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**To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.**

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**Related Clinical Coverage Policies**

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:  
1-0-1, *Reconstructive and Cosmetic Surgery*

## **1.0 Description of the Procedure, Product, or Service**

Surgery for clinically severe or morbid obesity is performed for long-term surgical weight loss management. This may result in improvement of the co-morbidities of obesity. The goal of the surgery is to reduce the morbidity associated with obesity, and to improve metabolic and organ function.

Surgery for clinically severe or morbid obesity (referred to as a bariatric surgical procedure for the purpose of this policy) falls into two general categories:

- a. gastric-restrictive procedures which create a small gastric pouch resulting in weight loss by producing early satiety and thus decreasing dietary intake **because the amount of food that can be eaten at one time is greatly reduced**; and
- b. malabsorptive procedures, which produce weight loss due to malabsorption by altering the normal transit of ingested food through the intestinal tract. **Following a malabsorption procedure, the number of calories, fats and nutrients that can be absorbed during digestion is reduced.**

Some bariatric surgical procedures have both a restrictive and a malabsorptive component.

**Note: Refer to Subsection 6.2 for provider accreditation.**

### **1.1 Definitions**

#### **1.1.1 Body Mass Index (BMI):**

Body Mass Index (BMI) is considered to represent the most practical measure of a beneficiary's body fat. It is calculated by dividing the weight in kilograms by the height in meters squared (kg/m<sup>2</sup>). Weight gained during pregnancy cannot be used to meet the pre-surgical requirements for this policy.

#### **1.1.2 Clinically Severe Obesity:**

Clinical Severe Obesity is defined as a BMI 35-39.9 kg/m<sup>2</sup> with co-morbid conditions.

#### **1.1.3 Morbid Obesity:**

Morbid Obesity is defined as a BMI greater than or equal to 40 kg/m<sup>2</sup>.

### **1.2 Bariatric Surgery and other Procedures (Bariatric Surgical Procedures)**

#### **1.2.1 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

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(roux limb greater than 150 cm) may be considered for a beneficiary with a BMI greater than or equal to 55 kg/m<sup>2</sup>.

**1.2.2 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.

**1.2.3 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.

**1.2.4 Revision of Bariatric Surgery**

Revision of a bariatric surgery is used to correct complications such as slippage of an adjustable gastric band, obstruction, or stricture for a beneficiary who meets medical necessity criteria for a primary bariatric surgical procedure.

**1.2.5 Sleeve Gastrectomy**

Sleeve Gastrectomy (SG), sometimes called gastric sleeve, achieves weight loss by gastric restriction only. When performed laproscopically, the term laparoscopic sleeve gastrectomy (LSG) is used. LSG is being used as a stand-alone approach. This laparoscopic procedure reduces the stomach to about 25% of its original size and is not reversible. The small size of the stomach limits food intake. It also lessens the sensation of hunger by decreasing ghrelin, a hormone that prompts appetite. LSG is usually considered for an extremely obese beneficiary.

**2.0 Eligibility Requirements**

**2.1 Provisions**

**2.1.1 General**

*(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)*

- a. An eligible beneficiary shall be enrolled in either:
  1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
  2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

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- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

**2.1.2 Specific**

**a. Medicaid**

An eligible Medicaid beneficiary shall be 18 years of age and older. A Medicaid beneficiary under 18 years of age is considered on a case-by-case basis under the EPSDT requirements.

**b. NCHC**

An NCHC beneficiary under the age of 18 is not eligible for bariatric surgical procedure. An eligible NCHC beneficiary shall be 18 years of age; and shall have the approved bariatric surgical procedure performed prior to reaching 19 years of age.

**2.2 Special Provisions**

**2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age**

**a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows

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that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**b. EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

*NCTracks Provider Claims and Billing Assistance Guide:*

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

**2.2.2 EPSDT does not apply to NCHC beneficiaries**

**2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age**

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

**3.0 When the Procedure, Product, or Service Is Covered**

*Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.*

**3.1 General Criteria Covered**

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when 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 beneficiary’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 statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary’s caretaker, or the provider.

