
Medical Policy



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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: GASTRIC BYPASS SURGERY FOR GASTROPARESIS

Description/Background

GASTROPARESIS

Gastroparesis is defined as a syndrome of objectively delayed gastric emptying in the absence of mechanical obstruction. Symptoms may include early satiety, postprandial fullness, nausea, vomiting, bloating, and upper abdominal pain; the same constellation of complaints may be seen with other etiologies, including gastritis secondary to *Helicobacter pylori* infection, peptic ulcer, and functional dyspepsia. Symptoms have not been well correlated with gastric emptying. Nausea, vomiting, early satiety, and postprandial fullness correlate better with delayed gastric emptying than upper abdominal pain and bloating.

Diagnosis

Documented delay in gastric emptying is required for the diagnosis of gastroparesis. Scintigraphic gastric emptying of solids is the standard for the evaluation of gastric emptying and the diagnosis of gastroparesis. The most reliable method and parameter for diagnosis of gastroparesis is gastric retention of solids at 4 h measured by scintigraphy. Studies of shorter duration or based on a liquid challenge result in decreased sensitivity in the diagnosis of gastroparesis.

Management

The first line of management for gastroparesis patients should include restoration of fluids and electrolytes, nutritional support and in diabetics, optimization of glycemic control. Patients should receive counseling from a dietician regarding consumption of frequent small volume nutrient meals that are low in fat and soluble fiber. If unable to tolerate solid food, then use of homogenized or liquid nutrient meals is recommended. If oral intake is insufficient, then enteral alimentation by jejunostomy tube feeding should be pursued (after a trial of nasogastric tube feeding). In addition to dietary therapy, prokinetic therapy should be considered to improve gastric emptying and gastroparesis symptoms, taking into account benefits and risks of treatment. Treatment with antiemetic agents should occur for improvement of associated

nausea and vomiting but will not result in improved gastric emptying. Tricyclic antidepressants (TCA) can be considered for refractory nausea and vomiting in gastroparesis but will not result in improved gastric emptying and may potentially retard gastric emptying.

Gastric Bypass Surgery

Gastric bypass surgery shrinks the size of the stomach. The surgeon may also re-route, or bypass, part of the digestive system. The most common gastric bypass surgery done in the U.S. is the Roux-en-Y gastric bypass.

Regulatory Status

Forms of surgery for gastroparesis performed without specific implantable devices are surgical procedures and, as such is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Medical Policy Statement

Gastric bypass surgery for gastroparesis is experimental/investigational. This procedure has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

43644

43645

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

GASTROPARESIS

Clinical Context and Therapy Purpose

The purpose of gastric bypass surgery in patients who have gastroparesis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with gastroparesis.

Interventions

The therapy being considered is gastric bypass surgery.

Comparators

The following therapies and practices are currently being used to treat gastroparesis: dietary therapy, prokinetic therapy and medications.

Outcomes

The general outcomes of interest are improvement in gastric emptying and gastroparesis symptoms. Treatment-related adverse events are minor.

Literature Review

Papasavas et al (2014) conducted a retrospective review of adult patients who underwent laparoscopic Roux-en-Y gastric bypass (RYGB).¹ Clinical data pre- and post-surgery and at a follow-up of up to 2 years were reviewed. Total symptom scores for gastroparetic symptom severity and frequency were compared pre-surgery and at follow-up using paired t tests. Seven obese and morbidly obese patients (body mass index [BMI] = 39.5, range = 33-54; 6 women) with idiopathic or diabetic gastroparesis reported marked symptom improvement, and total symptom scores decreased after RYGB. All 4 patients who were taking prokinetics preoperatively no longer required their medication after surgery. Three patients required prolonged treatment with anti-nausea medications in the postoperative period. Mean BMI change was 9.1 units and mean percent excess weight lost was 71.6 lbs. No perioperative complications were experienced. Two required readmissions due to various concerns (dysphagia, nausea, anastomotic ulcer). In this cohort, the authors suggest that RYGB may be an alternative treatment for gastroparesis in obese patients. However further studies are required to evaluate this treatment in nonobese patients as well as long-term effects.

Wakamatsu et al (2018) conducted a chart review on patients who underwent surgical treatment of gastroparesis from February 2003 to December 2014.² Subgroup analysis was performed based on etiology of gastroparesis (diabetic [DM] versus idiopathic [IP]) and the procedure received (gastric electrical stimulator [GES] versus RYGB). Postoperative outcomes and postoperative symptom improvements were compared between groups. Of 93 patients, 47 (50.5%) had IP and 46 (49.5%) had DM. The majority underwent GES implantation (83.8%, n = 78), and 15 patients (16%) underwent RYGB. There were significant differences in hospital stay (2 versus 3 days) and reoperation rate (30% versus 7%) between IP and DM. Operation time, complication rate, and 30-day readmission rate were similar in both groups. DM patients significantly improved GP related complaints compared with preoperatively. IP patients also improved nausea and vomiting and had no change in abdominal pain between pre- and postoperative period. GES showed significant improvement of nausea, vomiting, and abdominal pain. RYGB showed improvement of nausea, but not vomiting or abdominal pain. The authors concluded that surgery was a feasible intervention for GP for both DM and IP patients; however, based on the data presented in this manuscript and the current literature, the use of gastric bypass as an effective treatment modality for patients with intractable GP remains highly controversial.

Cuenca et al (2020) analyzed 6 patients in whom an RYGB was performed for non-bariatric purposes.³ Symptom questionnaire was used to evaluate response. None of the patients qualified for bariatric surgery, as all had a body mass index (BMI) <35 kg/m. Five patients were operated on for severe gastroesophageal reflux disease symptoms, and one for gastroparesis. All patients had good to excellent results, with marginal modification of their BMI. Further randomized controlled trials are needed to assess whether RYGB can be considered in patients with functional diseases of the upper gastrointestinal tract, regardless of their BMI.

