Miscellaneous Bariatric Procedures

Medical Policy #: 02.01.56
Original Effective Date: December 2015
Reviewed: July 2022
Revised: July 2022

DESCRIPTION

Bariatric surgery is performed to treat morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m^2 or a BMI greater than 35 kg/m^2 with associated complications including, but not limited to, diabetes, hypertension, or obstructive sleep apnea. Morbid obesity results in a very high-risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectal, prostate; for women: breast, uterine, ovarian), and a shortened lifespan. A morbidly obese man at age 20 can expect to live 13 fewer years than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches and there are numerous gastric and intestinal surgical techniques available.

There is a vast literature on bariatric surgery for adults with morbid obesity. This literature is characterized by a preponderance of single-arm clinical series from individual institutions. These types of studies can be used to determine the amount of weight loss expected from surgery, the durability of the weight loss, and the rate of adverse events. However, these studies are not adequate for determining the comparative efficacy of bariatric surgery versus conservative treatment, or the comparative efficacy of different bariatric surgery techniques. Some comparative trials, including randomized and nonrandomized designs, compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedures. RCTs of bariatric surgery have been performed but are limited and insufficient to draw conclusions about comparisons of bariatric surgery and conservative treatments for weight loss. RCTs are difficult in bariatric surgery because many experts consider it inappropriate or unethical to randomize patients to bariatric surgery. Also, most patients and clinicians have strong preferences for treatment, which result in a select population that might agree to randomization and, therefore, limited generalizability.

Clinical Context and Therapy Purpose

The purpose of gastric bypass is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals who are adults with morbid obesity.

Populations

The relevant population of interest are individuals who are adults with morbid obesity. Morbid obesity is defined as a BMI 40 kg/m^2 or more or a BMI 35 kg/m^2 or more with at least 1 clinically significant obesity-related disease such as diabetes, OSA, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

Interventions

The therapy being considered is gastric bypass. The procedure involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal); thus, food bypasses the duodenum and proximal small bowel.

Comparators

Comparators of interest include standard medical care. Treatment for adults with morbid obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Negative outcomes can include surgical complications, including leakage and operative margin ulceration at the, and metabolic complications, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia.

The existing literature evaluating gastric bypass as a treatment for morbid obesity has varying lengths of follow-up, ranging from 1 to 10 years. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Review of Evidence
This medical policy addresses the following surgical or minimally invasive bariatric procedures and orally administered Hydrogel capsules (e.g., Gelesis100) for the treatment of obesity that are considered investigational because the evidence in the current peer reviewed medical literature is insufficient to determine the effects of the technology on net health outcomes.

Investigational Surgical or Minimally Invasive Bariatric Procedures

Bariatric Arterial Embolization/Gastric Artery Embolization (e.g., Nanoblock Procedure)
During this procedure, a small catheter into is passed through the radial artery in the wrist or the femoral artery in the groin and utilize live x-ray imaging to guide the catheter to the artery that supplies blood to the left side of the stomach. Here the physician injects tiny particles that are just large enough to block and kill the cells that make the appetite hormone ghrelin.

Gastrointestinal Liners
Gastrointestinal liners including (e.g., EndoBarrier ValenTxEndo Bypass System)**,** an endoscopically delivered duodeno-jejunal bypass liner (DJBL), is a plastic flexible tube that is placed in the duodenal bulb, directly behind the pylorus. It extends from the duodenum to the proximal jejunum.

Intestinal Bypass
Intestinal Bypass, (e.g., jejunoileal) is created by dividing the small bowel 30 cm distal to the ligament of Treitz. The proximal cut end of the small bowel is anastomosed to the terminal ileum 50 cm proximal to the ileocecal valve. The rest of the small bowel remains a blind loop.

The Intragastric B**alloon**
The Intragastric balloon (also known as the silicone intragastric balloon or SIB) has been developed as a temporary aid for obese patients who have had unsatisfactory results in their clinical treatment for obesity. Intragastric balloon is intended to reduce gastric capacity, causing satiety, making it easier for patients to take smaller amounts of food.

