

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	1
1.1	Definitions	1
1.2	Bariatric Procedures:.....	1
2.0	Eligible Recipients	2
2.1	General Provisions	2
3.0	When the Procedure, Product, or Service Is Covered.....	2
3.1	General Criteria.....	2
3.2	Specific Criteria	2
3.3	Revision of Bariatric Surgery	6
4.0	When the Procedure, Product, or Service Is Not Covered.....	7
4.1	General Criteria.....	7
4.2	Specific Criteria	7
4.3	Cosmetic Follow-up.....	8
4.4	Pregnancy.....	8
5.0	Requirements for and Limitations on Coverage	8
5.1	Prior Approval	8
5.2	Prior Approval Requirements	8
5.3	Lifetime Limitation.....	8
5.4	Postoperative Adjustments to Gastric Band.....	8
6.0	Providers Eligible to Bill for the Procedure, Product, or Service	8
6.1	Provider Qualifications	9
7.0	Additional Requirements	9
7.1	Compliance	9
8.0	Policy Implementation/Revision Information.....	9
	Attachment A: Claims-Related Information	10
A.	Claim Type	10
B.	Diagnosis Codes	10
C.	Procedure Code(s).....	10
D.	Modifiers.....	10
E.	Billing Units.....	10
F.	Place of Service	11
G.	Co-payments	11
H.	Reimbursement	11

1.0 Description of the Procedure, Product, or Service

Surgery for clinically severe or morbid obesity, termed bariatric surgery, is performed for long-term surgical weight loss management under 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 by altering the normal transit of ingested food through the intestinal tract. Some bariatric procedures may include both a restrictive and a malabsorptive component. This may result in improvement of the comorbidities of obesity. The goal of bariatric surgery is to reduce the morbidity associated with obesity, and to improve metabolic and organ function.

1.1 Definitions

Body Mass Index (BMI) is considered to represent the most practical measure of a recipient's body fat. It is calculated by dividing the weight in kilograms by the height in meters squared (kg/m²).

Clinically severe or morbid obesity is defined as a BMI greater than or equal to 40 kg/m² or a BMI 35-39.9 kg/m² with comorbid conditions. Super-obesity is defined as a BMI greater than 50 kg/m².

Surgical Review Corporation (SRC) is an internationally recognized healthcare leader committed to advancing the safety, efficacy and efficiency of surgical care worldwide. The company administers center of excellence (COE) programs on behalf of the world's largest and fastest growing bariatric surgery societies. The COE programs are specific to the needs of obese recipients and reflect the unique roles and responsibilities of bariatric and metabolic surgery providers.

The American Society for Metabolic and Bariatric Surgery (ASMBS) is the world's largest professional organization for the bariatric surgery specialty. Founded in 2004, the society's Bariatric Surgery Center of Excellence[®] (BSCOE) program has helped establish bariatric surgeons as leaders in healthcare quality. Designation is available to surgeons, hospitals and freestanding outpatient facilities in the US and Canada. Membership in the ASMBS is not required.

The bariatric surgery specialty is a multidisciplinary team that provides the long-term care needed to achieve durable weight-loss success and resolution of comorbidities. The COE programs recognize this by awarding designation to both the surgeon and facility as a Bariatric Surgery Center of Excellence. Recertification is required.

1.2 Bariatric Procedures:

a. Roux-en-Y Gastric Bypass

The Roux-en-Y gastric bypass achieves weight loss by gastric restriction and malabsorption. Gastric bypass may be performed with either an open or laparoscopic approach. The short limb procedure (roux limb that is 150 centimeters or less) is the benchmark standard for bypass surgery. The long limb (roux limb greater than 150

cm) may be considered for recipients with a Body Mass Index (BMI) greater than or equal to 55 kg/m².

b. Adjustable Gastric Banding

Adjustable gastric banding achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cubic centimeters encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted, allowing the size of the gastric outlet to be modified as needed, depending on the rate of weight loss.

c. Biliopancreatic Diversion with or without Duodenal Switch

Biliopancreatic diversion is primarily a malabsorptive procedure created with minimal gastric restriction and a small common channel for digestion. The procedure is performed with or without duodenal switch.