Landreneau et al (2020) retrospectively reviewed 53 patients who underwent RYGB for the treatment of gastroparesis between September 2010 through March 2018.⁴ Patients with prior gastric resection or whose primary operative indication was not gastroparesis were excluded from analysis. Twenty-six patients underwent Roux-en-Y with stomach left in situ (RY-SIS) and twenty-seven patients underwent gastrectomy with Roux-en-Y reconstruction during the study period. The mean age was 49.7 years in the RY-SIS cohort and 48.5 years in the gastrectomy cohort. Etiology of GP was similar between the two cohorts. Patients undergoing gastrectomy were more likely to have previous interventions for GP (63.0% vs. 26.9%). RY-SIS was associated with a shorter operative time (155 vs. 223 min), less blood loss (24 vs. 130 mL), and shorter length of stay (4.0 vs. 7.2 days). Twelve patients (44.4%) had complications within 30 days following gastrectomy compared to two patients (7.7%) following RY-SIS (p = .001). Patients in the RY-SIS cohort were more likely to require further subsequent surgical intervention for GP (23.1% vs. 3.7%, p = .04). At last follow-up, there were no differences in reported GP symptoms or symptom scoring. Gastrectomy was associated with greater perioperative morbidity compared to leaving the stomach in situ. Symptomatic improvement at intermediate follow-up was equivalent following either procedure. However, patients undergoing RY-SIS were more likely to require subsequent surgical intervention, suggesting that gastrectomy may be a more definitive operation for the management of medically refractory gastroparesis.

Moszkowicz et al (2022) reported on a retrospective review of adult patients who underwent laparoscopic RYGB.⁵ Severity and frequency of gastroparesis symptoms were compared before and 1 year post surgery using the Gastroparesis Cardinal Symptom Index (GCSI) score (0-5), vomiting (VM) score (0-4) and visual analog score (VAS) for abdominal pain. Of the 9 patients with refractory GP, 7 were malnourished and 2 had obesity. There were no postoperative deaths. One patient was operated on for internal hernia without bowel necrosis. The mean GCSI score decreased significantly from 3.6 (range: 1-5) preoperatively to 2.1 (range: .3-4.4) postoperatively (P = .0019). The mean VM score improved significantly after surgery, from .22 (range: 0-1 units) preoperatively to 2.55 (range: 1-4) postoperatively (P = .007). The mean VAS score also decreased significantly from 7.0 (range: 5-9) preoperatively to 2.44 (range: 0-7) postoperatively (P = .0015). A nonsignificant weight and albumin change was observed at 1 year postoperatively, with a tendency for weight regain in malnourished patients.

Summary of Evidence

For individuals who have gastroparesis who receive RYGB surgery, the evidence includes retrospective reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The reviews concluded that surgery was a feasible intervention for gastroparesis for both DM and IP patients; however, based on the data presented and the current literature, the use of gastric bypass as an effective treatment modality for patients with intractable GP remains highly controversial. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Gastroenterology (ACG)

The ACG clinical guideline on the management of gastroparesis (2022) does not address RYGB as a recommended treatment for gastroparesis.⁶

Ongoing and Unpublished Clinical Trials

No studies were identified on www.clinicaltrials.gov that may influence this review.

Government Regulations

National:

There is no national coverage determination for gastric bypass surgery for gastroparesis.

Local:

There is no local coverage determination for gastric bypass surgery for gastroparesis.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis
 - Gastric Electrical Stimulation
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References

1. Pappasavas PK, NG JS, Stone AM, et al. Gastric bypass surgery as treatment of recalcitrant gastroparesis. Surg Obes Relat Dis. 2014;10(5):795-799.
2. Wakamatsu K, Perez QF, Montorfano L, et al. Laparoscopic treatment of gastroparesis: a single center experience. Surg Obes Relat Dis. 2018;14(2):200-205.
3. Cuenca AF, Puma R, Ithurrealde AJ, et al. Non-bariatric Roux-en-Y gastric bypass. J Laparoendosc Adv Surg Tech A. 2020;30(1):31-35.
4. Landreneau JP, Strong AT, El-Hayek K, et al. Gastrectomy versus stomach left in situ with Roux-en-Y reconstruction for the treatment of gastroparesis. Surg Endosc. 2020; 34(4):1847-1855.
5. Moszkowicz D, Mariano G, Soliman H, et al. Roux-en-Y gastric bypass as a salvage solution for severe and refractory gastroparesis in malnourished patients. Surg Obes Relat Dis. 2022 May;18(5):577-580. doi: 10.1016/j.soard.2022.01.017. Epub 2022 Feb 1. PMID: 35221251.
6. Camilleri M, Kuo B, Nguyen L, et al. ACG Clinical Guideline: Gastroparesis. The American Journal of Gastroenterology 117(8):p 1197-1220, August 2022.
7. McCarty TR and Rustagi T. Endoscopic treatment of gastroparesis. World J Gastroenterol. 2015;21(22):6842-6849.
8. Camilleri M. Treatment of gastroparesis. Available at: www.uptodate.com. Last updated April, 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 30, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/20	8/18/20		Joint policy established
11/1/21	8/17/21		Routine policy maintenance. No change in policy status.
11/1/22	8/16/22		Routine maintenance. No change in policy status.
11/1/23	8/15/23		Routine maintenance. No change in policy status. Vendor: N/A. (ky)
11/1/24	8/20/24		Routine maintenance. No change in policy status. Vendor: N/A. (ky)

Next Review Date: 3rd Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: GASTRIC BYPASS SURGERY FOR GASTROPARESIS**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.