Other balloons being investigated include the SatiSphere (Endosphere, Columbus, OH), Spatz Adjustable Balloon System (Spatz Medical, NY, USA), Elipse (Allurion Technologies, Wellesley, M)A, Full Sense Bariatric Device (Baker, Foote, Kemmeter, Walburn [BFKW] LLC, Grand Rapids, MI), Heliosphere® (Helioscopie Medical Implants, Vienne, France), Silimed Gastric Balloon (Silimed, Rio de Janeiro, Brazil) and

the Ullorex® Oral Intragastric Balloon (Phagia Technologies, Inc., Fort Lauderdale, FL). These devices are currently not FDA approved for use in the United States.

The FDA has received reports of unanticipated patient deaths related to liquid-filled intragastric balloon systems for treating obesity. The reports involved Apollo Endosurgery's (Austin, TX, USA) Orbera® Intragastric Balloon System, and ReShape Medical Inc.'s (San Clemente, CA, USA) ReShape® Integrated Dual Balloon System. All reported patients died within a month or less of receiving the balloon.

On August 10, 2017, FDA released an updated letter to alert healthcare providers of additional information regarding these adverse events (AEs). The letter discusses that FDA still does not know the root cause and incidence rate of patient deaths in relation to liquid-filled intragastric balloons and has not been able to definitively attribute the deaths to the actual devices or device insertion procedures (e.g., gastric and esophageal perforation, intestinal obstruction).

Long Limb Gastric Bypass
The long-limb gastric bypass differs from the conventional gastric bypass only in the length of defunctionalized jejunum. The long-limb gastric bypass was designed to induce greater malabsorption by diverting bile and pancreatic secretions distally in the digestive tract. This was felt to produce a greater malabsorption of fats without the protein malabsorption associated with intestinal bypass.

Mini Gastric Bypass or **Single-Anastomosis Gastric Bypass/Stomach Intestinal Pylorus Sparing Surgery (SIPS)**
The Mini gastric bypass or Single-Anastomosis Gastric Bypass (similar to the Billroth II operation, can also be called Gastrojejunostomy intestinal anastomosis,) mini-gastric bypass is a variation of the gastric bypass. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach.

Silastic Ring Vertical Gastric Bypass (Fobi Pouch)
In a traditional gastric bypass procedure, surgeons create a smaller stomach by stapling off a large section. A problem with the traditional procedure is that the staples can break down, causing the stomach to regain its original shape -- and patients to start gaining weight again. Also, the stomach opening that leads into the intestines, which in surgery is made smaller to allow less food to pass through, often stretches as the years go by. With the Fobi pouch, there is no use of staples; rather, the stomach is bisected and hand-sewn them to maintain the separation. A synthetic band is placed around the stomach opening to keep it from stretching**.** This has not been fully endorsed by the American Society for Metabolic and Bariatric Surgery (ASMBS) as a primary weight loss procedure.

Surgically Placed Gastric Tubes Intended to Drain a Portion of the Stomach Contents (e.g., The AspireAssist® Device).
This procedure is intended to provide control of calorie consumption to those with BMI 35-55 kg/m² who have been unsuccessful in weight loss through non-surgical means. To place the device, surgeons insert a tube in the stomach with an endoscope via a small incision in the abdomen. A disk-shaped port valve that lies outside the body, flush against the skin of the abdomen, is connected to the tube and remains in place. Approximately 20 to 30 minutes after meal consumption, the patient attaches the device's external connector and tubing to the port valve, opens the valve and drains the contents. Once opened, it takes approximately five to 10 minutes to drain food matter through the tube and into the toilet. The device removes approximately 30 percent of the calories consumed. Only 1 randomized control trial has been initiated, with no literature available on the long-term effects of therapy on health outcomes. With no completed randomized control trials, the evidence is lacking that proves device use shows an improvement in net health outcomes or that the service is as beneficial as any established alternative service.

