



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

COVERAGE:

Prior to determining the coverage for surgical treatment of obesity, conservative treatment options must have been tried and have failed. The screening criteria listed below should be used:

1. Weight must have a BMI of 40 kg/meter squared OR greater than 35kg/meters squared in conjunction with comorbidities such as cardiopulmonary complications or severe diabetes.
2. The condition of morbid/clinically severe obesity must be of at least five years duration.
3. Nonsurgical methods of weight reduction must have been unsuccessfully attempted for at least five years under physician supervision.

(Refer to the Height and Weight table or BMI table found in the description section of this policy.)

GASTRIC RESTRICTIVE PROCEDURES

Gastric bypass using a Roux-en-Y anastomosis (short limb up to 100cm) or vertical banded gastroplasty is considered **medically necessary** in the treatment of morbid obesity that has not responded to conservative measures.

Note: This policy does not address Roux-en-Y Gastric Bypass performed primarily for the treatment of gastric reflux even though this condition may improve following a Roux-en-Y performed for the treatment of morbid obesity.

Gastric bypass using a Billroth II type of anastomosis, popularized as the "mini gastric bypass" is considered **experimental or investigational** as a treatment of morbid obesity.

Gastric banding (including the adjustable Lap Band) performed laparoscopically or open and consisting of an external band placed around the stomach, is considered **experimental or investigational** as a treatment of morbid obesity.

MALABSORPTIVE PROCEDURES

- Biliopancreatic bypass (i.e., the Scopinaro procedure),
- Biliopancreatic bypass with duodenal switch, or
- Long limb gastric bypass procedures (i.e. >100cm)

are considered **experimental or investigational** as a treatment of morbid obesity.

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

DESCRIPTION:

Morbid obesity is defined as an increase in weight over the optimal weight which results in significant complications and a shortened life span. For example, morbid obesity has a significant impact on

- cardiac risk factors,
- incidence of diabetes,
- obstructive sleep apnea, and
- various types of cancers (for men colon, rectum, and prostate; for women, breast, uterus, and ovaries).

The first treatment of morbid obesity should be dietary and life style changes. Although this strategy may be effective in some patients, frequently the weight loss is not durable with only 5%-10% of patients maintaining the weight loss for more than a few years. When conservative measures fail, some patients may consider surgical approaches. A 1991 National Institutes of Health (NIH) Consensus Conference defined surgical candidates as those patients with a body mass index (BMI)* of greater than 40 kg/m², or greater than 35 kg/m² in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes. Super obesity has been described as a BMI greater than 50 kg/m².

*BMI is calculated by dividing a patient's weight (in kilograms) by height (in meters) squared.

To convert pounds to kilograms, multiply pounds by 0.45

To convert inches to meters, multiply inches by .0254

Surgery for morbid obesity (termed bariatric surgery) falls into two general categories;

1. **Gastric restrictive procedures** that create a small gastric pouch resulting in weight loss by producing early satiety and thus decreasing dietary intake; and
2. **Malabsorptive procedures**, which produce weight loss due to malabsorption without necessarily requiring dietary modification.

The following summarizes the different **restrictive** and **malabsorptive** procedures:

GASTRIC RESTRICTIVE PROCEDURES

1. Vertical Banded Gastroplasty

This is probably the most common kind of gastric restrictive procedure performed in this country. The stomach is segmented along its vertical axis to create a durable reinforced and rate-limiting stoma at the distal end of the pouch. A plug of stomach is then removed and a

Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company
Southwest Texas HMO, Inc.* d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



**BlueCross BlueShield
of Texas**

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are rare. Complications include esophageal reflux, dilation or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical banded gastroplasty may be performed using an open or laparoscopic approach.

2. Adjustable Gastric Banding

Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band and the stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions (if necessary) are relatively simple. Complications include slippage of the external band or band erosion through the gastric wall. Although adjustable gastric banding has been widely used in Europe, there is currently one device approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States (Lap-Band Adjustable Gastric Banding System manufactured by BioEnterics Corp., Carpinteria, CA) June 5, 2001. These procedures are sometimes performed laparoscopically.

