Guidelines for Medical Necessity Determination for Bariatric Surgery

These Guidelines for Medical Necessity Determination ("Guidelines") identify the clinical information that MassHealth needs to determine medical necessity for bariatric surgery. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 415.000 (acute inpatient hospital services), 433.000 (physician services), and 450.000 (administrative and billing regulations), and Subchapter 6 of the Physician Manual for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) or a MassHealth-contracted integrated care organization (ICO) should refer to the MCO's or ICO's medical policies for covered services.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

Bariatric surgery (weight-loss surgery) consists of several open or laparoscopic procedures that revise the gastrointestinal anatomy to restrict the size of the stomach and/or reduce absorption of nutrients.

Weight-loss surgery is an effective treatment for severe, medically complicated, and refractory obesity with attendant risks that, in some rare cases, may include death. Candidates for this surgery benefit from preoperative and postoperative multidisciplinary (medical, nutritional, behavioral/psychological, and exercise/physiological) care. Weight loss immediately preceding surgery has been shown to decrease the technical complexity of the surgery, shorten operating time, and decrease perioperative risk. An exercise regimen should be implemented to improve pulmonary reserve, decrease the risk of perioperative complications, and engage the patient in a healthy active lifestyle to be continued after surgery. Nutrition and eating behavioral modifications should be addressed to prepare patients for the strict postoperative eating behaviors that optimize the success of the surgery.

MassHealth determines the medical necessity of bariatric surgery on an individual, case-by-case basis, in accordance with 130 CMR 450.204, when needed to either alleviate or correct medical problems caused by morbid obesity.

SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for bariatric surgery on a combination of clinical data and the presence of indicators that would affect the relative risks and benefits of the procedure (if appropriate, including postoperative recovery). These criteria include, but are not limited to, the following.
(1) ADULT CRITERIA (AGE 18+): BARIATRIC SURGERY

**Surgery Team and Accreditation**

- The surgery must be performed under the guidance of a multidisciplinary team (including at a minimum a surgeon, physician, nutritionist, and licensed qualified mental health professional) particularly experienced in the performance of bariatric surgery and the pre- and postoperative management of bariatric surgery patients.
- The treating bariatric surgery program must be accredited by the American College of Surgeons Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).

**Medical Necessity Criteria**

For adults, bariatric surgery is generally considered for refractory morbid obesity that persists despite medical therapy. To be considered medically necessary, all of the following adult criteria (a–c) must be met, and the chosen surgical procedure must be optimal for the patient and have sufficient medical evidence to support its use.

a. Adult candidates for bariatric surgical eligibility must meet either i. or ii. below:
   
i. Body mass index (BMI) equal to or > 40 kg/m² (Class III obesity); OR
   
ii. BMI = 35–39.9 kg/m² (Class II obesity) with one or more of the following high-risk comorbid medical conditions listed in (a)–(i), below:

   a. Type 2 diabetes; or
   
b. Cardiovascular disease (e.g., history of stroke, myocardial infarction, congestive heart failure, peripheral arterial disease, or a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty); or
   
c. Refractory hyperlipidemia (unable to achieve acceptable levels of lipids with diet and appropriate doses of lipid-lowering medications); or
   
d. Hypertension requiring at least three medications to establish blood-pressure control appropriate for age; or
   
e. Obesity-induced cardiomyopathy; or
   
f. Clinically significant obstructive sleep apnea (OSA), defined as:

      1. Apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events/hour with a minimum of 30 events; or
      
2. AHI or RDI greater than or equal to 5 and less than 15 events/hour with a minimum of 10 events and at least one of the following (A)–(C) is met:

         A. Symptoms of impaired cognition, mood disorders, or insomnia; or
         
         B. Excessive daytime sleepiness (Epworth greater than 10); or
         
         C. Greater than 20 episodes of oxygen desaturation (i.e., oxygen saturation of less than 85%) during a full night sleep study, or any one episode of oxygen desaturation (i.e., oxygen saturation of less than 70%); or
         
         g. Obesity-related hypoventilation syndrome (Pickwickian syndrome); or
         
         h. Severe arthropathy of spine and/or weight-bearing joints that interferes with daily
functioning (when the obesity itself prohibits the appropriate medical or surgical treatment and management of the joint dysfunction); or

