Guidelines for Medical Necessity Determination for Bariatric Surgery

This edition of the Guidelines for Medical Necessity Determination ("Guidelines") identifies 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*, 130 CMR 433.000: *Physician Services*, and 130 CMR 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 accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO) plan, or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies, respectively, for covered services

MassHealth requires PA for bariatric surgery. 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.

1 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. A preoperative exercise regimen is recommended 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.

2 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).
- If the proposed procedure is endoscopic, the treating surgeon or gastroenterologist must submit documentation of the credentialing caseload of the hospital in which the procedure will be performed. Endoscopic procedures may only be performed at institutions whose credentialling minimum caseload is 55 or greater.

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. Evidence-based bariatric surgical procedures include Roux-en-Y gastric bypass, single anastomosis duodeno-ileal bypass (SADI), and single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S).

a. Adult candidates for bariatric surgical eligibility must meet either i. *or* ii. below:
   i. Body mass index (BMI) equal to or > 35 kg/m2 (Class III obesity); OR
   ii. BMI = 30–34.9 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) obstructive sleep apnea (OSA); or

(g) Obesity-related hypoventilation syndrome (Pickwickian syndrome); or

(h) Severe arthroplasty 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 5-10% weight loss OR an attempt of weight loss control through participation in structured program(s) before bariatric surgery or medical therapy 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 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 participation, must be included; and

ii. Documentation that the patient is a reasonable operative candidate, without evidence of significant substance use, including alcohol and tobacco, that would increase operative morbidity; and

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

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

v. Evidence that symptoms of gastroesophageal reflux disease have been assessed and has been evaluated in the context of the chosen bariatric surgical intervention; 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 > 30 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 > 35 kg/m2 with other medical comorbidities (hypertension, insulin resistance, glucose intolerance, dyslipidemia, sleep apnea with AHI >5); AND
b. Documentation of 5-10% weight loss OR an attempt of weight-loss control through participation in structured program(s) or medical therapy 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, 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 participation must be included; and
    ii. Documentation that the patient is a reasonable operative candidate, without evidence of significant substance use, including alcohol and tobacco, that would increase operative morbidity; and
    iii. Evidence that reversible endocrine or metabolic causes of obesity have been ruled out; and
    iv. Evidence that diabetes when present is under control or, if difficult to control, evidence that the condition is under supervision and management; and
    v. Evidence that symptoms of gastroesophageal reflux disease (GERD) have been assessed and have been evaluated in the context of the chosen bariatric surgical intervention (e.g., GERD is a relative contraindication to sleeve gastrectomy); 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

Revision of bariatric surgery to manage refractory symptoms or surgical complications may be considered medically necessary in the following instances:

- persistence of metabolic dysfunction, such as diabetes a minimum of six months following primary surgery; or
- surgical complications, such as anastomotic leak, refractory gastroesophogeal reflux disease (GERD); or
- weight regain or inadequate weight loss in response to primary surgical intervention (<50% of excess weight loss over six months following primary surgical intervention).

Requests for revision for other reasons including, but not limited to, laparoscopic adjustable banding (LAP band) revision, will be evaluated for medical necessity on an individual case-by-case basis. Documentation must reflect *all* of the following:

i. Adherence to postoperative care plan and program participation, including detailed records of postoperative weight loss, 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. Documentation that the patient is a reasonable operative candidate, without evidence of significant substance use, including alcohol and tobacco, that would increase operative morbidity; and

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

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

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

vi. If intractable reflux is the indication for the revision of a bariatric surgery, the methodology for diagnosis of intractable reflux must be made by upper endoscopy and pH probe studies to support the diagnosis and rule out other etiologies. In addition, the patient must be on, and compliant with, maximal anti-reflux therapy with lifestyle management.

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 procedures with limited evidence of efficacy, such as "band over sleeve" or laparoscopic adjustable silicone gastric banding (LASGB) revision; and

(2) Bariatric surgery not meeting the medical-necessity criteria above.

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SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for bariatric surgery must be submitted by the MassHealth-enrolled surgeon who is performing the procedure 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 (including GERD); 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 history, and physical exam(s), including height and weight and BMI; and

(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; and

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

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

(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, weight regain, or GERD, a psychiatric reevaluation is required; and

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

(7) a description of the multidisciplinary aftercare plan; and

(8) preoperative care plan, particularly attempt at weight loss (must include specific commentary on duration of attempted weight loss.); and

(9) preoperative cardiopulmonary evaluation and testing, if medically indicated; and

(10) 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 the MassHealth-enrolled surgeon who is performing the procedure.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver (hereinafter, "waiver"). Please see All Provider Bulletin 369 for further waiver information. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-masshealth-providers.

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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: March 24, 2025

Approved by 

Clara Filice, MD, MPH, MHS
Acting Chief Medical Officer, MassHealth

Policy Effective Date: February 7, 2024