

Title of Rule: Revision to the Medical Assistance Health Program Services and Supports Rule Concerning the Bariatric Surgery Services Section 8.300.C
Rule Number: MSB 14-07-07-28-B
Division / Contact / Phone: Medicaid Programs & Services / Ana Lucaci / 303-866-6163

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

The Department is updating this rule to include content from the Bariatric Surgery Benefit Coverage Standard. Specifically, the rule will define the amount, scope and duration of the benefit..

2. An emergency rule-making is imperatively necessary

- to comply with state or federal law or federal regulation and/or
- for the preservation of public health, safety and welfare.

Explain:

3. Federal authority for the Rule, if any:

§1905(a)(1) of the Social Security Act

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2012);

Initial Review **10/10/2014**
Proposed Effective Date **12/30/2014**

Final Adoption **11/14/2014**
Emergency Adoption

DOCUMENT #01

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REGULATORY ANALYSIS

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1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

This rule will impact the providers of Bariatric Surgery Services.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Clearly defined and updated rules will improve client access to appropriate, high quality, cost-effective and evidence-based services while improving the health outcomes of Medicaid clients. Established criteria within rule will provide guidance to clients and providers regarding benefit coverage. For example, this rule will help ensure the appropriate clients are receiving this service at an appropriate age. The age limit is set for clients over the age of 16, with additional provisions regarding psychological maturity for clients that are under 18.

Through this rule, the providers are given specific criteria, steps and necessary documentation needed prior to requesting approval for client's procedure from the Department: weight, height and BMI of the client, co-morbid conditions, details regarding client's weight loss attempts, a recent psychiatric or psychological assessment, a description of the post-surgical follow-up program, a statement from the client agreeing the detailed commitment program after the surgery.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

This rule does not have any costs to the Department or any other agency as a result of its implementation and enforcement.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Clearly defined and updated rules increase client access to appropriate services and allow the Department to administer benefits in compliance with federal and state regulations, as well as

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clinical best practices and quality standards. Defining this benefit in rule will educate clients about their benefits and provide better guidance to service providers. The cost of inaction could result in decreased access to services, poor quality of care, and/or lack of compliance with state and federal guidance.

All of the above translates into appropriate cost-effective care administered by the state.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly methods or less intrusive methods for achieving the purpose of this rule. The department must appropriately define amount, scope and duration of this benefit in order to responsibly manage it.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

N/A. The Department also documents its benefit coverage policies in written coverage standards. The benefit coverage policies must be written into rule to have the force of rule.

~~8.300.3.C. Bariatric Surgery Benefit Coverage Standard Incorporated by Reference~~

~~All eligible providers of Bariatric Surgery enrolled in the Colorado Medicaid program services shall be in compliance with the Colorado Medicaid Bariatric Surgery Benefit Coverage Standard (approved August 1, 2012), which is hereby incorporated by reference. The incorporation of the Bariatric Surgery Benefit Coverage Standard excludes later amendments to, or editions of, the referenced material.~~

~~The Benefit Coverage Standard is available from Colorado Medicaid's Benefits Collaborative Web site at Colorado.gov/hcpf. Click "Boards & Committees," and click "Benefits Collaborative," and click "Approved Benefit Coverage Standards." Pursuant to § 24-4-103 (12.5), C.R.S., the Department maintains copies of this incorporated text in its entirety, available for public inspection during regular business hours at: Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Certified copies of incorporated materials are provided at cost upon request.~~

8.300.3.C. Bariatric Surgery

1. Eligible Clients

- a. All currently enrolled Medicaid clients over the age of sixteen when:
- i) The client has clinical obesity; and
 - ii) It is Medically Necessary.

2. Eligible Providers

- a. Providers must enroll in Colorado Medicaid.
- b. Surgeons must be trained and credentialed in bariatric surgery procedures.
- c. Preoperative evaluations and treatment may be performed by:
- i) Primary care physician,
 - ii) Nurse Practitioner,
 - iii) Physician Assistant,
 - iv) Registered dietician,
 - v) Mental health providers available through the Client's Behavioral Health Organization.

3. Eligible Places of Service

- a. All surgeries shall be performed at a Hospital, as defined at 8.300.1.
- i) Facilities must have safety protocols in place specific to the care and treatment of bariatric clients.
- b. Pre- and Post- operative care may be performed at a physician's office, clinic, or other medically appropriate setting.

- 1 4. Covered Services and Limitations
- 2 a. Colorado Medicaid covers participating providers for one bariatric procedure per
- 3 client lifetime unless a revision is appropriate based one of the identified
- 4 complications.
- 5 i) Appropriate revision procedures are identified at section 8.300.3.C.4.d.
- 6 b. Covered primary procedures Include:
- 7 i) Roux-en-Y Gastric Bypass;
- 8 ii) Adjustable Gastric Banding;
- 9 iii) Biliopancreatic Diversion with or without Duodenal Switch;
- 10 iv) Vertical-Banded Gastroplasty;
- 11 v) Vertical Sleeve Gastroplasty.
- 12 c. Criteria for Primary Procedures
- 13 All Clients must meet the first four following criteria, clients under age 18 must meet
- 14 criteria five:
- 15 i) The client is clinically obese with one of the following:
- 16 1) BMI of 40 or higher, or
- 17 2) BMI of 35-40 with objective measurements documenting one or
- 18 more of the following co-morbid conditions:
- 19 a) Severe cardiac disease;
- 20 b) Type 2 diabetes mellitus;
- 21 c) Obstructive sleep apnea or other respiratory disease;
- 22 d) Pseudo-tumor cerebri;
- 23 e) Hypertension;
- 24 f) Hyperlipidemia;
- 25 g) Severe joint or disc disease that interferes with daily
- 26 functioning;
- 27 h) Intertriginous soft-tissue infections, nonalcoholic
- 28 steatohepatitis, stress urinary incontinence, recurrent or
- 29 persistent venous stasis disease, or significant
- 30 impairment in Activities of Daily Living (ADL).
- 31 ii) The BMI level qualifying the client for surgery (>40 or >35 with one of the
- 32 above co-morbidities) must be of at least two years' duration. A client's

