

Sample Letter of Medical Necessity

Provided to you by Allergan

Note: This is a sample only. Letters of medical necessity must be customized for each patient as supported by documentation in the patient's medical record(s). Payers vary on their requirement for letters of medical necessity, and it may be necessary to submit with copies of medical records.

Attention: Medical Director

[date]

[Insurer name]

[Address]

Re: [Patient name]

Date of birth: [patient DOB]

Policy ID/Group number: [patient's policy ID/group number]

Policyholder: [name of patient's policyholder]

I am writing on behalf of my patient, [patient name], to request prior authorization and to document the medical necessity of the LAP-BAND AP® Adjustable Gastric Banding System,* reported under code 43770, for treatment of morbid obesity and its related comorbidities.

The LAP-BAND AP® System was approved for marketing in June 2001. The LAP-BAND AP® System for treatment of morbid obesity is supported by evidence from multiple clinical studies as well as published, peer-reviewed literature:

- The LAP-BAND AP® Experience (APEX) Study is a multicenter, prospective, open-label, 5-year evaluation of 500 severely obese patients undergoing LAP-BAND AP® surgery. Interim results have demonstrated mean percent excess weight loss (%EWL) of 34% at Week 24 (n=303) (APS + APL) and 47.5% at Week 48 (n=139) (APS + APL)¹
- The trial that supported FDA approval of the LAP-BAND AP® System included the experience of 8 centers involving 299 subjects who received the LAP-BAND® System. Mean %EWL increased steadily throughout the trial and demonstrated significant improvement in %EWL versus baseline at 12 months (34.5%), 24 months (37.8%), and 36 months (36.2%)
- Blue Cross and Blue Shield Association Technology Evaluation Center assessment (2007) includes the key finding that laparoscopic gastric banding (LAGB) surgery results in substantial weight loss of approximately 40% excess weight at 1 year. This weight reduction is associated with a substantial reduction in comorbidities. This assessment also states that LAGB surgery is less risky than gastric bypass, specifically noting that greater short-term weight loss with gastric bypass may be outweighed by operative risks (Blue Cross and Blue Shield Association. Laparoscopic Adjustable Gastric Banding for Morbid Obesity, February 2007, 21[15])

*The LAP-BAND® System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 kg/m² or a BMI of at least 35 kg/m² with one or more severe comorbid conditions, or those who are 100 pounds or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

- American Society for Bariatric Surgery consensus panel (2005) states that bariatric surgery is the most effective therapy available for morbid obesity and that the weight loss experienced following bariatric surgery can result in improvement or complete resolution of obesity-related comorbidities[†] (Buchwald H. Consensus Conference Statement Bariatric Surgery for Morbid Obesity: Health Implications for Patients, Health Professionals, and Third-Party Payers. *Surg Obes Relat Dis.* 2005;1:371-381.)
- National Institutes of Health Consensus Statement (1998) concluded that bariatric surgery can be considered for appropriate patients (BMI of 40 kg/m² or BMI between 35 kg/m² and 39.9 kg/m² with severe comorbid conditions). They note risk-benefit assessment before surgery should include weight loss potential, likelihood of improvement in comorbidity measures, psychological effects, and likelihood of perioperative/long-term complications or mortality. A multidisciplinary team evaluation is emphasized. This consensus statement also notes that patients who undergo surgery will require lifelong surveillance[‡] (NIH. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, 1998. <<http://www.nhlbi.nih.gov/guidelines/obesity/index.htm>> [accessed July 27, 2009])

Copies of published clinical studies and the LAP-BAND AP[®] System Directions for Use are enclosed for your review.

[Mr/Mrs/Ms] [patient's last name] is a [age]-year-old [sex] who has been morbidly obese (ICD-9-CM diagnosis code 278.01) for [insert duration of morbid obesity]. [He/she] is [height] tall and weighs [weight], giving a BMI of [BMI and corresponding ICD-9-CM code for BMI of [Mr/Mrs/Ms] [patient's last name] presented to me on [date] with [details such as physical exam results and clinical impressions]. [Mr/Mrs/Ms] [patient's last name]'s morbid obesity contributes to [his/her] [describe comorbid condition(s) and ICD-9-CM codes to report those comorbidities].

(If other treatments were used prior to considering the LAP-BAND AP[®] System, add: Other therapies tried as part of the treatment of [Mr/Mrs/Ms] [patient's last name]'s morbid obesity included [describe treatment; specifically, but briefly, describe nature and duration of any medically supervised weight loss program as well as outcomes]. Despite these treatments, [Mr/Mrs/Ms] [patient's last name] remains morbidly obese.)