Transoral Gastroplasty
Transoral gastroplasty (TG) is a minimally invasive, incisionless, reversible weight-loss procedure in which the stomach size is restricted with staples or sutures by using endoscopic surgical tools guided through the mouth and esophagus into the stomach. Two examples of this procedure that are proposed for revisions of standard weight loss surgery are Stomaphyx and the ROSE procedure. This may also be referred to as endoscopic sleeve gastroplasty. Newly approved to assist in transoral procedures. The OverStitch™ Endoscopic Suturing System allows placement of full-thickness sutures through a flexible endoscope during bariatric and gastrointestinal surgeries. It allows deployment of both running and interrupted sutures, has a curved needle design to control suture depth, and allows knotless fixation.

1. StomaphyX is a non-invasive procedure where the surgeon literally does an endoscopy where a scope is put in through your mouth and is fed down into the stomach pouch. No incisions are needed for this procedure as it goes directly into the mouth. Once the scope has been inserted, the surgeon will then suction out the stomach tissue into a small StomaphyX opening. This allows a fold of tissue to be created which is then secured with fasteners in the shape of an "H." These small folds will eventually create a smaller stomach pouch about the same size as the one created during gastric bypass. The number of folds needed depends on the size of the stomach.
2. Another non-invasive weight loss surgery is transoral ROSE. While this surgery is similar to StomaphyX, a surgeon will insert a similar tool to the endoscope that has four different channels into the mouth, down through the esophagus and into the stomach. He or she then puts specialized instruments through those four channels to sew the connection between the small intestine and stomach pouch together. In the transoral ROSE procedure, the surgeon sutures tissue to make several folds around the opening of the small intestine (the stoma) to decrease its diameter. Anchored sutures are then placed into the stomach pouch minimizing how much the stomach can actually hold.

Transpyloric Shuttle/TransPyloric Shuttle Delivery Device (TPS)
The Transpyloric Shuttle/TransPyloric Shuttle Delivery Device (TPS) (BAROnove, Inc. San Carols, CA) was FDA PMA approved for obese adult patients with a Body Mass Index (BMI) of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with an associated medical condition who have been unable to lose weight on a diet and behavior modification program and exercise. It is intended to be used while a patient participates in a diet and exercise plan supervised by a health care provider (FDA, 2019). The TPS is placed into the stomach through the mouth during an endoscopic procedure. Once in place, the TPS is formed, using the TPS Delivery Device, into a smooth large bulb connected to a smaller bulb by a flexible silicone tether. The large bulb remains in the stomach. The smaller bulb can remain in the stomach or cross the stomach into the small intestine to slow the time it takes for food to leave the stomach and enter the small intestine (gastric emptying). The TPS remains in the stomach for up to 12 months to help patients lose weight (FDA, 2019).

Vertical Banded Gastroplasty (VBG)
Vertical banded gastroplasty (VBG), also known as stomach stapling. In this procedure the upper stomach near the esophagus is stapled vertically to create a small pouch along the inner curve of the stomach. The outlet from the pouch to the rest of the stomach is restricted by a band made of special material. The band delays the emptying of food from the pouch, causing a feeling of fullness. The percentage of reoperations necessary with vertical banded gastroplasty is increased from all other approved procedures. This procedure is no longer the standard of care.

Investigational Orally Administered Hydrogel Capsules
Hydrogel capsules (i.e., Gelesis100) are pills that are designed to treat the physiological symptoms of hunger without surgery, other invasive procedures or systemically absorbed drugs. Twenty minutes before a meal, a patient swallows capsules containing hydrogel particles. Once in the stomach, these particles are released from the capsules and rapidly absorb water, hydrating to approximately one hundred times their dry weight. The particles will pass through the digestive tract and be excreted from the body.

Practice Guidelines and Position Statements

American Society for Metabolic and Bariatric Surgery (ASMBS)
In 2018, the ASMBS released an addendum to their intragastric balloon therapy position statement in response to the FDA's warnings on complications not identified during initial clinical trials, and worldwide mortalities associated with intragastric balloons. They recommend that: As with all procedures, it is important that patients give informed consent and are aware of potential adverse events. Laypeople may need to be counseled to correct a misperception that endoluminal treatments are nonsurgical and thus risk-free. When less powerful treatments are chosen, behavioral modification increases in importance and there is risk of weight regain after the device is retrieved. The ASMBS routinely advocates for

multidisciplinary care and support of the weight loss patient, and this recommendation is even more crucial for intragastric balloon recipients.