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### 3.2 Specific Criteria Covered

#### 3.2.1 Specific criteria covered by both Medicaid and NCHC

- a. Medicaid and NCHC shall cover ONE of the following bariatric procedures when criteria is met:
  1. Gastric bypass with roux limb 150 cm or less (Roux-en-Y gastroenterostomy);
  2. Adjustable gastric banding, for a beneficiary with a BMI of less than 50 kg/m<sup>2</sup>. A beneficiary with a BMI greater than or equal to 50 kg/m<sup>2</sup> is considered on a case-by-case basis when information is provided as to the medical necessity of this procedure for the specific beneficiary;
  3. Biliopancreatic diversion with or without duodenal switch, for a beneficiary with a BMI greater than or equal to 50 kg/m<sup>2</sup>, to be considered on an individual basis with appropriate documentation of the indications for this procedure under current standards of care;
  4. Gastric bypass, with small intestine reconstruction to limit absorption, with roux limb greater than 150 cm (long-limb Roux-en-Y) for a beneficiary with a BMI greater than or equal to 55 kg/m<sup>2</sup>, to be considered on an individual basis; or
  5. Laparoscopic sleeve gastrectomy (LSG) as a stand-alone procedure.
- b. Medicaid and NCHC shall cover a bariatric surgical procedure for clinically severe or morbid obesity when health records substantiate that a beneficiary has met ALL the following criteria (a through f e) for the past 12 calendar months prior to the request for surgery:
- c. A diagnosis of morbid obesity or clinically severe obesity with at least ONE of the following conditions:
  1. Arteriosclerosis, type 2 diabetes mellitus, heart disease, cardiomyopathy, heart failure, pseudotumor cerebri;
  2. Gastroesophageal reflux disease with secondary asthma or erosive esophagitis, not controlled despite maximum dosages of proton pump inhibitors;
  3. Limitation of motion in any weight-bearing joint or lumbosacral spine as documented by the health record, including x-ray findings of degenerative osteoarthritis, or severe osteoarthritis;
  4. Significant respiratory insufficiency as evidenced by partial pressure of carbon dioxide (PCO<sub>2</sub>) greater than 50 mmHg, hypoxemia at rest, as evidenced by PCO<sub>2</sub> less than 55 mmHg on room air; forced expiratory volume in 1 second (FEV<sub>1</sub>), forced vital capacity (FVC) less than 65%, or carbon monoxide diffusion in the Lung (DLCO) less than 60% (such as Obesity Hypoventilation Syndrome); or sleep apnea documented by respiratory function studies, blood gases, sleep studies;
  5. 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 or coronary bypass. Carotid artery disease documented by ultrasound with greater than 70%

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blockage. Aortic disease documented by CT or MRI. Severe valvular disease documented by doppler echo;

6. **Pulmonary hypertension;**
7. Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and 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;
8. 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;
9. **Metabolic syndrome, nonalcoholic steatohepatitis (NASH); or**
10. **Extreme obesity, a Body Mass Index (BMI) greater than or equal to 40, or BMI greater than 35 with a significant comorbid condition that is related to obesity; and the beneficiary has demonstrated evidence of attempts to lose weight through non-surgical means such as follow up with medical provider for weight-related comorbid conditions, nutritional counseling and physical activity through a professional qualified to provide these services or through a proprietary weight loss program.**

**Note:** The health record must substantiate that ONE of the above existing conditions is not a contraindication for the requested surgery.

11. Documentation in the health record substantiates ALL the following (1 - 4) criteria: The beneficiary has been unsuccessful with medical treatment for clinically severe or morbid obesity for the past 12 calendar months prior to the request for a bariatric surgical procedure, of at least three (3) calendar months duration, provided or supervised by a medical provider.
12. The monthly encounter notes must document ALL the following:
13. Body weight greater than 100 pounds or 45kg above ideal weight with at least one height documented;
14. Caloric requirements, and eating behaviors being modified; and
15. Measurable activity prescribed relevant to the beneficiary's medical condition(s) (such as: type of exercise, frequency, duration.) A statement in the encounter note to "increase activity" or failure to prescribe a measurable activity does not meet this requirement;
16. The beneficiary has no correctable cause for obesity, such as an endocrine disorder; and
17. The treatment of any medical condition(s) listed in Subsection 3.2.1.a.

d.

- e. **Dietician or Nutritionist Comprehensive Evaluation:** Evaluation by a registered dietician or nutritionist experienced in the issues associated with bariatric surgery procedures, documenting diet history, problem areas,

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obstacles, eating disorders, or need for dietary behavior modifications, reduced calorie, and dietary recommendations in the past six calendar months prior to the request for surgery. The required evaluation must be conducted face-to-face, and not in a group setting. The comprehensive evaluation must document at a minimum the following:

1. History of weight loss management;
2. History of weight loss attempts with supervised diets and exercise programs as well as independent attempts; and
3. Ability to comply with postsurgical medical care, dietary restrictions, and lifetime commitment required to maintain a successful outcome.

