Bariatric Surgery (for Indiana Only)

Policy Number: CS007IN.01
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Instructions for Use

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Related Policies

- Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Indiana Only)
- Obstructive and Central Sleep Apnea Treatment (for Indiana Only)

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Surgical Services Provider Reference Module.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)

CPT Code	Description
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Bariatric surgical procedures are not subject to FDA regulation. FDA approval information for several devices related to bariatric surgery is described below.

The FDA approved the ORBERA™ Intragastric Balloon System (Apollo Endosurgery, Inc.) on August 5, 2015. The ORBERA System is indicated for use as an adjunct to weight reduction in obese adults with BMI ≥30 and ≤40 kg/m^2. It is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the likelihood of significant long-term weight loss and weight loss maintenance. It is indicated for adults who have failed conservative weight reduction strategies, such as supervised diet, exercise and behavior modification program. ORBERA has a maximum placement period of 6 months. For more information, please see:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140008
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140008S016

(Accessed August 19, 2020)

The FDA approved the implantable EnteroMedics Maestro Rechargeable System to be marketed on January 4, 2015). The Maestro Rechargeable System is an implantable pacemaker-like device for patients who are morbidly obese or who are obese with one or more obesity-related conditions. For more information, please see: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130019. (Accessed August 19, 2020)

Gastric banding involves the use of an adjustable or nonadjustable gastric band, which is subject to FDA marketing approval. In 2001, the BioEnterics® LAP-BAND System was approved by FDA for marketing under the premarket approval process. According to the FDA labeling, this is approved for surgical treatment for severely obese adults for whom more conservative treatments (e.g., diet, exercise, behavioral modification) have failed. 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 co-morbid conditions, or those who are 100 lbs. 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.

In February 2011, the FDA approved the Lap-Band Adjustable Gastric Banding System, by Allergan, for weight reduction in obese patients, with a Body Mass Index (BMI) of at least 40 kg/m2 or less obese patients who have at least a body mass index (BMI) of 30 kg/m^2 and one or more additional obesity-related co-morbid condition, such as diabetes or hypertension. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf. (Accessed August 19, 2020)

On September 28, 2007, the FDA approved the REALIZE™ Adjustable Gastric Band (REALIZE Band) manufactured by Ethicon Endo-Surgery, Inc. The REALIZE Band also consists of a silicone band, tubing, and an injection port. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070009b.pdf. (Accessed August 19, 2020)

In October 2010, the manufacturer voluntarily recalled the REALIZE Band due to the potential for a small ancillary component called the Strain Relief to move out of its intended position. The device was changed to add a silicone adhesive to bond the strain relief sleeve and the locking connector components of the injection port. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95101. (Accessed August 19, 2020)

Adjustable gastric bands are contraindicated in patients younger than 18 years of age.

Surgical stapling devices are used in all bariatric surgical procedures except gastric banding. These devices have been approved by FDA for use in various general surgical procedures. One device is the Endo Gia Universal Auto Suture, which inserts six parallel rows of staples into tissue. Other surgical staplers are manufactured by Ethicon Endo-Surgery. Additional information, product code GDW and GAG, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm. (Accessed August 19, 2020)

StomaphyX was granted 510(k) marketing approval on March 9, 2007. EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is substantially equivalent in intended use and method of operation to a combination of the LSI Solutions Flexible Suture Placement Device and the Bard Endoscope Suturing System/Bard Endocinch. According to the FDA, the StomaphyX system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062875.pdf. (Accessed August 19, 2020)

According to EndoGastric Solutions, StomaphyX is no longer being manufactured.

The AspireAssist received FDA pre-market approval on June 14, 2016 for adults who are at least 22 years old and are obese, with a BMI of 35.0-55.0 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150024. (Accessed August 19, 2020)

Transoral gastroplasty (TOGA) is not currently FDA approved.

The TransPyloric Shuttle/TransPyloric Shuttle Delivery Device was granted Premarket Approval on April 18, 2019 and is indicated for weight reduction in adult patients with obesity with a BMI of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with one or more obesity related comorbid conditions and intended to be used in conjunction with a diet and behavior modification program. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180024a.pdf. (Accessed August 19, 2020)

Policy History/Revision Information

Date	Summary of Changes
04/01/2021	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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