- 1 BMI may fluctuate around the required levels during this period around
2 the required levels, and will be reviewed on a case-by-case basis.
- 3 iii) The client must have made at least one clinically supervised attempt to
4 lose weight lasting at least six consecutive months or longer within the
5 past eighteen months of the prior authorization request, monitored by a
6 registered dietician that is supervised by a physician, nurse practitioner,
7 or physician's assistant.
- 8 iv) Medical and psychiatric contraindications to the surgical procedure must
9 have been ruled out through:
- 10 1) A complete history and physical conducted by or in consultation
11 with the requesting surgeon; and
- 12 2) A psychiatric or psychological assessment, conducted by a
13 licensed mental health professional, no more than three months
14 prior to the requested authorization. The assessment must
15 address both potential psychiatric contraindications and client's
16 ability to comply with the long-term postoperative care plan.
- 17 v) For clients under the age of eighteen, the following must be documented:
- 18 1) The exclusion or diagnosis of genetic or syndromic obesity, such
19 as Prader-Willi Syndrome;
- 20 2) Whether female clients have attained Tanner stage IV breast
21 development; and
- 22 3) Whether bone age studies estimate the attainment of 95% of
23 projected adult height.
- 24 4) Mental health evaluations for clients age 17 must address issues
25 specific to these clients' maturity as it relates to compliance with
26 postoperative instructions.
- 27 d. Revision Procedures
- 28 i) Colorado Medicaid covers Revisions of a surgery for clinical obesity if it
29 is used to correct complications such as slippage of an adjustable gastric
30 band, intestinal obstruction, or stricture, following a primary procedure.
- 31 ii) Indications for surgical revision:
- 32 1) Weight loss to 20% below the ideal body weight;
- 33 2) Esophagitis, unresponsive to nonsurgical treatment;
- 34 3) Hemorrhage or hematoma complicating a procedure;
- 35 4) Excessive bilious vomiting following gastrointestinal surgery;
- 36 5) Complications of the intestinal anastomosis and bypass;
- 37 6) Stomal dilation, documented by endoscopy;

- 1 7) Documented slippage of the adjustable gastric band;
- 2 8) Pouch dilation documented by upper gastrointestinal
- 3 examination or endoscopy producing weight gain of 20% of
- 4 more, provided that:
- 5 a) The primary procedure was successful in inducing
- 6 weight loss prior to the pouch dilation; and
- 7 b) The client has been compliant with a prescribed nutrition
- 8 and exercise program following the procedure (weight
- 9 and BMI prior to surgery, at lowest stable point, and at
- 10 current time must be submitted along with surgeon's
- 11 statement to document compliance with diet and
- 12 exercise);
- 13 9) Other and unspecified post-surgical non-absorption
- 14 complications.
- 15 e. Non-Covered Services:
- 16 i) For Clients with clinically diagnosed COPD (Chronic Obstructive
- 17 Pulmonary Disease), including Chronic Bronchitis or Emphysema.
- 18 ii) Repeat procedures not associated with surgical complications.
- 19 iii) Cosmetic Follow-up: Weight loss following surgery for clinical obesity can
- 20 result in skin and fat folds in locations such as the medial upper arms,
- 21 lower abdominal area, and medial thighs. Surgical removal of this skin
- 22 and fat for solely cosmetic purposes is not a covered benefit.
- 23 iv) During pregnancy.
- 24 5. Prior Authorization Requirements
- 25 All bariatric surgical procedures require prior authorization, which must include:
- 26 a) The Client's height, weight, BMI with duration.
- 27 b) A list and description of each co-morbid condition, with attention to any
- 28 contraindication which might affect the surgery including all objective
- 29 measurements.
- 30 c) A detailed account of the Client's clinically supervised weight loss attempt(s),
- 31 including duration, medical records of attempts, identification of the supervising
- 32 clinician, and evidence of successful completion and compliance.
- 33 d) A current psychiatric or psychological assessment regarding contraindications for
- 34 bariatric surgery, as described in 8.300.3.C.4.c(iv)(2).
- 35 e) A statement written or agreed to by the client, detailing for the interdisciplinary
- 36 team the client's:
- 37 i) Commitment to lose weight;

- 1 ii) Expectations of the surgical outcome;
- 2 iii) Willingness to make permanent life-style changes;
- 3 iv) Be willing to participate in the long-term postoperative care plan offered
- 4 by the surgery program, including education and support, diet therapy,
- 5 behavior modification, and activity/exercise components; and
- 6 v) If female, client's statement that she is not pregnant or breast-feeding
- 7 and does not plan to become pregnant within two years of surgery.
- 8 f) A description of the post-surgical follow-up program.
- 9 g) For clients under the age of eighteen, documentation of the physical criteria
- 10 requirements at 8.300.3.C.4.c(v).

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