~~substantiate the beneficiary's suitability for a bariatric surgical procedure, and their ability to comply with postoperative medical care, dietary restrictions, and the lifetime commitment required for a successful outcome.~~

~~During the Dietician or Nutritional Evaluation, the beneficiary keeps a food diary to record their daily intake and learn the principles of post-operative gastric bypass, including dietary progression, protein and fluid requirements, and lifelong vitamin and mineral supplementation.~~

- f. **Psychological Evaluation:** Evaluation by a licensed psychologist, psychiatrist or licensed medical clinical social worker, documenting the absence of significant psychopathology in the past six calendar months. This documentation must substantiate the beneficiary's suitability for a bariatric surgical procedure, and their ability to comply with postoperative medical care, dietary restrictions, and the lifetime commitment required for a successful outcome. Inability to comply results in denial of the surgery. The psychological evaluation must document, at a minimum the following, to substantiate suitability for surgery:
1. psychiatric history;
  2. current psychological function;
  3. weight and dieting history;
  4. current eating behaviors;
  5. level of physical activity; and
  6. history of substance use and dependence (as well as any current use).

~~During the psychological evaluation, a beneficiary is educated on the behavioral changes necessary to ensure good post-operative results, as well as any psychological changes that can be anticipated after surgery.~~

- g. The requesting surgeon shall (with the prior approval request) submit ALL health records that meet the following requirements:
1. **Conducts the Initial Assessment**, face to face, **to** determine medical or surgical alternatives. If a covered bariatric surgical procedure is recommended, and mutually agreed upon, the surgeon shall inform and evaluate the beneficiary's understanding of the procedure to be performed, the procedure's risks and benefits; behavioral changes required prior to and after the bariatric surgical procedure ( pre- and post-

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- operative dietary and increasing exercise requirements); psychological changes, and commitment for following the surgeon's post-surgical program.
2. Make the appropriate referrals to the dietician or nutritionist and psychological professional for evaluations **if** they have not been completed or treatment has not resolved contraindicated issues. Refer to **Subsection 4.2.1**.
  3. **IF** the surgeon prescribes additional pre-surgical requirement(s), not all inclusive of specified weight loss or smoking cessation, the surgeon shall either provide treatment or make a referral to assist the beneficiary in meeting additional requirement(s) before a prior approval is submitted. Health records substantiating that the requirement(s) have been met must be submitted with the prior approval request.
  4. If the surgeon deems the primary mutually agreed upon procedure is no longer medically appropriate, another face-to-face assessment must be conducted as defined under (1.) above.
  5. When ALL pre-surgical requirements are met, the requesting surgeon, group associate, or group physician extender shall perform a complete History & Physical examination, which must document **current weight, height, BMI, laboratory values (that includes thyroid levels)** and a list of current medication(s).

Appropriate medical work up may consist of a chest x-ray, upper gastrointestinal series, endoscopy, appropriate pre-op labs and ECG.

**Note:** Routine pre-admission work-up must be held pending approval to prevent repeating time-sensitive services.

- ~~a. The bariatric surgical procedure is ONE of the following procedures:~~
- ~~1. Gastric bypass with Roux limb 150 cm or less (roux en Y);~~
  - ~~2. Adjustable gastric banding, for beneficiaries with a BMI of less than 50 kg/m<sup>2</sup>. Beneficiaries with a BMI greater than or equal to 50 kg/m<sup>2</sup> are considered on a case-by-case basis when information is provided as to the medical necessity of this procedure for the specific beneficiary.~~
  - ~~3. Biliopancreatic diversion with or without duodenal switch, for beneficiaries with a BMI greater than or equal to 50 kg/m<sup>2</sup>, to be considered on an individual basis with appropriate documentation of the indications for this procedure under current standards of care;~~
  - ~~4. Gastric bypass, with small intestine reconstruction to limit absorption, with roux limb greater than 150 cm (long limb roux en Y) for a beneficiary with a BMI greater than or equal to 55 kg/m<sup>2</sup>, to be considered on an individual basis;~~  
~~or~~
  - ~~5. Laparoscopic sleeve gastrectomy (LSG) as a stand alone procedure.~~

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### 3.2.2 Medicaid Additional Criteria Covered

None Apply.