3. Gastric Bypass

The original gastric bypass surgeries were based on the observation that post-gastrectomy patients tended to lose weight. The current procedure involves a horizontal or vertical partition of the stomach in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). The flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome" in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweets eaters." Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted there are more metabolic complications compared to other gastric restrictive procedures. These complications include iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia (all of which can be corrected by oral supplementation). Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

4. Mini Gastric Bypass

Recently a variant of the gastric bypass called the "mini-gastric bypass" has been popularized. Using a laparoscopic approach the stomach is segmented (similar to a traditional gastric bypass) but



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

instead of creating a Roux-en-Y anastomosis the jejunum is anastomosed directly to the stomach (similar to a Billroth II procedure). The type of anastomosis used makes this procedure unique.

MALABSORPTIVE PROCEDURES

1. Biliopancreatic Bypass Procedure

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

- a. A distal gastrectomy functions to induce a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
- b. A 200-cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.
- c. A 300- to 400-cm "biliary tract," that connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- d. A 50- to 100-cm "common tract" where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.
- e. Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

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

2. Biliopancreatic Bypass with Duodenal Switch

The duodenal switch procedure is essentially a variant of the biliopancreatic bypass described above. However, instead of performing



SURGERY FOR MORBID OBESITY
 SUR716.003
 POSTED DATE: 6/11/2003
 EFFECTIVE DATE: 8/15/2003

a distal gastrectomy, a "sleeve" gastrectomy is performed along the vertical axis of the stomach preserving the pylorus and initial segment of the duodenum. This is then anastomosed to a segment of the ileum (similar to the above procedure) to create the alimentary segment. Preservation of the pyloric sphincter is designed to be more physiologic. The sleeve gastrectomy decreases the volume of the stomach and also decreases the parietal cell mass with the intent of decreasing the incidence of ulcers at the duodenoileal anastomosis. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass; i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

3. Long Limb Gastric Bypass (i.e., > 100 cm)

Recently variations of gastric bypass procedures have been described that consist primarily of long limb Roux-en-Y procedures. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump to create the alimentary limb. The remaining pancreaticobiliary limb (consisting of stomach remnant, duodenum, and length of proximal jejunum) is then anastomosed to the ileum creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass (essentially a gastric restrictive procedure) these very long limb Roux-en-Y gastric bypasses function as a malabsorptive procedure more similar in concept to the biliopancreatic bypass. The long limb gastric bypass is designed to reduce the incidence of metabolic complications but the potential complications are similar to those of the biliopancreatic bypass.

Body Weights in Pounds According to Height and Body Mass Index

Each entry gives the body weight in pounds (lbs) for a person of a given height and body mass index. Pounds have been rounded off. To use the table, find the appropriate height in the left hand column. Move across the row to a given weight. The number at the top of the column is the body mass index for the height and weight.

Body Mass Index (kg/m²)

BMI	19	20	21	22	23	24	25	26	27	28	29	30	35	40
------------	----	----	----	----	----	----	----	----	----	----	----	----	----	----

HT (in.)

Body Weight (lbs)

58	91	96	100	105	110	115	119	124	129	134	138	143	167	191
----	----	----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----



SURGERY FOR MORBID OBESITY
 SUR716.003
 POSTED DATE: 6/11/2003
 EFFECTIVE DATE: 8/15/2003

59	94	99	104	109	114	119	124	128	133	138	143	148	173	198
60	97	102	107	112	118	123	128	133	138	143	148	153	179	204
61	100	106	111	116	122	127	132	137	143	148	153	158	185	211
62	104	109	115	120	126	131	136	142	147	153	158	164	191	218
63	107	113	118	124	130	135	141	146	152	158	163	169	197	225
64	110	116	122	128	134	140	145	151	157	163	169	174	204	232
65	114	120	126	132	138	144	150	156	162	168	174	180	210	240
66	118	124	130	136	142	148	155	161	167	173	179	186	216	247
67	121	127	134	140	146	153	159	166	172	178	185	191	223	255
68	125	131	138	144	151	158	164	171	177	184	190	197	230	262
69	128	135	142	149	155	162	169	176	182	189	196	203	236	270
70	132	139	146	153	160	167	174	181	188	195	202	207	243	278
71	136	143	150	157	165	172	179	186	193	200	208	215	250	286
72	140	147	154	162	169	177	184	191	199	206	213	221	258	294
73	144	151	159	166	174	182	189	197	204	212	219	227	265	302
74	148	155	163	171	179	186	194	202	210	218	225	233	272	311
75	152	160	168	176	184	192	200	208	216	224	232	240	279	319
76	156	164	172	180	189	197	205	213	221	230	238	246	287	328

