Effective September 15, 2017
Policy replaced by NCD (100.1)

BlueCross BlueShield of Alabama

For Bariatric Surgery for Treatment of Morbid Obesity refer to NCD 100.1, 100.11, 100.14

Name of Blue Advantage Policy:
Revision of Gastric Restrictive Procedure

Policy #: 053
Category: Surgery

Latest Review Date: May 2017
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   a. *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   b. *Furnished in a setting appropriate to the patient's medical needs and condition;*
   c. *Ordered and furnished by qualified personnel;*
   d. *One that meets, but does not exceed, the patient's medical need; and*
   e. *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

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.

Surgical revision of bariatric surgery should be considered when the patient experiences complications from the original surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when slippage causes abdominal pain, inability to ingest or produces vomiting. Additionally, some patients have failed to achieve an adequate weight loss with certain gastric restrictive procedures, such as vertical banded gastroplasty or Lapband, even when fully compliant with postoperative nutritional and exercise recommendations. For many patients, it may take up to two years for patients to reach their maximum weight loss following bariatric surgery.

Prior to considering revision surgery, it is critically important to determine if the poor response to primary bariatric surgery is due to anatomic causes that led to inadequate weight loss or weight regain or to the patient's postoperative behavior, such as not following the prescribed diet and lifestyle changes (e.g., consuming large portions, high-calorie foods, and/or snacks between meals; not exercising).

Policy:

Effective for dates of service on or after August 5, 2016 and prior to September 15, 2017:

Blue Advantage will treat revision or conversion of a prior bariatric procedure (excluding adjustable gastric banding) as a **covered** benefit with documented evidence of **one or more** of the following:

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

AND

- The requested procedure must be a Blue Advantage covered bariatric surgery/procedure

***** See NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1, 100.11, 100.14) *****

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

Blue Advantage will treat revision or conversion of a prior bariatric procedure **without complicating factors** to another bariatric procedure as a non-covered benefit **when requested due to lack of weight loss or less than anticipated weight loss after another bariatric procedure.**

Blue Advantage will treat 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 **as a non-covered benefit.**

Adjustable Gastric Restrictive Devices

Blue Advantage will treat revision, conversion or removal of adjustable gastric restrictive device as a covered benefit for the following indications:

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

AND

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

Blue Advantage will treat complications (e.g., stomal dilatation, pouch dilatation) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure as a **non-covered benefit**.

Blue Advantage will treat revision or conversion of an adjustable gastric restrictive device **without complicating factors** to another bariatric procedure **as a non-covered benefit** when requested due to lack of weight loss or less than anticipated weight loss with the adjustable gastric restrictive device.

Blue Advantage will treat elective removal (i.e., removal not due to the above complications) of the adjustable gastric restrictive device as a **non-covered benefit.**

Blue Advantage will treat repeat surgery for morbid obesity for other than the stated surgical complications as a non-covered benefit.

If the **bariatric procedure does not meet** medical criteria for coverage, **the treatment of complications** that may arise from the bariatric procedure, regardless of cause, **does not meet medical criteria for coverage.**

Effective for dates of service April 15, 2016 to August 4, 2016:

Blue Advantage will treat revision of a prior bariatric procedure (excluding adjustable gastric banding) as a **covered** benefit with documented evidence of **one or more** of the following:

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

AND

- The requested procedure must be a Blue Advantage covered bariatric surgery/procedure

***** See NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)*****

Blue Advantage will treat 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 **as a non-covered benefit.**

Blue Advantage will treat revision or removal of adjustable gastric restrictive device as a covered benefit for the following indications:

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

Blue Advantage will treat elective removal of the adjustable gastric restrictive device as a non-covered benefit.

Blue Advantage will treat repeat surgery for morbid obesity for other than the stated surgical complications as a non-covered benefit.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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:

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.