d. Revision of Surgery for Clinically Severe Obesity

Revision of a surgery for clinically severe obesity is used to correct complications such as slippage of an adjustable gastric band, obstruction, or stricture for recipients who met medical necessity criteria for an initial bariatric surgery.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients shall be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers surgery for clinically severe or morbid obesity when it is medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Surgery for clinically severe or morbid obesity is covered when all of the following criteria (**a through g**) are met:

- a. The recipient is at least **18 years old**. Recipients less than 18 years of age will be considered on a case-by-case basis.
- b. Clinical health care record documentation substantiates that the recipient has:
 1. a BMI greater than or equal to 40 kg/m²; **or**

2. a BMI greater than or equal to 35 kg/m² with **at least one** of the following conditions **complicated by clinically severe or morbid obesity**:
 - A. Arteriosclerosis, diabetes, heart disease, pseudotumor cerebri;
 - B. limitation of motion in any weight-bearing joint or lumbosacral spine as documented by the clinical health care record, including x-ray findings of degenerative osteoarthritis;
 - C. significant respiratory insufficiency as evidenced by pCO₂ greater than 50 mmHg, hypoxemia at rest, as evidenced by pO₂ less than 55 mmHg on room air; FEV₁/FVC less than 65%, or DLCO less than 60% (e.g., Obesity Hypoventilation Syndrome); or sleep apnea documented by respiratory function studies, blood gases, sleep studies, etc;
 - D. Significant circulatory insufficiency such as Peripheral vascular disease documented with arteriography or ultrasound and brachial and ankle pressure before and after exercise. Documented coronary artery disease by stress test or previous need for angioplasty of coronary bypass. Carotid artery disease documented by ultrasound with greater than 70% blockage. Aortic disease documented by CT or MRI. Severe valvular disease documented by doppler echo;
 - E. Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or greater than 90 mmHg diastolic measured with appropriate size cuff) that has not responded to medical management including at least two anti-hypertensive drugs at maximum tolerated dosages; **or**
 - F. Hypercholesterolemia greater than 240 mg/dL or hypertriglyceridemia greater than 400 mg/dL or low density lipoprotein (LDL) greater than 160 mg/dL or high density lipoprotein (HDL) less than 40 mg/dL; despite appropriate medical therapy defined as at least one appropriate drug at maximum dosage.

Note: If the recipient has any comorbid conditions **there must be clinical health care records submitted indicating these conditions are not contraindications for the proposed surgery** therefore rendering the recipient incapable of undergoing the requested procedure.

- c. Clinical health care record documentation substantiates that clinically severe obesity, as indicated by BMI as outlined above, must have been present for the past two years prior to the Prior Approval Request (for example, a weight from each of the past two years along with the recipient's height).
- d. Clinical health care record documentation substantiates **all** of the following criteria:
 1. The recipient has attempted weight loss for the past two years prior to the request without achieving long-term weight reduction. Encounter notes obtained from the referring primary physician (s), must be submitted by the requesting surgeon, for review.
 2. The recipient has met **all criteria** of the **Multidisciplinary Pre-Surgical** preparatory regimen as follows:
 - A. The recipient must have completed an organized Multidisciplinary Pre-Surgical preparatory regimen of at least three consecutive months

duration within six months of the submitted Prior Approval Request to improve surgical outcomes, reduce the potential for surgical complications, and establish the recipient's suitability for surgery as well as to their ability to comply with postoperative medical care, dietary restrictions and required five year follow-up:

- B. The requesting surgeon is the team leader of his/her bariatric team for the Multidisciplinary Pre-surgical preparatory regime and **must meet all the following requirements:**
- i. Conducts the initial assessment to determine medical and or surgical alternatives. If surgery is recommended, and the procedure mutually agreed upon, the surgeon must inform and certify the recipient's and parent or guardian: understanding of the procedure to be performed, including the procedure's risks and benefits; behavioral changes required prior to and after the surgical procedure (including pre and post operative dietary and increasing exercise requirements); psychological changes, and commitment for following the required five year post-surgical program.
 - ii. On completing and agreeing on the procedure, the surgeon must make the appropriate referrals to the bariatric team members for their respective evaluations.
 - iii. Responsible in instructing the recipient on specific measurable exercises to increase physical activity, based on existing health condition(s).
 - iv. Timely reviews recommendations from the bariatric team, develop, supervise and provide a three month program that is individualized for the recipient.
 - v. Must develop a five year post surgical program specific to the recipient in collaboration with the bariatric team.
 - vi. After the bariatric team members have completed the required three month multi-disciplinary treatment program, **and all of them recommend surgical candidacy**, the surgeon must perform a complete physical examination. The documented exam must include History & Physical, **current weight**, height, BMI, list of current medications, findings, and the bariatric team's recommendation for candidacy.
 - vii. Responsible for the completion and submitting of the Prior Approval Request form, and all required documentation under **Subsection 5.2**, Prior Approval, at time of request.
- e. **Dietician/Nutritionist Evaluation:** The bariatric team must include a registered dietician and or nutritionist on the requesting surgeon's multi-disciplinary pre-surgical preparatory regime and meet all the following:
1. Complete a thorough individualized Initial Evaluation which must include diet history, identifying problem areas, obstacles, eating disorders, and or need for dietary behavior modifications. The required evaluation must be conducted face-to-face, not in a group setting.
 2. Timely communicates individualized pre-surgical reduced-calorie and dietary recommendations to the surgeon based on the initial evaluation.
 3. Follows the recipient per surgeon's dietary treatment plan until completion, and