Refer to **Subsection 3.2.4** below.

~~The bariatric surgical procedure must be ONE of the following procedures:~~

- ~~a. Gastric bypass with roux limb 150 cm or less (Roux-en-Y gastroenterostomy);~~
- ~~b. Adjustable gastric banding, for a beneficiary with a BMI of less than 50 kg/m<sup>2</sup>.<sup>a</sup> A beneficiary with a BMI greater than or equal to 50 kg/m<sup>2</sup> is considered on a case by case basis when information is provided as to the medical necessity of this procedure for the specific beneficiary;~~
- ~~c. Biliopancreatic diversion with or without duodenal switch, for a beneficiary with a BMI greater than or equal to 50 kg/m<sup>2</sup>, to be considered on an individual basis with appropriate documentation of the indications for this procedure under current standards of care;~~
- ~~d. Gastric bypass, with small intestine reconstruction to limit absorption, with roux limb greater than 150 cm (long limb Roux-en-Y) for a beneficiary with a BMI greater than or equal to 55 kg/m<sup>2</sup>, to be considered on an individual basis; or~~
- ~~e. Laparoscopic sleeve gastrectomy (LSG) as a stand alone procedure.~~

### 3.2.3 NCHC Additional Criteria Covered

None apply. Refer to **Subsection 3.2.4** below.

### 3.2.4 Medicaid and NCHC Additional Criteria Covered

- a. Medicaid and NCHC shall cover **revision** of a primary bariatric surgical procedure for a documented perioperative or late complication for a beneficiary who meets **ONE** of the below conditions:
  1. weight loss of 20% or more below the ideal body weight;
  2. esophagitis unresponsive to nonsurgical treatment;
  3. hemorrhage or hematoma complicating a procedure;
  4. excessive bilious vomiting following gastrointestinal surgery;
  5. complications of the intestinal anastomosis and bypass;
  6. stomal dilation, confirmed by endoscopy;
  7. slippage of adjustable gastric band that cannot be corrected with manipulation or adjustments;
  8. stricture;
  9. obstruction;
  10. erosion;
  11. staple-line failure; or
  12. non-absorption (such as hypoglycemia or malnutrition following gastrointestinal surgery).
- b. Medicaid and NCHC shall cover **revision** of a primary bariatric surgical procedure that has failed when pouch dilation is confirmed by upper

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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 beneficiary 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 of compliance with diet and exercise).

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

*Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.*

### 4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

### 4.2 Specific Criteria Not Covered

#### 4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC **shall not cover** the following:

- a. Jejunioileal bypass;
- b. Biliopancreatic diversion with or without duodenal switch for a beneficiary with a BMI < 50 kg/m<sup>2</sup>;
- c. Gastric wrapping;
- d. Adjustable gastric banding for a beneficiary with a BMI > 50 kg/m<sup>2</sup>;
- e. Jejunocolostomy;
- f. Mini-gastric bypass;
- g. Open sleeve gastrectomy;
- h. Gastric bypass with roux limb greater than 150 cm for a beneficiary with a BMI less than 55 kg/m<sup>2</sup>;
- i. **Bariatric surgical procedures for a beneficiary with a BMI less than 35 kg/m<sup>2</sup>;**
- j. Gastric electrical stimulation;
- k. Revision of a primary bariatric surgical procedure when the beneficiary does not meet the criteria in **Subsection 3.2.4**;
- l. Staged procedures; or
- m. Cosmetic surgery: Weight loss following bariatric surgical procedures 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.

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n. BMI less than 35 kg/m<sup>2</sup>

**Note:** Refer to NC Medicaid clinical coverage policy 1-O-1 *Reconstructive and Cosmetic Surgery* found at <https://medicaid.ncdhhs.gov/> for excessive skin removal criteria.

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

#### 4.2.2 Medicaid Additional Criteria Not Covered

Medicaid shall not cover a bariatric surgical procedure during pregnancy.

- a. Medicaid and NCHC shall not cover a bariatric surgical procedure or a beneficiary who is:
  1. a preadolescent child.
  2. a pregnant or breast-feeding adult or adolescent
  3. planning to become pregnant within two years of surgery; and
  4. not demonstrating mastery of the principles of healthy dietary and activity habits.
- b. The following conditions are contraindications to a bariatric surgical procedure, and approval cannot be granted until there is health record documentation that the conditions are resolved:
  1. untreated major depression or psychosis.
  2. binge-eating disorders.
  3. current drug and alcohol abuse.

