

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
[INSURER NAME]
[Address]

[DATE]

Re: [Patient name]
Date of birth: [patient DOB]
Policy ID/Group Number: [Patient's Policy ID/Group Number]
Policy Holder: [Name of Patient's Policy Holder]

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

The LAP-BAND AP[®] System was initially approved for marketing in June 2001 for 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. It was subsequently approved in February 2011 for patients with a BMI of at least 40 kg/m² or a BMI of at least 30 kg/m² with one or more obesity-related comorbid conditions. The LAP-BAND AP[®] System for treatment of obesity is supported by evidence from published, peer-reviewed literature:

- The trial that supported the FDA approval of the LAP-BAND AP[®] System for patients with a BMI of at least 30 kg/m² to 40 kg/m² with one or more obesity-related comorbid conditions is a single-arm, multicenter study involving 149 subjects.¹ Subjects achieved significant improvement in percent excess weight loss (%EWL), excess weight, weight loss, percent weight loss (%WL), and BMI at 12 months after placement of the LAP-BAND AP[®] System.¹ Moreover, 83.9% ($P < 0.0001$) of subjects achieved %EWL of at least 30% at one year postsurgery.¹
- 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.² Interim results have demonstrated mean %EWL of 34% at week 24 ($n = 303$) and 47.5% at week 48 ($n = 139$) among patients who are using either the standard or large sizes of the LAP-BAND AP[®] System.

^aIndications: The LAP-BAND[®] System is indicated for weight reduction for patients with obesity, with a Body Mass Index (BMI) of at least 40 kg/m² or a BMI of at least 30 kg/m² with one or more obesity related comorbid conditions.

- The trial that supported the initial FDA approval of the LAP-BAND AP[®] System (for patients with a BMI of at least 40 kg/m² or a BMI of at least 35 kg/m² with one or more severe comorbid conditions) included the experience of 8 centers involving 299 subjects who received the LAP-BAND[®].¹ Mean %EWL increased steadily from 9.9% at 3 weeks to 37.8% at 24 months, and improvements through 36 months were significant ($P < .0001$) when compared to baseline.¹ Mean weight decreased steadily from 293 pounds at baseline to 235 pounds at 30 months ($P < .0001$), and mean excess weight was reduced from 156 pounds to 98.2 pounds ($P < .0001$).¹ Mean BMI also steadily decreased from 47.5 kg/m² at baseline to 38.1 kg/m² at 24 months ($P < .0001$).¹
- The Blue Cross Blue Shield Association Technology Evaluation Center Assessment includes the key finding that laparoscopic adjustable gastric band (LAGB) surgery results in substantial weight loss of approximately 40% excess weight at one year with substantial reduction in comorbidities.³ 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.³
- The American Society for Bariatric Surgery Consensus states that bariatric surgery^b is the most effective therapy available for morbid obesity and that bariatric surgery can result in improvement or complete resolution of obesity-related comorbidities.

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 obese (ICD-9-CM diagnosis code 278.00 or 278.01) for [insert duration of obesity]. [H/She] is [HEIGHT] tall and weighs [WEIGHT], giving a BMI of [BMI and corresponding ICD-9-CM code for BMI]. [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] 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, would add: Other therapies tried as part of the treatment of [Mr./Mrs./Ms.] [Patient's Last Name]'s 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 obese.

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

^bTypes 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.

[Insert if applicable: [PATIENT'S NAME]'s 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. Please note that the list of diagnosis codes provided below is for illustrative purposes only, and is not intended to serve as a comprehensive list of the ICD-9-CM codes that could potentially support the decision to provide the LAP-BAND AP® System to a patient with a BMI of at least 30 kg/m²:

- 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)]

[If applicable, be sure to describe the severity and effect of the comorbidities on daily activities.]

[Mr./Mrs./Ms.] [Patient's Last Name] is an excellent candidate for the LAP-BAND AP® System for treatment of [his/her] 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, would 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 LAP-BAND® SYSTEM SAFETY INFORMATION

Indications: The LAP-BAND® System is indicated for weight reduction for patients with obesity, with a Body Mass Index (BMI) of at least 40 kg/m² or a BMI of at least 30 kg/m² with one or more obesity related comorbid conditions.

It is indicated for use in 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. Patients who become pregnant or severely ill, or who require more extensive nutrition may require deflation of their bands. 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 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, talk with your doctor or call Allergan Product Support at **1-800-624-4261**.

CAUTION: Rx only.

References: **1.** LAP-BANDAP® System [directions for use]. Irvine, CA: Allergan, Inc.; 2011. **2.** Data on file, Allergan, Inc. **3.** Blue Cross and Blue Shield Association. Laparoscopic adjustable gastric banding for morbid obesity. February 2007. **4.** Buchwald H; Consensus Conference Panel. Consensus conference statement bariatric surgery for morbid obesity: health implications for patients, health professionals, and third-party payers. *Surg Obes Relat Dis.* 2005;1(3):371-381.