4. On completing the recipient's nutritional component of the pre-surgical three month program renders opinion to the recipient's ability to make the lifelong dietary changes for surgical candidacy.
- f. The recipient has no correctable cause for the obesity, such as an endocrine disorder
- g. **Psychological Evaluation:** The bariatric team must include a licensed psychologist, psychiatrist and or licensed social worker on the requesting surgeon's multi-disciplinary pre-surgical preparatory regime and meet all the following requirements:
 1. There is clinical health care record documentation of a psychological **initial** evaluation assessing for any psychopathology which may interfere with the recipient's suitability for surgery, ability to comply with lifelong dietary changes and medical follow-up;
 2. The initial evaluation **must** include the components of such an assessment to include:
 - A. Adult Mental health history, mental health diagnoses, current mental health treatments, status;
 - B. eating behaviors-past and present;
 - C. substance abuse evaluation;
 - D. stress management;
 - E. cognitive abilities;
 - F. social functioning;
 - G. self-esteem;
 - H. personality factors;
 - I. readiness and ability to adhere to required lifestyle modifications,;
 - J. follow up recommended for any issues identified; and
 - K. identify social support system in place.

The **following conditions are contraindications** to bariatric surgery and approval cannot be granted until there is clinical health care record documentation that the conditions are resolved: **untreated major depression or psychosis, binge-eating disorders, current drug and or alcohol abuse.**

All pre-surgical team members shall work collaboratively on identifying and treating any behavior requiring modification (i.e. eating disorder, etc). Group presentations will not meet the requirements of face-to-face interactions with the recipient. **Documentation of the recipient's inability to comply with lifelong requirements by one or more team members will result in denial of surgery.** Bariatric team member statements of candidacy without supporting clinical health care record documentation will not meet the requirement of recommendation of candidacy. **All team members shall substantiate candidacy before the surgeon can submit a request for Prior Approval.**

Documentation Requirements for all pre-surgical team members: A provider's summary letter will not be considered as clinical health care record documentation. ALL bariatric team members must complete encounter notes which include: recipient's name on each page, date of service, exclusive purpose for pre-surgical bariatric evaluation or treatment, assessments/findings, individualized intervention, recipient's response to the team's treatment plan. All documentation must be completed **timely to date of service**, and if a late entry is unavoidable, must be identified as such, signed, and dated with referencing to the date and time relating back to. Handwritten documentation will not be processed for consideration of the request. Please refer to **Subsection 5.2**, Prior Approval Requirements, for additional clinical health care record documentation requirements; and

- h. The surgery is **one** of the following procedures:
1. gastric bypass with Roux limb 150 cm or less (roux-en-Y);
 2. adjustable gastric banding, for recipients with a BMI of less than 50 kg/m². Recipients with a BMI greater than or equal to 50 kg/m² will be considered on a case by case basis when information is provided as to the necessity of this procedure for the specific recipient. Furthermore, gastric banding is the **only** bariatric surgical procedure that may be performed in the outpatient setting, and have also met all criteria as well.
 3. biliopancreatic diversion with or without duodenal switch, for the most severely obese recipients (typically with a BMI greater than or equal to 50 kg/m²), to be considered on an individual basis with appropriate documentation of the indications for this procedure under current standards of care; or
 4. gastric bypass, with small intestine reconstruction to limit absorption, with roux limb greater than 150 cm (long-limb roux-en-Y) for recipients with a BMI greater than or equal to 55 kg/m², - to be considered on an individual basis.