#### 4.2.3 NCHC Additional Criteria Not Covered

- a. In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, NCHC shall not cover the surgeon's post-surgical program for a beneficiary who has reached the age of 19.
- b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
  1. No services for long-term care.
  2. No nonemergency medical transportation.
  3. No EPSDT.
  4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

## **5.0 Requirements for and Limitations on Coverage**

*Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.*

### **5.1 Prior Approval**

Medicaid and NCHC shall require prior approval for a covered bariatric surgical procedure.

### **5.2 Prior Approval Requirements**

#### **5.2.1 General**

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

**Note:** A letter from the surgeon stating that all criteria have been met is not sufficient documentation.

The approval does not transfer to a different provider or allow for change in bariatric surgical procedure. If either occurs, a new request must be submitted and all policy requirements met for approval.

#### **5.2.2 Specific**

In addition to the general requirements in **Subsection 5.2.1**, the provider(s) shall submit a description of the type of bariatric surgical procedure planned.

The beneficiary shall meet all policy requirements and the provider shall obtain prior approval before performing a bariatric surgical procedure, if the primary insurance does not cover the procedure.

A provider's summary letter alone is not considered a health record. **Encounter notes must document the following: Documentation must include encounter notes which report the:**

- a. beneficiary's name on each page;
- b. date of service;
- c. exclusive purpose for pre-surgical bariatric evaluation or treatment, assessments and findings;
- d. individualized intervention; and
- e. beneficiary's response to the treatment plan.

All documentation-must be completed **timely to date of service**. If a late entry is unavoidable, it must be identified as such, signed, and dated with referencing to the date and time relating back to the date of service. Illegible documentation is not processed for a prior approval request.

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The facility's documentation of their Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation must be submitted with each prior approval request.

Note: Refer to Subsection 6.2 for provider accreditation.

### **5.3 Lifetime Limitation**

One bariatric surgical procedure from those listed in **Subsection 3.2.1.a** is allowed per beneficiary per lifetime.

When a beneficiary had a previous primary bariatric surgical procedure, other than as a Medicaid beneficiary, then the beneficiary may have an additional primary bariatric surgical procedure, if all prior approval requirements are met.

A primary bariatric surgical procedure may be revised if all prior approval requirements are met.

## **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 Medicaid or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; 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 and Occupational Licensing Entity Regulations**

None Apply.

### **6.2 Provider Certifications**

~~None Apply.~~

Medicaid shall require a bariatric facility to achieve accreditation and demonstrate the ongoing compliance with the requirements of the accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).

## **7.0 Additional Requirements**

*Note: Refer to Subsection 22 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.*

### **7.1 Compliance**

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for

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Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or its fiscal contractor(s).

**7.1.1 FDA Approved Devices**

Providers shall comply with FDA-approved indications for use for all bariatric surgical devices.

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## 8.0 Policy Implementation and History

**Original Effective Date:** January 1, 1985

**Revision Information:**

<b>Date</b>	<b>Revised</b>	<b>Change</b>
09/01/2004	Entire Policy	Changed all references to “morbid” obesity to “clinically severe” obesity
09/01/2004	Section 3.1	Removed less than 60 age restriction
09/01/2004	Section 3.2	Added BMI requirement
09/01/2004	Section 3.2	Made co-morbidity requirements more specific.
09/01/2004	Section 3.2	Removed “in excess of 100 pounds over ideal weight for height and age.”
09/01/2004	Section 3.3	Changed duration of obesity from “shall exceed three years” to “at least three years”
09/01/2004	Section 3.4	Specified a requirement for previous weight loss attempt of six months or longer under physician supervision or in an organized weight loss program.
09/01/2004	Section 5.1	Added components of psychological evaluation
09/01/2004	Section 5.1	Added “Documentation of a psychosocial, nutritional and activity based follow up plan for at least five years”
09/01/2004	Section 5.2	Revised text to clarify that surgical removal of this skin and fat solely for cosmetic purposes is not covered.
09/01/2004	Section 8.3	Documented covered codes.
02/01/2005	Section 3.0 #6	The unlisted procedure code 43659 was replaced with 43644 for the laparoscopic version of gastric bypass/roux-en-Y.
02/01/2005	Section 8.3	CPT code 43644 was added to the list of covered codes.
09/01/2005	Section 2.0	A special provision related to EPSDT was added.
12/01/2005	Section 2.2	The web address for DMA’s EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0, 4.0, and 5.0	A note regarding EPSDT was added to these sections.
07/01/2008	Sections 2 through 5	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age
07/01/2008	Section 1.0	Language was added to indicate that surgery for clinically severe obesity may result in improvement of the co morbidities of obesity.
07/01/2008	Section 1.1 through 1.5	Descriptions of roux-en-Y gastric bypass, adjustable gastric banding, biliopancreatic diversion with or without duodenal switch, and revision surgery were added as new sections to the policy.
07/01/2008	Section 3.1	General coverage criteria were added to the policy as Section 3.1.