In 2016, the American Society for Metabolic and Bariatric Surgery provided the following guidance: single anastomosis duodenal switch procedures are considered investigational at present and should be performed under a study protocol with third-party oversight to ensure continuous evaluation of patient safety and to review adverse events and outcomes.

National Institute for Health (NICE)
A 2016 NICE guidance on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity stated that the current evidence on the safety shows that there are well-recognized complications. Evidence on efficacy is limited in both quality and quantity. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Regulatory Status
Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, are not subject to regulation by the FDA.

The below information shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process:

In March 2007, the FDA granted 510(k) pre-marketing clearance to the StomaphyX (EndoGastric Solutions, Inc.), an endoluminal fastener and delivery system used to tighten esophageal tissue.

On July 28, 2015, the Food and Drug administration (FDA) approved the ReShape Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, CA) to treat obesity without the need for invasive surgery.

August 2015, the FDA approved ORBERA® intragastric balloon system (Apollo Endosurgery) for use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.

On June 14, 2016, the FDA approved the AspireAssist device to assist in weight loss in patients aged 22 and older who are obese, with a BMI of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy.

September 2016, the FDA approved Obalon^{TM} intragastric balloon system (Obalon Therapeutics, Inc) for use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement

in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 months treatment period.

In April 2019 FDA approved the TransPyloric Shuttle non-surgical device intended for treating obesity, now cleared as a weight loss solution for adults with obesity and a body mass index of 30 to 40 kg/m2.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies

- 07.01.60 Vagus Nerve Stimulation (VNS) and Vagal Blocking Therapy
- 07.01.62 Gastric Electrical Stimulation

Surgical or Minimally Invasive Procedures

The following surgical or minimally invasive procedures are considered **investigational** as a treatment of morbid obesity including but not limited to the following due to insufficient evidence demonstrating an impact on improved net health outcomes:

- Adjustable banding as an open procedure
- Bariatric arterial embolization (BAE)
- Biliopancreatic bypass without duodenal switch (i.e., the Scopinaro procedure)
- Duodenal-jejunal sleeve
- Gastrointestinal liners including but not limited to the following:
    - Endobarrier
    - Gastric Vest System
    - ValenTx,
- Intragastric balloon (e.g., ReShape® Integrated Dual Balloon System, Orbera device or Obalon device)
- Laparoscopic gastric plication, also known as laparoscopic greater curvature plication
- Long-limb gastric bypass (i.e., greater than 150 cm)
- Mini-gastric bypass, also known as loop gastric by-pass (includes the use of Billroth II type)
- Silastic Ring Vertical Gastric Bypass (Fobi pouch)
- Single anastomosis bypass with sleeve gastrectomy/stomach intestinal pylorus sparing surgery [SIPS])
- Sleeve gastrectomy as an open procedure
- Surgically placed gastric tubes intended to drain a portion of the stomach contents (e.g., the AspireAssist® device)

- Transoral gastroplasty/Endoscopic gastroplasty as primary bariatric procedure or as a revision procedure (Also called: Natural Orifice Transluminal Endoscopic Surgery [NOTES™] or TOGA), including but not limited to Restorative Obesity Surgery Endoluminal or ROSE procedure, endoscopic closure devices, StomaphyX™, EndoCinch, OverStitch™, Apollo transoral outlet reduction (43290, 43291)
- The Transpyloric Shuttle/TransPyloric Shuttle Delivery Device (TPS)
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Vertical-banded gastroplasty

Hydrogel Capsules
The following which is orally administered Hydrogel capsules (e.g., Gelesis100) for the treatment of morbid obesity is considered **investigational**, because the evidence is insufficient to determine the effects of the technology on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 43290 Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
- 43291 Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
- 43659 Unlisted, laparoscopic, stomach
- 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
- 43999 Unlisted, stomach
- 44799 Unlisted procedure small intestine