Adapted with permission from Bray, G.A., Gray, D.S. Obesity.
 Part 1. Pathogenesis. West J. Med. 1988; 149:429-41

RATIONALE:

Outcomes of bariatric surgeries are notoriously difficult to evaluate due in part to the constantly evolving nature of the surgery. Small modifications are commonly made to decrease the incidence of postoperative and long-term complications. In addition there have been no controlled studies (with one exception discussed below) that have directly measured the weight loss and complications associated with the different surgical approaches, especially comparing gastric restrictive procedures with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. The outcomes for specific surgeries may differ widely among institutions or surgeons, perhaps due to small variations in surgical technique, intensity of follow-up, or patient selection criteria. However, during the 1970s and 1980s both vertical banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These two procedures were the focus of the 1991 NIH Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass. Therefore, vertical banded gastroplasty and gastric bypass are considered the gold standards for the purpose of this discussion. The results of these procedures will be compared to the newer procedures not addressed by the 1991 conference; i.e., gastric banding and biliopancreatic bypass with or without duodenal switch.



SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

The following outcomes are considered relevant for bariatric surgery:

Weight loss

There is no uniform standard for reporting results of weight loss and no uniform standard for describing a successful procedure. Common methods of reporting the amount of weight loss are percent of ideal body weight achieved or percent of excess weight loss (with the latter most commonly reported). These two methods are generally preferred over the absolute amount of weight loss since they reflect the ultimate goal of surgery; to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of excess weight is lost, or when the patient returns to within 30% of ideal body weight.

Durability of weight loss

Weight change (i.e., gain or loss) at yearly intervals is often reported. The weight loss with gastric restrictive procedures is thought to be less durable compared to malabsorptive procedures, due to the dilation of the gastric pouch.

Operative and peri-operative complications

There is an increased incidence of operative and peri-operative complications in obese patients in general, particularly the incidence of thromboembolism and wound healing.

Reoperation Rate

Reoperation may be required to either "take down" or revise the original procedure. Reoperation may be particularly common in vertical banded gastroplasty due to pouch dilation.

Metabolic Side Effects

Metabolic side effects are of particular concern in malabsorptive procedures.

Final health outcomes in terms of complications of obesity

Aside from psychosocial concerns (which may be considerable) one of the motivations for bariatric surgery is to decrease the incidence of complications of obesity, such as:

- diabetes,



SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

- cardiovascular risk factors (i.e., increased cholesterol, hypertension),
- obstructive sleep apnea, or
- arthritis.

Unfortunately, these final health outcomes are not consistently reported.

The following discussion provides a representative summary of the literature on bariatric surgery, focusing on malabsorptive procedures compared to gastric restrictive procedures.

Vertical Banded Gastroplasty

As a representative example of a large case series with long-term follow-up, MacLean and colleagues reported on 201 patients who underwent vertical banded gastroplasty and who were followed for a minimum of 2 years. Staple line perforation occurred in 48% of patients and 36% underwent reoperation either to repair the perforation or to repair a stenosis at the rate-limiting orifice. However, the more than 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight. The procedure was less successful in the super obese, defined as a BMI of >50 kg/m², in whom only 85 achieved an excellent result. These results suggest that failures of vertical banded gastroplasty are primarily technical in nature. Based on these results the authors have altered their surgical technique by reinforcing the staple lines to reduce the incidence of perforation. It is this type of small change in surgical technique that can markedly affect results among different surgeons. In a 1987 case series of 305 patients undergoing vertical banded gastroplasty, there was a mean weight loss of 60% of excess weight at 2-year follow-up. In contrast to MacLean's report, there was only a 1.3% incidence of staple line disruption. Significant decreases in cardiovascular risk factors, incidence of diabetes and sleep apnea have also been reported. For example, Melissas and colleagues evaluated obesity's co-morbid conditions in 62 patients who had undergone a vertical banded gastroplasty. All patients were followed up for 12 to 48 months, with 84% of patients losing at least 50% of their excess weight. Of the 218 weight-related pathologic conditions existing before the operation, 83% were either cured or improved.