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<b>Date</b>	<b>Revised</b>	<b>Change</b>
07/01/2008	Section 3.2, item a	The age limitation was revised to “at least 18” and a note was added to indicate that surgeries for individuals under the age of 18 are considered on a case-by-case basis under EPSDT requirements.
07/01/2008	Section 3.2, item b.2	Language was added to clarify that medical justification of criteria shall be documented in the medical record.
07/01/2008	Section 3.2, item c	The requirement that medical record documentation of clinically severe obesity shall be available for at least three years was revised to two years and was clarified.
07/01/2008	Section 3.2, item d	The types of activities that qualify as meeting the requirement of attempted weight loss were expanded and an additional option of a 3-month surgical preparatory regimen was added.
07/01/2008	Section 3.2, item f	This item was added to document the requirement for a psychological evaluation, the components of the evaluation, and potential follow-up.
07/01/2008	Section 3.2, item g	Coverage criteria for gastric bypass was clarified; criteria for vertical-banded gastroplasty was revised; and criteria for adjustable gastric banding, biliopancreatic diversion with or without duodenal switch, and gastric bypass with small intestine reconstruction to limit absorption with long limb roux-en-Y were added. Information was added concerning medical record requirements.
07/01/2008	Section 3.3	Coverage criteria and requirements for bariatric surgery revision were added to the policy.
07/01/2008	Section 4.1	General criteria for noncoverage was added to the policy.
07/01/2008	Section 4.2	Additional criteria for non coverage were added and other criteria clarified.
07/01/2008	Section 4.3	Specific criteria for non coverage of cosmetic follow-up surgery was added to the policy.
07/01/2008	Section 4.4	Added a statement that bariatric surgery is not covered during pregnancy.
07/01/2008	Section 5.1	Prior approval requirements and medical necessity documentation were clarified. Information on coordination of benefits was also added.
07/01/2008	Section 5.2	This section was renumbered to Section 4.3.
07/01/2008	Section 5.2 through 5.6	Limitations on adjustable gastric banding, biliopancreatic diversion with or without duodenal switch, gastric bypass with roux limb greater than 150 cm, vertical-banded gastroplasty, and revisions of bariatric surgery were added to the policy.
07/01/2008	Section 5.7	Lifetime limitations were added to the policy.
07/01/2008	Section 5.8	Limitation on billing for postoperative adjustments was added to the policy.
07/01/2008	Section 7.1	A statement was added to indicate that providers shall comply with all applicable federal and state regulations and laws was added to the policy.

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<b>Date</b>	<b>Revised</b>	<b>Change</b>
07/01/2008	Section 7.2	Requirements related to records retention were added to the policy.
07/01/2008	Attachment A	Section 8.0 was moved to Attachment A, and the list of procedure codes was revised. CPT procedures codes 43645, 43770, 43771, 43772, 43773, 43774, 43845, 43847, 43848, and 43999 were added to the policy as covered codes.
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
10/01/2010	Throughout	The policy was end-dated secondary to Legislative order.
01/01/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 1A-15 under Session Law 2011-145, § 10.41.(b)
06/15/2012	Section 4.2	Reference in 4.2 that per 2010-31, Panniculectomy [Excision, excessive skin and subcutaneous tissue (includes lipectomy)] is not a covered service, hence, effective October 1, 2010 Medicaid and NCHC no longer covered this service.
06/15/2012	Section 5.3	Clarification and renumbering of Prior Approval Requirements for Initial Bariatric Surgery
06/15/2012	Section 5.4	Clarification and renumbering of Prior Approval Requirements for Revision of Bariatric Surgery
06/15/2012	Attachment A, Section C	Separated billing codes into two tables by place of service.
06/15/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
09/01/2015	All Sections and Attachments	Updated policy template language
09/01/2015	Section 1.0	Added: Surgery for clinically severe or morbid obesity will be referred to as a bariatric surgical procedure for the purpose of this policy.
09/01/2015	Subsection 1.1	Clarification of the description of the procedures covered. Removal of Definitions: Surgical Review Corporation, The American Society for Metabolic and Bariatric Surgery, and Bariatric Surgery Specialty and Super Obesity. Added: BMI : Weight gained during pregnancy cannot be used to meet the pre-surgical requirements for this policy.
09/01/2015	Subsection 1.2	Changed to include other Bariatric Surgical Procedures
09/01/2015	Subsection 1.2 e	Added: Sleeve gastrectomy LSG as a bariatric surgical procedure.
09/01/2015	Subsection 2.1.2 item b	Added: Specific Eligibility Requirements for Medicaid is 18 years of age and older to include EPSDT. NCHC is 18 years of age and approved bariatric surgery shall be performed prior to reaching 19 years of age.