(i) Pseudotumor cerebri (documented idiopathic intracerebral hypertension); AND

b. Documentation of an attempt of weight loss control through participation in structured program(s) before bariatric surgery for at least four-to-six months in the two years before the request for the procedure. Among structured programs, participation in a preoperative surgical program supervised by a physician or other professional health care provider is required; must directly precede the surgical procedure; and may be included in the four-to-six months. Documentation must reflect all of the following (i–vii):

i. Adherence to preoperative care plan and program participation, including weight-loss history and progress toward diet and exercise goals in order to improve surgical outcomes, reduce the potential for surgical complications, and establish the member’s ability to comply with postoperative medical care and dietary restrictions. Note: A physician summary letter is not sufficient documentation. Medical and program records documenting progress, participation, and specific behavioral changes must be included; and

ii. No evidence of active substance abuse, including alcohol abuse; and

iii. Tobacco cessation or significant attempt to decrease smoking; and

iv. Evidence that reversible endocrine or metabolic causes of obesity have been ruled out;

v. Evidence that diabetes when present is under control or, if difficult to control, evidence that the condition is under supervision and management; and

vi. Any history of binge-eating disorder has been documented and discussed; and

vii. Female candidates for bariatric surgery have been counseled to avoid pregnancy preoperatively and for at least 12 months postoperatively; AND

c. Psychological evaluation has been performed that ruled out uncontrolled mental health disorders that would contraindicate surgery and/or impair patient adherence with pre- and postoperative management, including dietary instructions.

(2) ADOLESCENT CRITERIA (AGE 13-17): BARIATRIC SURGERY

Surgery Team and Accreditation

- The surgery must be performed under the guidance of a multidisciplinary team (including at a minimum a surgeon, physician, nutritionist, and licensed qualified mental health professional) particularly experienced in the performance of bariatric surgery and the pre- and postoperative management of bariatric surgery patients.

- For an adolescent member, the treating bariatric surgery program must be accredited as an MBSAQIP Comprehensive Center with Adolescent Qualifications or an Adolescent Center.

Medical Necessity Criteria

In adolescents, bariatric surgery for the treatment of clinically severe obesity may be considered medically necessary when all of the criteria below (a–c) have been met, including surgical eligibility criteria adapted from the American Society for Metabolic and Bariatric Surgery pediatric committee best practice guidelines.

a. Adolescent candidates for bariatric surgical eligibility must meet i and either ii or iii, below:
i. Growth and Development: Achieved greater than 95% of estimated adult height based on documented individual growth pattern, or a minimum Tanner stage of 4; AND

ii. Patients with BMI equal to or > 35 kg/m² who also have one or more of the following major medical comorbid conditions (Type 2 diabetes mellitus, moderate-to-severe sleep apnea (AHI>=15), pseudotumor cerebri, or severe NASH); OR

iii. Patients with BMI equal to or > 40 kg/m² with other medical comorbidities (hypertension, insulin resistance, glucose intolerance, dyslipidemia, sleep apnea with AHI >5); AND

b. Documentation of an attempt of weight-loss control through participation in structured program(s) before bariatric surgery for at least four-to-six months in the two years before the request for the procedure. Among structured programs, participation in a preoperative surgical program supervised by a physician or other professional health care provider is required; must directly precede the surgical procedure; and may be included in the four-to-six months. Documentation must reflect all of the following (i–vii):

i. Adherence to surgical preoperative care plan and program participation, including weight-loss history and progress toward diet and exercise goals in order to improve surgical outcomes, reduce the potential for surgical complications, and establish the member’s ability to comply with postoperative medical care and dietary restrictions. Note: A physician summary letter is not sufficient documentation. Medical and program records documenting progress, participation, and specific behavioral changes must be included; and

ii. No evidence of active substance abuse, including alcohol abuse; and

iii. Tobacco cessation or significant attempt to decrease smoking; and

iv. Evidence that reversible endocrine or metabolic causes of obesity have been ruled out;

v. Evidence that diabetes when present is under control or, if difficult to control, evidence that the condition is under supervision and management; and

vi. Any history of binge-eating disorder has been documented and discussed; and

vii. Female candidates for bariatric surgery have been counseled to avoid pregnancy preoperatively and for at least 12 months postoperatively; AND

c. Psychological evaluation has been performed that ruled out uncontrolled mental health disorders that would contraindicate surgery and/or impair patient adherence with pre- and postoperative management, including dietary instructions.

(3) ADULTS AND ADOLESCENTS: REVISION OF BARIATRIC SURGERY

Surgery Team and Accreditation

The multidisciplinary team and accreditation requirements as set forth above in Section II.A.(1) for adult members, or Section II.A.(2) for adolescent members, as applicable, also apply to any revision of bariatric surgery.