Gastric Bypass with Short Limb (<100 cm)

Griffen summarized the experience of over 10,000 gastric bypass operations from a number of bariatric surgeons. It was estimated that 85% of patients reduced their weight to at least 50% above the ideal weight. In about 5,000 patients who were followed up for 10 years, 80% were able to maintain this result. Pories and colleagues reported on 608 patients who underwent a gastric bypass procedure and were

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

followed up for 1-14 years. One of the unique features of this report is that only 3% of patients were lost to follow-up. The average weight loss was 75% of excess weight at one year, declining to 50% by the eighth year. The authors observed an immediate drop in both blood glucose and exogenous insulin requirements after surgery. Long-term observation of 298 patients with preoperative diabetes or impaired glucose intolerance revealed that 91% had normal values for blood glucose and hemoglobin A1-C after surgery. The incidence of hypertension declined from 58% before surgery to 14% after gastric bypass.

Flickinger and colleagues reported on the incidence of diabetes and hypertension in a case series of 397 patients. Prior to surgery, 22% had diabetes mellitus and 13% had impaired glucose intolerance. After surgery, all but one of the patients remained euglycemic. A total of 57% of patients were hypertensive before surgery compared to only 18% after surgery. Similarly, Pories and colleagues reported that of 163 obese patients with diabetes or impaired glucose tolerances; only 5% remained with inadequate control after gastric bypass surgery and associated weight loss. Other studies have reported that gastric bypass surgery and weight loss are associated with improvements in the lipid profile.

In the one controlled trial reported, Sugarman and colleagues randomized 40 patients to receive either a vertical banded gastroplasty or a gastric bypass procedure. After 9 months the gastric bypass patients had significantly greater weight loss that persisted a 3-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight. In this study technical differences could not explain the discrepancy, since small intact gastric pouches were seen in patients who experienced unsuccessful vertical banded gastroplasty procedures. The authors hypothesized that the unpleasant dumping syndrome, seen most frequently in sweets eaters, may have been responsible for the increased success of the gastric bypass procedure. A nonrandomized study of 200 patients reported that gastric bypass and vertical banded gastroplasty may be equally effective in achieving 40% excess weight loss. However gastric bypass patients may achieve 50%-60% of excess weight loss. Metabolic abnormalities are seen more frequently in gastric bypass patients compared to those receiving a vertical banded gastroplasty. Anemia, iron deficiency, vitamin B 12 deficiency, and red blood cell folate deficiency are commonly seen abnormalities. Marginal ulcerations are also seen in gastric bypass patients, particularly in those whose gastric pouches are too large and include acid-secreting parietal cells. There is currently no data in the published medical literature regarding a gastric bypass using a Billroth II anastomosis (the "mini gastric bypass"). While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis. This is one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

away from the stomach.

Gastric Banding

Gastric banding (using an external adjustable band placed around the stomach) has been extensively used in Europe. The procedure is designed to mimic the vertical banded gastroplasty, but is an easier, reversible, and more flexible surgery. Similar to all gastric surgeries, the literature is dominated by large case series from individual surgeons who report varying results. Gastric banding surgery is still an evolving procedure with band migration being addressed by altering the position of the band and band erosion addressed by stabilizing the placement of the band. Therefore, it is very difficult to compare one series to another. For example, in this country Doherty and colleagues reported on an initial experience with adjustable gastric banding in 40 patients. The authors reported an unacceptable reoperation rate of 80%, due primarily to technical problems with the subcutaneously implanted reservoir. While those with an intact gastric band achieved 41% excess weight loss, the authors concluded that revisions to the surgical procedure and improvements in the device itself must be implemented. In a subsequent study the authors reported several surgical modifications (including location of the gastric band) and modifications in the device itself. Also, the surgery was performed laparoscopically. Seven of the 22 patients (33%) required reoperation, a considerable improvement. In contrast to this American experience, as a representative example, Miller and Hell report a reoperation rate of only 7% in a case series of 158 patients. Median BMI decreased from 44 kg/m² preoperatively to 28 kg/m² after 36 months. Suter and colleagues compared vertical banded gastroplasty with laparoscopic gastric banding in consecutive case series. They reported that laparoscopic gastric banding was associated with a significant decrease in postoperative morbidity, due primarily to a decrease in thromboembolism and wound infections. After 2 years of follow-up there was no significant difference in weight loss between the 2 groups.