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<b>Date</b>	<b>Revised</b>	<b>Change</b>
09/01/2015	Subsection 2.2	Added: Sleeve Gastrectomy as a laparoscopic stand alone procedure.
09/01/2015	Subsection 3.2.1	Clarification and renumbering done specific to Removal of 2 year obesity /attempt weight loss, Added: 12 calendar months obesity prior to the PA Request with 3 months medical management, and exercise defined. Removal of Multidisciplinary program Changed: Dietician /Nutritionist Evaluation and Psychological Evaluations documented within the past 6 calendar months Added: If surgeon prescribes additional pre-surgical requirements, must treat or refer, and health records substantiate requirements met. Clarification: The requesting surgeon does the Initial Assessment but his/her associate, or group physician extender can do the H&P prior to submitting the PA. Added: Routine pre-surgical work-up must be held pending approval to prevent repeating time sensitive services. Added: LSG coverage as a stand-alone bariatric surgical procedure.
09/01/2015	Subsection 3.2.2	Added: Medicaid Additional Criteria Covered referred to 3.2.4.
09/01/2015	Subsection 3.2.3	Added: NCHC Additional Criteria Covered referred to 3.2.4.
09/01/2015	Subsection 3.2.4	Renumbered from 3.3 and divided into two categories for clarity: Revision of Bariatric Surgery to Medicaid and NCHC Additional Criteria Covered.
09/01/2015	Subsection 4.2.1	This section was numbered 4.2 Moved from 3.2.f: Conditions contraindicated for bariatric surgery until resolved as substantiated by health record documentation. Moved: Non-covered cosmetic surgery to k from 4.2.1 Removed: S.L 2010-13 non-coverage of panniculectomy Added Reference Clinical Policy 1-0-1 <i>Reconstructive and Cosmetic Surgery</i>
09/01/2015	Subsection 4.2.1.b	Added: “for a beneficiary with a BMI<50kg/m2.
09/01/2015	Subsection 4.2.d	Added: “for a beneficiary with a BMI> 50kg/m2.
09/01/2015	Subsection 4.3	Renumbered to 4.23 .NCHC Additional Criteria not covered: Added: (a)..the surgeon’s post-surgical program for a beneficiary who has reached the age of 19.
09/01/2015	Subsection 4.4	Renumbered to 4.2.2
09/01/2015	Subsection 5.1	Moved: When Medicaid is secondary the secondary payor to Attachment A. H. Reimbursement.