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of comorbidities with somewhat higher complication rates than for primary surgery. In 2014, Sudan et al reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database. The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) There were a total of 449,473 bariatric operations in the database of which 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3 %) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective operations and 8750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1%), AGB (N=153,142, 36.5%), SG (N=42,178, 10%), and BPD±DS (N=4,260, 1%), with the rest classified as miscellaneous. AGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Rouxen-Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs 1.8±4.9, $p<0.001$) and for conversions (2.86±4.58 vs 1.8±4.9, $p<0.001$). The mean percent EBWL at 1 year was 43.5 % after primary operation, 39.3 % after conversions, and 35.9 % after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions compared with primary operations (0.31% vs 0.17%, $p<0.001$), but not for corrections compared with primary operations (0.24% vs 0.17%, p=*NS*). One-year serious adverse event (SAE) rates were higher for conversions compared with primary operations (3.61% vs 1.87%, $p<0.001$), but not for corrections compared with primary operations (1.9% vs 1.87%, p=*NS*). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

As part of the American Society for Metabolic and Bariatric Surgery Revision Task Force, Brethauer et al conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews. The review is primarily descriptive, but the authors make the following conclusions:

> "The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary

bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise."

A sample of some of the outcomes reported in retrospective series of revision surgeries follows. Mognol et al reported on conversion of AGB to Roux-en-Y in 70 patients. Indications for conversion were insufficient weight loss or weight regain after band deflation for gastric pouch dilatation in 34 patients (49%), inadequate weight loss in 17 patients (25%), symptomatic proximal gastric pouch dilatation in 15 patients (20%), intragastric band migration in 3 patients (5%), and psychological band intolerance in 1 patient. Median excess body weight loss was 70%. Sixty percent of patients achieved a BMI of less than 33 with mean follow-up of 18 months. The early complication rate was 14.3% (10/70). Late major complications occurred in 6 patients (8.6%). Brolin and Cody, reporting on a series of 151 revision surgeries, observed that "Weight loss after revision of pure restrictive operations is significantly better than after revision of operations with malabsorptive components. Improvement of comorbidities in the great majority of patients justifies revision of all types of bariatric operations for unsatisfactory weight loss." Bueter et al reported that of 172 patients who underwent adjustable gastric band placement between May 1997 and June 2006, 41 had 1 or more revision procedures. There were no deaths following the reoperations. Band replacement (n=18), band repositioning (n=7), conversion to SG (n=2), and Roux-en-Y gastric bypass (RYGBP, n=2) or band removal without any further substitution (n=12) were performed as first reoperation. Seven patients had a second reoperation. Median follow-up since reoperation was 56 months (range, 7-113). Excess weight loss (percent EBWL) of patients was 59.4% after RYGBP (n=5), 45.1% after rebanding (n=18), and 33.4% after SG (n=2). Comorbidities were further reduced or even resolved after reoperation.

Endoscopic Revision Procedures

While bariatric surgery revision/correction can be conducted 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 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 et al reported on a feasibility study in animals. Thompson et al 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, which has been used in this approach, was cleared by 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 tract surgery. In 2014, Eid et al reported results from a single-center RCT of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after RYGBP at least 2 years earlier. Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow- up was completed by 45 patients in the StomaphyX group and

29 patients in the sham control group after preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphyX patients. The primary efficacy end point (reduction in pre-Roux-en-Y gastric bypass excess weight by ≥15%, excess BMI loss, and BMI <35, at 12 months postprocedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1 of 29 (3.4%) of the sham control group ($p<0.01$).

A survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons indicates different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. They were "willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures." Durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven. A systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by ASMBS's Emerging Technology and Procedures Committee concluded, "The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available."

Section Summary
For surgical revision of bariatric surgery after failed treatment, evidence from nonrandomized studies suggests that revisions are associated with improvements in weight similar to those seen in primary surgery. However, the published scientific literature on use of endoscopic devices and procedures in patients who regain weight after bariatric surgery is very limited. These endoscopic procedures are considered investigational.

Key Words:
Revision, Gastric banding, Roux-en-Y procedure, Adjustable Gastric Banding, Gastric, Biliopancreatic Bypass Procedure, Jejunoileal Bypass, Biliopancreatic Bypass with Duodenal Switch, Long Limb Gastric Bypass, Sleeve gastrectomy, Longitudinal gastrectomy, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, Endoscopic Revision Procedures, StomaphyX™ device

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:
CPT Codes:

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

43848 Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

43860 Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy

43865 Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy

References:

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Policy History:

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