Biliopancreatic Bypass

Scopinaro (who developed the procedure) reports the largest experience with biliopancreatic bypass. In 1996, Scopinaro summarized his experience with 1,217 patients. The authors reported that during the first 3 to 4 months after the surgery patients had decreased appetites related to the dumping syndrome. These symptoms regressed with time to the point that the majority of patients could resume eating large meals. Most patients were eating more than they did before the operation. With follow-up of up to 9 years, the authors reported a durable excess weight loss of 75%, suggesting that weight loss is greater with this procedure compared to gastric restrictive procedures. In addition, the vast majority of patients reported disappearance of and improvement of such complications as obstructive sleep apnea, hypertension, hypercholesterolemia, and diabetes. The

Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company
Southwest Texas HMO, Inc.* d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

authors considered protein malnutrition the most serious metabolic complication (occurring in almost 12% of patients and responsible for 3 deaths). This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed (restoring normal intestinal continuity). The authors also found that protein malnutrition was strongly related to ethnicity and presumably eating habits with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first four postoperative years. All patients were encouraged to maintain an oral calcium intake of 2 gr. daily with monthly vitamin D supplementation.

Totte and colleagues in Belgium reported their experience with biliopancreatic bypass in 180 patients. Prior to surgery the mean BMI was 48.8 kg/m² and dropped to 28.8 kg/m² at 36 months, corresponding to about 70% of excess weight loss. Six patients (3.3%) experienced serious perioperative complications including acute dilatation of the stomach, diffuse peritonitis, and acute pancreatitis. Late complications included incisional hernia in 17%, anastomotic ulcers in 10%, and severe protein malnutrition requiring total parenteral nutrition in 1.1% of the patients. Obesity-related complications (such as diabetes, hypertension, or arthritis) was resolved or improved in all patients. Nanni and colleagues reported on a case series of 59 patients. Weight loss was similar to Totte and colleagues with 78% of excess weight loss after 2 years. Protein deficiency was noted in 2 (3.4%) patients.

The bulk of the experience with biliopancreatic bypass appears to be in Europe, particularly Italy. There are no case series reported in this country. According to Murr and colleagues, biliopancreatic bypass has not been widely accepted in this country due to unacceptable serious long-term morbidities. For example, biliopancreatic bypass has largely been abandoned at the Mayo clinic due to the occurrence of steatorrhea, diarrhea, foul-smelling stools, severe bone pain, and the need for a life-long commitment to supplemental vitamins and minerals. In addition, there have been scattered case reports of liver damage, resulting either in death or liver transplant. In addition, Murr hypothesizes that the incidence of protein malnutrition may be higher in this country compared to Scopinaro's Italian series since the North American has a higher percentage of fat and lesser amounts of carbohydrates.

Gastric Bypass with Long Limb (>100 cm)

Long limb gastric bypass is designed primarily to be a malabsorptive

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



BlueCross BlueShield
of Texas

SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

procedure, differing in the lengths of the various limbs and the fact that the jejunum is used for the alimentary limb compared to the ileum in biliopancreatic bypass. In addition, as described by Murr, the common segment is increased from 50 to 100 cm allowing for greater food absorption. These modifications have been developed in an effort to decrease the metabolic side effects associated with biliopancreatic bypass. However, there has been limited reported experience. Murr reported on 26 patients who underwent a "very long limb Roux-en-Y gastric bypass." In comparison to a case series of 11 patients who underwent biliopancreatic bypass the authors reported similar weight loss but decreased metabolic or nutritional abnormalities. This was attributed in part to the increased length of the common segment (100 cm) compared to 50 cm used in biliopancreatic bypass. Sugarman also attributes increasing the length of the common segment to decreasing metabolic morbidities.

Biliopancreatic Bypass with Duodenal Switch

The largest case series of the above procedure is reported by Marceau, who reported on 465 patients who underwent the duodenal switch procedure compared to 252 who underwent the biliopancreatic bypass. It should be noted that in addition to the preservation of the duodenum, the common segment was elongated to 100 cm. The authors noted similar weight loss in the 2 groups. In the duodenal switch group, there was a lower incidence of metabolic abnormalities (such as protein malnutrition) which prompted reversal of the procedure in 1.7% of those undergoing biliopancreatic bypass vs. only 0.1% after the duodenal switch procedure. However, it is not known whether this outcome is attributed to the lengthening of the common segment vs. retention of the pylorus. Hess reported on a case series of 440 patients with variable lengths of the common channel. The percentage excess weight loss varied between 60% and 90% depending on the length of the common segment and alimentary limb. There were 2 late deaths, 1 due to septic shock secondary to an infected panniculus and 1 related to liver failure. A total of 10 patients underwent revision to lengthen the common segment secondary to low protein or excessive diarrhea. Seven patients underwent shortening of the common segment due to inadequate weight loss. Baltasar and colleagues reported on a case series of 60 patients undergoing the duodenal switch procedure with a common segment length of 75 cm. One patient succumbed to liver failure and another due to malnutrition. The authors questioned the safety of the procedure.