Medical Necessity Criteria

Requests for revision of bariatric surgery to manage refractory symptoms or surgical complications will be evaluated for medical necessity on an individual case-by-case basis. Some potential reasons for revision may include persistence of metabolic dysfunction such as diabetes, surgical complications such as anastomotic leak, and weight regain or inadequate weight loss (<50% of excess weight loss)
in response to primary surgical intervention. Complication rates are generally reported to be higher after reoperative surgery compared to primary surgery. Patient must be managed in a postoperative nutrition program, be participating in physical activity at recommended levels, and, in some cases, have psychiatric reevaluation. Documentation must reflect all of the following:

i. Adherence to postoperative care plan and program participation, including detailed records of postoperative weight loss, strict diet, and exercise regimen. Note: A physician summary letter is not sufficient documentation. Medical and program records documenting progress, participation, and specific behavioral changes must be included; and

ii. No evidence of active substance abuse, including alcohol abuse; and

iii. Tobacco cessation or significant attempt to decrease smoking; and

iv. Evidence that reversible endocrine or metabolic causes of obesity have been ruled out; and

v. Evidence that diabetes when present is under control or, if difficult to control, evidence that the condition is under supervision and management; and

vi. If inadequate weight loss or weight regain is the cause for the revision, a psychological reevaluation has been performed to identify unrecognized or untreated eating and psychiatric disorders after bariatric surgery that may be contributing to suboptimal surgical response; and

vii. Female candidates for bariatric surgery revision have been counseled to avoid pregnancy preoperatively and for at least 12 months postoperatively from the revision date.

**B. NONCOVERAGE**

MassHealth does not provide coverage for bariatric surgery (primary or revision) when the procedures have not been sufficiently studied to determine their effectiveness and safety for the medical indication. MassHealth also does not consider bariatric surgery to be medically necessary under certain other circumstances. Examples of when the surgery may not be considered medically necessary include, but are not limited to, the following:

(1) Bariatric surgery as a treatment for infertility;

(2) Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass as a treatment of gastroesophageal reflux disease (GERD);

(3) Bariatric procedures with limited evidence of efficacy, such as "Band over sleeve" or Laparoscopic adjustable silicone gastric banding (LASGB) revision of prior sleeve gastrectomy; and

(4) Bariatric surgery not meeting the medical-necessity criteria above.
SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for bariatric surgery must be submitted by a MassHealth-enrolled surgeon and accompanied by clinical documentation supplied by the surgeon that supports the medical necessity for this procedure.

A. DOCUMENTATION

Documentation of medical necessity must include all of the following, and any other pertinent clinical information that MassHealth may request:

1. a complete history and physical that includes obesity-related comorbid conditions; causes of obesity; weight-loss history; commitment; the most recent medical evaluation, including the medical, surgical, social, and family history, medications past and current, drug and alcohol use and abuse history, and physical exam(s) including height and weight and BMI;

2. a description of the pre- and postsurgical treatment plans, including the specific procedure(s) requested, the reason the specific bariatric procedure was chosen, and a list of CPT codes for any planned procedures;

3. results from diagnostic and/or laboratory tests pertinent to the diagnosis and, if present, comorbid conditions;

4. initial and follow-up nutritional evaluation(s) and the member’s ability to adhere to nutritional restrictions;

5. initial and follow-up psychological-behavioral evaluation(s) to assess the member’s understanding of, and psychological preparedness for, the surgery and the postsurgical requirements. If revisional bariatric surgery is indicated for inadequate weight loss or weight regain, a psychiatric reevaluation is required.

6. documentation that the member has been informed of the risks of the surgery, the possible long-term complications, and the postoperative nutritional requirements;

7. a description of the multidisciplinary aftercare plan;

8. preoperative care plan, including a weight and weight-loss history documenting a serious attempt at weight loss, including the duration of the attempt during the presurgical period;

9. preoperative cardiopulmonary evaluation and testing, if medically indicated;

10. identification of social supports;

11. history of smoking, including current smoking status; and

12. any other documentation as specified in Section II.A.(1), II.A.(2) or II.A.(3), as applicable, not otherwise listed above.

B. CLINICAL INFORMATION

Clinical information must be submitted by a MassHealth-enrolled surgeon. Providers are strongly encouraged to submit requests electronically. Providers must submit all information pertinent to the diagnosis using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at www.mass.gov/masshealth) and attaching pertinent documentation. The PA-1 form and documentation should be mailed to the address on the back
of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

SELECT REFERENCES


These Guidelines are based on review of the medical literature and current practice in bariatric surgery. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

Policy Revision Effective Date __02/13/18____  Approved by _________________________________
Jill Morrow-Gorton, MD  
Acting MassHealth CMO  
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