SELECTED REFERENCES

- U.S. Food and Drug Administration (FDA). Orbera Intragastric Balloon System - P140008. Rockville, MD: FDA; August 6, 2015.
- Lim RB. Bariatric operations for management of obesity: Indications and preoperative preparation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2015.
- Mechanick JI, Youdim A, Jones DB, et al; American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic & Bariatric Surgery. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient -- 2013 update: Cosponsored by American Association of Clinical Endocrinologists, the Obesity

Society, and American Society for Metabolic & Bariatric Surgery. Endocr Pract. 2013;19(2):337-372.
- SAGES Guidelines Committee. SAGES guideline for clinical application of laparoscopic bariatric surgery. Surg Endosc. 2008;22(10):2281-2300.
- Parikh M, Chung M, Sheth S, et al. Randomized pilot trial of bariatric surgery versus intensive medical weight management on diabetes remission in type 2 diabetic patients who do NOT meet NIH criteria for surgery and the role of soluble RAGE as a novel biomarker of success. Ann Surg. 2014;260(4):617-622; discussion 622-624.
- Georgiadou D, Sergentanis TN, Nixon A, et al. Efficacy and safety of laparoscopic mini gastric bypass. A systematic review. Surg Obes Relat Dis. 2014;10(5):984-991.
- Eid GM, McCloskey CA, Eagleton JK, et al. StomaphyX vs a sham procedure for revisional surgery to reduce regained weight in Roux-en-Y gastric bypass patients : A randomized clinical trial. JAMA Surg. 2014;149(4):372-379.
- Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014;129(25 Suppl 2):S102-S138.
- Escalona A, Pimentel F, Sharp A, et al. Weight loss and metabolic improvement in morbidly obese subjects implanted for 1 year with an endoscopic duodenal-jejunal bypass liner. Ann Surg. 2012;255(6):1080-1085.
- Adams TD, Davidson LE, Litwin SE, et al. Health benefits of gastric bypass surgery after 6 years. JAMA. 2012;308(11):1122-1131.
- Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med. 2012;366(17):1567-1576
- U.S. National Institutes of Health (NIH). ClinicalTrials.Gov. Transoral Gastroplasty for the Treatment of Morbid Obesity (TOGA®). NCT00661245
- Mingrone G, Panunzi S, Gaetano A, et. al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. N Engl J Med 2012. March: 2012: 10.1056
- ECRI Institute. Laparoscopic sleeve gastrectomy for obesity. [Emerging Technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2011 Feb 28. Available at URL address: http://www.ecri.org
- FDA News Release FDA approves AspireAssist obesity device, June 14, 2016 @ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm506625.htm
- Thompson CC, et al. Abstract #381. Presented at: Digestive Disease Week; May 21-24, 2016; San Diego.
- Sullivan S, Stein R, Jonnalagadda S., et al. Aspiration therapy leads to weight loss in obese subjects: A pilot study. Gastroenterology 2016 145(6): 1245-1252
- Ali MR, Moustarah F, Kim JJ, et al. American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy endorsed by the Society