(If patient was referred by a primary care physician, add: The patient was referred to me by their primary care physician (PCP), Dr [physician's last name]. If appropriate/available, add: Attached is a copy of the PCP referral or letter of recommendation.)

[Patient's name]'s morbid obesity is accompanied by the following significant comorbidities: [list any that are documented in the patient medical record] (Diagnosis codes are included for searching in coded records and may not need to be listed in the letter.) [Be sure to describe the severity and effect on daily activities.]

- Diabetes mellitus (250.00-250.03, 250.40-250.93)
- Disorders of lipid metabolism (272.0-272.4, 272.9)
- Essential hypertension (401.1, 401.9)
- Secondary hypertension (405.11, 405.19, 405.91, 405.99)
- Asthma (493.00, 493.10, 493.20, 493.90)

[†]Types of bariatric surgery reviewed in 2005 ASBS consensus: gastric bypass (standard, long-limb, and very long-limb Roux), alone or in combination with vertical banded gastroplasty; laparoscopic adjustable gastric banding; and biliopancreatic diversion and duodenal switch.

[‡]Types of bariatric surgery reviewed in 1998 NIH consensus statement: conventional Roux-en-Y gastric bypass, vertical banded gastroplasty, horizontal-banded gastroplasty, modest biliopancreatic diversion without intestinal exclusion, and adjustable silicone gastric banding.

[Mr/Mrs/Ms] [patient's last name] is an excellent candidate for the LAP-BAND AP® System for treatment of [his/her] morbid obesity. I plan to treat [Mr/Mrs/Ms] [patient's last name] by laparoscopically placing the LAP-BAND AP® System [indicate the planned course of treatment and duration]. My clinical expectations for treatment with the LAP-BAND AP® System are [indicate expectations]. Follow-up is expected to involve [include expected additional evaluations and treatments].

(If appropriate, add: The facility at which the surgery will be performed is certified by the American College of Surgeons as a Level XX Bariatric Surgery Center. [or] The facility, surgical group, and surgeons performing the surgery satisfactorily meet the requisite standards and are designated by the American Society for Metabolic and Bariatric Surgery (ASMBS) as an ASMBS Bariatric Surgery Center of Excellence.)

Please confirm that this procedure is authorized for reimbursement and that benefits are available for this patient. Thank you for your review of this information and for your coverage consideration. If you have any questions or require additional information, please contact me through our bariatric patient care coordinator, [contact name and phone].

Sincerely,

[Physician's signature]

[Physician's full name]

[Address]

[Telephone number]

Enclosures

Please see following page for Important Safety Information.

Important Safety Information

A BRIEF DESCRIPTION OF RELEVANT INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, AND ADVERSE EVENTS FOR THE LAP-BAND® SYSTEM.

Indications: The LAP-BAND® System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight. The LAP-BAND® is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

Contraindications: The LAP-BAND® System is not recommended for non-adult patients, patients with conditions that may make them poor surgical candidates or increase the risk of poor results, (e.g., inflammatory or cardiopulmonary diseases, GI conditions, symptoms or family history of autoimmune disease, cirrhosis), who are unwilling or unable to comply with the required dietary restrictions, who have alcohol or drug addictions, or who currently are or may be pregnant.

Warnings: The LAP-BAND® System is a long-term implant. Explant and replacement surgery may be required at some time. Patients who become pregnant or severely ill, or who require more extensive nutrition may require deflation of their bands. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should proceed in small increments. Anti-inflammatory agents, such as aspirin, should be used with caution and may contribute to an increased risk of band erosion.

Adverse Events: Placement of the LAP-BAND® System is major surgery and, as with any surgery, death can occur. Possible complications include the risks associated with the medications and methods used during surgery, the risks associated with any surgical procedure, and the patient's ability to tolerate a foreign object implanted in the body. Band slippage, erosion and deflation, reflux, obstruction of the stomach, dilation of the esophagus, infection, or nausea and vomiting may occur. Reoperation may be required. Rapid weight loss may result in malnutrition, anemia, or other complications that may require additional surgery. Deflation of the band may alleviate excessively rapid weight loss or esophageal dilation.

Important: For full safety information, please visit www.lapband.com or call Allergan Product Support at **1-800-624-4261**.

CAUTION: This device is restricted to sale by or on the order of a physician.

Reference: 1. Data on file. Allergan, Inc.