Summary:

As noted in the Policy section, this policy suggests that malabsorptive procedures for treatment of morbid obesity remain investigational. This interpretation of the term investigational may be questioned by those who would point out the procedure, particularly the Scopinaro procedure, has been performed for some 20 years with results of large case series reported in the peer-reviewed literature.

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

The percent of excess weight loss for malabsorptive procedures, typically at or above 70%, may be higher than that reported with gastric restrictive procedures (reported at around 60%) but higher among those patients who maintain intact stomas. However, one of the criteria used to define the term investigational is whether the malabsorptive procedures are at least as good as the alternatives; i.e., gastric restrictive procedures. This involves a judgment as to whether the acknowledged increased metabolic risks associated with malabsorptive procedures are more than outweighed by an increased benefit associated with potentially greater weight loss. While most of the studies of bariatric surgeries report results in terms of weight loss, the degree of weight loss is essentially an intermediate outcome. The underlying *medical* rationale for the surgery (the basis for its coverage eligibility) is not the degree of weight loss but the decreased risk of the morbid complications of obesity, i.e., a decreasing incidence of diabetes and cardiac risk factors, among others. While the psychosocial benefits of achieving normal weight may be compelling they are not necessarily equivalent to the medical benefit. As noted by Brolin, a substantial number of morbidly obese patients experience marked improvement of medical problems with a relatively modest amount of weight loss. For example, in his case series of 130 patients undergoing bariatric surgery, over 90% experienced resolution or improvement in associated symptoms even though only 41% of patients lost weight to within 50% of their ideal weight. Ideally, one would like to compare the incidence of morbidities in gastric restrictive vs. malabsorptive procedures. However, there is no report of a head-to-head comparison among similar patients. It is difficult to compare results between case series due to variations in surgical procedures and different outcome measurements. In addition, the literature focuses on the degree of weight loss and not the incidence of obesity-related morbidities. However, it appears that the reduction in incidence of diabetes and cardiovascular risk factors is excellent with either a gastric restrictive or malabsorptive procedure. Therefore, this policy regarding the investigational status of malabsorptive procedures is based on the judgment that there is not sufficient evidence to demonstrate that the increased risks of malabsorptive procedures compared to restrictive procedures is outweighed by a significantly greater reduction in obesity-related morbidities.

In the future, further modifications of malabsorptive procedures, including further experience with long limb gastric bypasses and refinement of surgical technique may be associated with a declining risk of metabolic complications. However, gastric restrictive surgeries are also evolving at the same time, with techniques focused on fortifying the stoma such that durable weight loss can be maintained. Finally, the results of multicentered, peer reviewed studies using gastric banding must be evaluated when available.

PRICING:

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**
Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

None

Reference

- Brolin RE. "Results of obesity surgery." *Gastroenterol Clin North Am* 1987; 16:317-336.
- Willbanks OL. "Long term results of silicone elastomer ring vertical gastroplasty for the treatment of morbid obesity." *Surgery* 1987; 101:606-10.
- Griffen WO. Gastric bypass. In: *Griffen WO, Printen KJ eds. "Surgical management of morbid obesity."* New York, NY. Marcel Dekker, Inc, 1987:27-45.
- Brolin RE. "Results of obesity surgery." *Gastroenterol Clin North Am* 1987; 16:317-35.
- Flickinger EG, Sinar DR, Swanson M. "Gastric bypass." *Gastroenterol Clin North Am* 1987; 16:283-92.
- Sugarman HJ, Starkey JV, Birkenhauer R. "A randomized prospective trial of gastric bypass versus vertical banded gastroplasty for morbid obesity and their effects on sweets versus non sweets eaters." *Ann Surg* 1987; 205:618-24.
- Fobi MA, Fleming AW. "Vertical banded gastroplasty vs. gastric bypass in the treatment of obesity." *J Natl Med Assoc* 1988; 78:1091-98.
- MacLean LD, Rhode BM, Forse RA. "Late results of vertical banded gastroplasty for morbid and super obesity." *Surgery* 1990; 107:20-27.
- Consensus Development Panel. "Gastrointestinal surgery for severe obesity." *Ann Int Med* 1991; 1991; 115:956-61.
- Grimm IS, Schindler W, Halusza O. "Steatohepatitis and fatal hepatic failure after biliopancreatic diversion." *Am J Gastroenterol* 1992; 87:775-79.
- Langdon DE, Leffingwell T, Rank D. "Hepatic failure after biliopancreatic diversion." *Am J Gastroenterol* 1993;88:321.
- Kolanowski J. "Gastroplasty for morbid obesity: The internist's view." *Int J Obesity* 1995; 19(suppl 3):S61-S65.
- Pories WJ, Swanson MS, MacDonald Kg et al. "Who would have thought it? An operation proves to be the most effective therapy for adult onset diabetes mellitus." *Ann Surg* 1995; 222:339-52.
- Scopinaro N, Gianetta E, Adami GF. "Biliopancreatic diversion for obesity at eighteen years." *Surgery* 1996; 119:261-8.
- Nanni G, Balduzzi GF, Capuluongo R et al. "Biliopancreatic diversion: Clinical experience." *Obesity Surg* 1997; 7:26-29.
- Sugarman HJ, Kellum JM, DeMaria EJ. "Conversion of proximal to distal gastric bypass for failed gastric bypass for superobesity." *J Gastrointest Surg* 1997; 1:517-25.
- Hess DS, Hess DW. "Biliopancreatic bypass with a duodenal switch." *Obes Surg* 1998; 8:267.