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<b>Date</b>	<b>Revised</b>	<b>Change</b>
09/01/2015	Subsection 5.2	Changed to 5.2.1 General Removed: c: EPSDT requirements. Added: A letter from the surgeon stating that all criteria have been met is not sufficient documentation. Approval does not transfer to a different provider or allow for change in procedure. If either occurs, a new request has to be submitted and all requirements met for approval.
09/01/2015	Subsection 5.2.2	Added: Specific: Added: The provider shall submit a description of the type of bariatric surgical procedure planned. Added: Beneficiary shall meet all policy requirements and provider shall obtain prior approval for performing a bariatric surgical procedure, if the primary insurance does not cover the procedure. Moved from 3.2.f: The provider's summary letter alone is not considered a health record, and documentation requirements for submitted health records.
09/01/2015	Subsection 5.3	Removed: Additional Prior Approval Requirements for Initial Bariatric Surgery. Added: Lifetime Limitation from 5.5 and coverage for beneficiaries that had bariatric surgical procedures under other insurance must meet all prior approval requirements for primary or revision surgery.
09/01/2015	Subsection 5.4	Deleted.
09/01/2015	Subsection 5.5	Moved to 5.3
09/01/2015	Subsection 5.6	Moved: Postoperative Adjustments to Gastric Band to Attachment A.H.
09/01/2015	Subsection 6.1	Deleted.
09/01/2015	Subsection 7.1.1	Removed :FDA Approved Devices from 7.0 and added to 7.1.1b
09/01/2015	Attachment A	B: Clarification of ICD-9 revision guidelines C: Clarification of uses of codes C1: Adding procedure codes 43775, 43886, 43887, 43888 C2: Adding and defining the coverage of 43659 for revision/replacement of lap band C2: Clarification of the use of Unlisted procedures and HCPCS G: Added: Co-payments under the Medicaid State plan and NCHC general statues and their web locations H: Added: Medicaid is the payer of last resort therefore the claim must be submitted to the primary before billing Medicaid. Moved: Postoperative band adjustment coverage from Section 5.6
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.

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<b>Date</b>	<b>Revised</b>	<b>Change</b>
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
	<u>Section 1.0</u>	<u>Added to description of gastric-restrictive and malabsorptive procedures</u> <u>Added "Note: Refer to Subsection 6.2 for provider accreditation."</u>
	<u>Subsection 3.2.1</u>	<u>Added Subsection 3.2.2</u> <u>Added conditions to 3.2.1.c</u> <u>Added what the Dietician or Nutritional Comprehensive Evaluation must include.</u> <u>Added what the Psychological Evaluation must include.</u>
	<u>Subsection 3.2.2</u>	<u>Deleted Subsection 3.2.2</u>
	<u>Subsection 4.2.1</u>	<u>Added "Bariatric surgical procedures for a beneficiary with a BMI less than 35kg/m<sup>2</sup>"</u>
	<u>Subsection 4.2.2</u>	<u>Added Medicaid Additional Criteria Not Covered</u>
	<u>Subsection 5.2.2</u>	<u>Deleted "Documentation must include encounter notes which report the"</u> <u>Added "Encounter notes must document the following"</u> <u>Added "The facility's documentation of their Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation must be submitted with each prior approval request."</u>
	<u>Subsection 6.2</u>	<u>Added "Medicaid shall require a bariatric facility to achieve accreditation and demonstrate the ongoing compliance with the requirements of the accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)."</u>

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**Attachment A: Claims-Related Information**

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC, including obtaining appropriate referrals for a beneficiary enrolled in the Medicaid or NCHC managed care programs and the following:

**A. Claim Type**

Professional (CMS-1500/837P transaction)

**B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)**

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

**C. Code(s)**

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. List only the code. Use only the tables needed and delete the rest.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

**C1. The following may be performed in the inpatient hospital setting:**

CPT Code(s)		
43644	43773	43847
43645	43774	43848
43770	43775	43886
43771	43845	43887
43772	43846	43888

**C2. The following may be performed in the outpatient hospital or ambulatory surgical setting:**

CPT Code(s)		
43659*	43771	43773
43770	43772	43774

\*As a bariatric surgical procedure, this procedure code is only covered for revision of lap banding **when both the gastric band and subcutaneous port components are to be removed and replaced** and ALL criteria are met in **Subsection 3.2.4**.

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

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**Unlisted Procedure or Service**

**CPT:** The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

**HCPCS:** The provider(s) shall refer to and comply with the Instructions for Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

**D. Modifiers**

Provider(s) shall follow applicable modifier guidelines.

**E. Billing Units**

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

**F. Place of Service**

Inpatient Hospital, Outpatient Hospital, Ambulatory Surgical Centers.

Outpatient Hospitals and Ambulatory Surgery Centers are only covered to perform the procedures listed in **Table C2**.

**G. Co-payments**

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

**H. Reimbursement**

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

When a beneficiary is covered by Medicare or private insurance, prior authorization must be requested from their primary payor. If the primary payor determines that the procedure is not medically necessary, or the claim is denied because the provider did not follow the primary payor's requirements, Medicaid and NCHC shall not pay for these services. A claim must be submitted with the primary payor before billing Medicaid. If the primary payor approves, and ~~or~~ processes payment for the procedure, Medicaid is only responsible for portions of the coinsurance and deductible remaining.

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