3.3 Revision of Bariatric Surgery

Medically necessary surgery to correct complications from the initial bariatric surgery is covered. Refer to **Subsection 1.2.d**. Revisions to the initial procedure for clinically severe or morbid obesity may be covered for a recipient if one of the following conditions is met:

- a. weight loss of 20% or more below the ideal body weight;
- b. esophagitis, unresponsive to nonsurgical treatment;
- c. hemorrhage or hematoma complicating a procedure;
- d. excessive bilious vomiting following gastrointestinal surgery;
- e. complications of the intestinal anastomosis and bypass;

- f. stomal dilation, documented by endoscopy;
- g. documented slippage of adjustable gastric band;
- h. pouch dilation documented by upper gastrointestinal examination or endoscopy, producing weight gain of 20% or more, provided that:
 - 1. the primary procedure was successful in inducing weight loss prior to the pouch dilation, and
 - 2. the recipient has been compliant with a prescribed nutrition and exercise program following the procedure (weight and BMI prior to surgery, at lowest stable point, and at current time must be submitted along with surgeon's statement to document compliance with diet and exercise)
- i. other and unspecified post surgical non-absorption (such as hypoglycemia and malnutrition following gastrointestinal surgery); or
- j. in the case of stricture, obstruction and or staple line failure.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

NCHC shall not cover the following procedures:

- a. Jejunioleal bypass
- b. Biliopancreatic diversion with or without duodenal switch when the criteria in **Subsection 3.2.h.3**, are not met
- c. Gastric wrapping
- d. Adjustable gastric banding for recipients when the criteria in **Subsection 3.2.h.2**, are not met
- e. Jejunocolostomy
- f. Mini-gastric bypass
- g. Gastric sleeve
- h. Gastric bypass with roux limb greater than 150 cm (except as noted in **Subsections 3.2.g.4**, and **5.4**)
- i. Gastric electrical stimulation
- j. Revision of an initial gastric restrictive surgery when the recipient does not meet the criteria in **Subsection 3.3**, and
- k. Staged procedures

4.3 Cosmetic Follow-up

Weight loss following surgery for clinically severe or morbid obesity can result in skin and fat folds in locations such as the medial upper arms, lower abdominal area, and medial thighs. Surgical removal of this skin and fat for solely cosmetic purposes is not covered.

4.4 Pregnancy

Bariatric surgery is not covered during pregnancy.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for all surgery for clinically severe or morbid obesity.

5.2 Prior Approval Requirements

The provider(s) shall submit all of the following:

- a. the Prior Approval Request ;
- b. all clinical health care records and any other records that support the recipient has met all the criteria in **Subsection 3.2** of this policy;
- c. a complete listing of all of the recipient's medications;
- d. documentation that all correctable causes of obesity have been ruled out, with description and results of laboratory tests performed; and
- e. description of the type of bariatric surgery planned and CPT code that describes the surgery planned
- f. documentation of their designation as a BSCOE and documentation of designation of BSCOE for the place of surgical service.

5.3 Lifetime Limitation

Only one procedure from those listed in **Section 3.2.g**, is allowed per lifetime.

5.4 Postoperative Adjustments to Gastric Band

Postoperative adjustments to the gastric band during the postoperative period (90 calendar days) are included in the global surgery reimbursement. Adjustments after the postoperative period are billed as an office visit and are not separately reimbursable.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; AND
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications

Approval for bariatric procedures shall be granted only to those providers (facilities and surgeons) who are designated as a bariatric surgery center of excellence (BSCOE) under session law 2011-145 Section 10.31 (d)(2)q.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

Providers shall comply with the indications for use of FDA approved devices for bariatric surgery.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
January 1, 2012	Throughout	Policy revised comparable to Medicaid Clinical Coverage Policy 1A-15 due to Session Law 2011-145

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

Code	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43845	Gastric restrictive procedure, with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass, for morbid obesity; with short limb (150 cm or less) roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass, for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

Note: The CPT procedure codes listed above are subject to the global surgery policy.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

In-patient Hospital, Outpatient patient Hospital, Ambulatory surgical centers

G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

H. Reimbursement

Providers shall bill their usual and customary charges.