SURGERY FOR MORBID OBESITY

SUR716.003

POSTED DATE: 6/11/2003

EFFECTIVE DATE: 8/15/2003

-
- Baltasar A, Del Rio J, Excriva C et al. "Preliminary results of the duodenal switch." *Obesity Surg* 1997; 7:500-04.
 - Mason EE, Doherty C, Maher JW et al. "Super obesity and gastric reduction procedures." *Gastroenterol Clin North Am* 1997; 16:495-502.
 - Melissas J, Christodoulakis M, Spyridakis et al. "Disorders associated with clinically severe obesity: Significant improvement after surgical weight loss." *South Med J* 1998; 91:1143-48.
 - Marceau P, Hould FD, Simrad S et al. "Biliopancreatic diversion with duodenal switch." *World J Surg* 1998; 22:947-54.
 - Broolin RE. "Gastrointestinal Surgery for Obesity." *Seminars in Gastrointestinal Disease, Vol 9, No.4 (October), 1998:163-175.*
 - Doherty C, Maher JW, Heitshusen DS. "Prospective investigation of complications, reoperations and sustained weight loss with an adjustable gastric banding device for treatment of morbid obesity." *J Gastrointest Surg* 1998;2:102-08.
 - Cowan GSM, Buffington CK. "Significant changes in blood pressure, glucose and lipids with gastric bypass surgery." *World J Surg* 1998; 22:987-92.
 - Murr MM, Balsiger BM, Kennedy FP et al. "Malabsorptive procedures for severe obesity; Comparison of pancreaticobiliary bypass and very very long limb Roux-en-Y gastric bypass." *J Gastrointest Surg* 1999; 3:607-12.
 - Totte E, Hendrickx L, van Hee R. "Biliopancreatic diversion for treatment of morbid obesity: Experience in 180 consecutive cases." *Obesity Surg* 1999; 9:161-65.
 - Suter M, Giusti V, Heraief E et al. "Early results of laparoscopic gastric banding compared with open vertical banded gastroplasty." *Obesity Surg* 1999: 9:374-80.
 - Miller K, Hell E. "Laparoscopic adjustable gastric banding: a prospective 4 year follow up study." *Obesity Surg* 1999; 9:183-87.
 - Doherty C, Maher JW, Heitshusen DS. "An interval report on prospective investigations of silicone gastric banding devices for the treatment of severe obesity." *Eur J Gastroenterol Hepatol.* 1999: 11:115-19.
 - Suter M, Jayet C, et al. "Vertical Banded gastroplasty: long term results comparing three different techniques." *Obes Surg* 2000 Feb: 10(1):41-6.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company**

Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*

** Independent Licensees of the Blue Cross and Blue Shield Association*



SURGERY FOR MORBID OBESITY
SUR716.003
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

and update Medical Policy periodically.
HMO Blue Texas physicians who are contracted/affiliated with a
capitated IPA/medical group must contact the IPA/medical group for
information regarding HMO claims/reimbursement information and other
general polices and procedures.