschach, MMPI) with interpretation and report, per hour **(deleted 01/01/2006)**

S2082 Laparoscopy, surgical; gastric restrictive procedure, adjustable gastric band includes placement of subcutaneous port **(deleted 01/01/2006)**

S2085 Laparoscopy, gastric restrictive procedure with gastric bypass for morbid obesity, with short limb (less than 100 cm) Roux-en-Y gastroenterostomy **(deleted 01/01/2005)**

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Policy History:

Medical Policy Administration Committee, June 2002
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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)**
Medical Policy Administration Committee, November 2005
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Medical Policy Group, May 2006 **(1)**
Medical Policy Administration Committee, May 2006
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Medical Policy Group, June 2006 **(1)**
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Medical Policy Group, April 2007 **(1)**
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Medical Policy Group, September 2008 **(1)**
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Medical Policy Group, April 2010 **(1)**
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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
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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.

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 September 23, 2004