of American Gastrointestinal and Endoscopic Surgeons. Surg Obes Relat Dis. Mar-Apr 2016;12(3):462-467. PMID 27056407
- Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Executive summary. Endocr Pract. Jul 2016;22(7):842-884. PMID 27472012
- Vilarrasa N, de Gordejuela AG, Casajoana A, et al. Endobarrier® in grade I obese patients with long-standing type 2 diabetes: role of gastrointestinal hormones in glucose metabolism. Obes Surg. 2016 Jul 28. [Epub ahead of print]
- Rohde U, Hedbäck N, Gluud LL, et al. Effect of the EndoBarrier Gastrointestinal Liner on obesity and type 2 diabetes: a systematic review and meta-analysis. Diabetes Obes Metab. 2016 Mar;18(3):300-5.
- Weiss CR, Gunn AJ, Kim CY, et al. Bariatric embolization of the gastric arteries for the treatment of obesity. J Vasc Interv Radiol. 2015 May; 26(5): 613–624.
- ourcoulas A, Abu Dayyeh BK, Eaton L, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. Int J Obes (Lond). Jan 24 2017. PMID 28017964
- Kang, S.H., Lee, Y., Park, Y.S. et al. OBES SURG (2017) 27: 3314. https://doi.org/10.1007/s11695-017-2934-9
- ECRI Institute. Intragastric Balloons (Obalon, Orbera, and ReShape) for Treating Obesity. Plymouth Meeting (PA): ECRI Institute; 2017 Mar 01. (Emerging Technology Report).
- Mahawar KK, Himpens J, Shikora SA, et al. The First Consensus Statement on One Anastomosis/Mini Gastric Bypass (OAGB/MGB) Using a Modified Delphi Approach. Obes Surg. 2018;28(2):303.
- Hemsfield, S., Aronne, L., et. al. Clinical Perspectives on obesity treatment:Challenges, gaps, and promising opportunities. National Academy of Medicine. September 10, 2018.
- Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm - 2017 Executive Summary. Endocr Pract. Feb 2017;23(2):207-238. PMID 28095040
- Carbajo MA, et al. Evaluation of weight loss indicators and laparoscopic one-anastomosis gastric bypass outcomes. Sci Rep 2018 Jan 31;8(1):1961.
- Almalki OM, Lee WJ, Chen JC, et al. Revisional Gastric Bypass for Failed Restrictive Procedures: Comparison of Single-Anastomosis (Mini-) and Roux-en-Y Gastric Bypass. Obes Surg. 2018 Apr;28(4):970-975. PMID: 29101719
- ECRI Institute. Ingestible Intragastric Balloons (Obalon, Orbera, and ReShape) for Treating Obesity. Plymouth Meeting (PA): ECRI Institute; 2020 April 15. (Custom Rapid Responses).
- Itani MI, Farha J, Marrache MK, Fayad L, Badurdeen D, Kumbhari V. The Effects of Bariatric Surgery and Endoscopic Bariatric Therapies on GERD: An Update [published online ahead of print, 2020 Jan 20]. Curr Treat Options Gastroenterol. 2020;10.1007/s11938-020-00278-y. doi:10.1007/s11938-020-00278-y

- Brooks M. Five deaths tied to intragastric balloons, FDA says. Medscape Pharmacists. August 10, 2017. Available at: http://www.medscape.com/viewarticle/884089?nlid=117258_3901&src=wnl_newsalrt_170810_MSCPEDIT&uac=15916AK&impID=1408009&faf=1.
- National Institute for Health and Care Excellence (NICE). Interventional procedure guidance 569. Singleanastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Nov 2016. https://www.nice.org.uk/guidance/ipg569
- Robert M, Espalieu P, Pelascini E, Caiazzo R, Sterkers A, Khamphommala L, Poghosyan T, Chevallier JM, Malherbe V, Chouillard E, Reche F, Torcivia A0, Maucort-Boulch D, Bin-Dorel S, Langlois-Jacques C, Delaunay D, Pattou F, Disse E. Efficacy and safety of one anastomosis gastric bypass versus Rouxen-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial. Lancet. 2019 Mar 30;393(10178):1299-1309.
- U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). TransPyloric Shuttle – P180024. April 23, 2019. https://www.fda.gov/medical-devices/recently-approved-devices/transpyloric-shuttletranspyloric-shuttledelivery-device-p180024
- Hayes Inc. OverStitch Endoscopic Suturing System (Apollo Endosurgery Inc.) for Endoscopic Sleeve Gastroplasty Updated May 2022
- Hayes Inc. OverStitch Endoscopic Suturing System (Apollo Endosurgery Inc.) for Transoral Outlet Reduction. Updated July 2022

POLICY HISTORY		
Date	**Reason**	**Action**
July 2022	Annual Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Interim Review	Policy Revised
December 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.