02.01.23 Miscellaneous Investigational Treatments for Reflux Disease

Original Effective Date: July 2001

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- 07.01.99 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)
- 01.01.38 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

Summary

Description

Summary of Evidence

For individuals who have a body mass index (BMI) of < 30 kg/m^2 who have gastroesophageal reflux disease (GERD) uncontrolled by proton pump inhibitors (PPIs) and receive a Roux-en-Y gastric bypass (RYGBP) no studies were identified which evaluated using RYBG as a primary procedure for GERD in nonobese individuals. Relevant outcomes are symptoms, change in disease status, QOL, medication

use, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have GERD who use an upper esophageal sphincter assist device the evidence includes 2 single-arm studies, Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. Although both studies showed improvement in RSI there is a lack of consistent improvements in longer term follow up. The longest-term outcomes were at 3 months, from the study by Yadlapati et al. In this study, at 3 months, 67% (14/31) were utilizing UES compression device, but seven discontinued for intolerance (4, 57%), poor symptom control (2, 29%), and rash (1, 14%). Limitations of these studies included the lack of a concurrent control group, risk of imprecision due to small sample size, and unclear durability of effects due to lack of long-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether miscellaneous treatments not covered in a separate policy improve the net health outcome in individuals with gastroesophageal reflux disease (GERD) and other related reflux diseases**.**

PRIOR APPROVAL

Not applicable.

POLICY

The following treatments for reflux disease are considered **investigational** including but not limited to the following because the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- A primary Roux-en-Y Gastric Bypass (RYGBP) (open or laparoscopic) surgery in individuals with a BMI < 30 kg/m^2.
- Upper Esophageal Sphincter Assist Device
    - Reza Band™, Reflux Band®

ALL Category III codes will be considered investigational unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

Note: For medical necessity clinical coverage criteria using InterQual® criteria related to Bariatric or Metabolic Surgery for obesity (BMI ≥ 30) regardless of GERD, refer to Wellmark's Authorization Table.

POLICY GUIDELINES

Coding

See the Codes table for details.

Category III codes are a set of temporary (T) codes for emerging technologies, services, and procedures that allow for data collection by the American Medical Association's (AMA). If a Category III code is available, providers must use that code instead of an unlisted or deleted Category I code. The services or

procedures represented by Category III codes may not have FDA approval, may not be performed by many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

BACKGROUND

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms (i.e., hoarseness, throat clearing, dysphagia, etc.) related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.

Pathophysiology

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is an abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some individuals will have a more serious disease, which results in complications such as erosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment

Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines. Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010) reported that PPIs demonstrated superiority to H2-receptor antagonists and prokinetics in both network meta-analyses and direct comparisons.

Surgical Treatment

The most common surgical procedure used for GERD remains laparoscopic Nissen fundoplication; however, the utilization of this procedure steadily declined between 2009 and 2013 with the advancement of novel nonmedical (endoscopic and surgical) techniques. Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991 and has been rapidly adopted because it avoids complications associated with an open procedure.

Although fundoplication results in a high proportion of individuals reporting symptom relief, complications can occur and sometimes require conversion to an open procedure. Individuals who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Roux-en-Y Gastric Bypass (RYGBP)
Roux-en-Y gastric bypass is well established in clinical practice as a safe and effective bariatric procedure in individuals with obesity (BMI ≥ 30). A small stomach pouch is created to restrict food intake. A Y-shaped section of the small intestine is attached to the pouch to allow food to bypass the lower stomach, the duodenum and the first portion of the jejunum. This reduces the number of calories and amount nutrients the body absorbs. Long-limb Roux-en-Y gastric bypass is similar to standard RYGBP, except that the limb through which food passes is long, which purportedly eases symptoms of GERD.

While a RYGB is generally considered a bariatric procedure it has been proposed as a treatment option for individuals with GERD with a BMI < 30 kg/m^2 when medication (i.e. proton pump inhibitors) and lifestyle modification are not effective. A RYGB may be successful due to anatomical changes the procedure accomplishes by the gastric pouch, diverting the pressure from the food on the lower esophageal, and reducing the acid amount from the stomach into the patient's esophagus.

Other Treatment Options
Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. (Please see Wellmark's related medical policies).

Upper Esophageal Sphincter Assist Device
An upper esophageal sphincter assist device is a novel medical device designed to prevent the reflux of gastric contents into the laryngopharynx. It is a non-pharmacologic, non-surgical medical device worn externally around the individual's neck while sleeping and applies a standardized external pressure to the cricoid cartilage. The Reflux Band is designed to provide a set pressure of 20-30 mmHg. The increase in pressures stops the stomach contents from passing through UES into the esophagus.

Regulatory Status
Roux-en-Y gastric bypass is a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Currently, the Food and Drug Administration (FDA) has approved 510(k) marketing clearance for the following upper esophageal sphincter devices:

Table 1: FDA Approved Upper Esophageal Sphincter Devices

Device	Manufacturer	DEN & K Numbers*	Date	Description
Reza Band® Upper Esophageal Sphincter (UES) Assist Device	Somna Therapeutics, L.L.C.	DEN130046	March 6, 2015	" … indicated for patients 18 years and older to reduce the symptoms of laryngopharyngeal reflux (LPR) disease by reducing the regurgitation of stomach contents from passing through the upper esophageal sphincter. The device is worn by the patient when sleeping." Reza was renamed as Reflux Band when Restech acquired Somna.

Device	Manufacturer	DEN & K Numbers*	Date	Description
Reza Band™, Reflux Band®	Restech acquired Somna	K173934	April 13, 2018	Same indication as above.

**Please note this list is not intended to be all inclusive.*

RATIONALE

This evidence review was created in December 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Roux-en-Y Gastric Bypass (RYGBP)

Clinical Context and Therapy Purpose

The purpose Roux-en-Y gastric bypass is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with reflux disease.

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

Populations

The relevant population of interest is individuals with a body mass index (BMI) of 29.9 or less with reflux disease uncontrolled by proton pump inhibitors (PPIs).

Interventions

The therapy being considered is Roux-en-Y gastric bypass.

Comparators

The following practice is currently being used to treat reflux: lifestyle modification, medications such as proton pump inhibitors (PPIs) and laparoscopic fundoplication.

Outcomes

The general outcomes of interest are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. Follow-up at 3 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

We did not identify any studies specifically focusing on using RYBG as a primary procedure for GERD in nonobese individuals.

Section Summary: Roux-en-Y Gastric Bypass (RYGBP) for the Treatment of GERD

No studies were identified that have evaluated whether a RYBG as a primary procedure for GERD in nonobese individual improves the health outcome such as a change in disease status, QOL, medication use, and treatment-related morbidity.

Upper Esophageal Sphincter Assist Device

Clinical Context and Therapy Purpose

The purpose an upper esophageal sphincter assist device is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with reflux disease.

Populations

The relevant population of interest is individuals with reflux disease uncontrolled by medication (i.e., proton pump inhibitors (PPIs).

Interventions

The intervention being considered is an upper esophageal sphincter assist device (i.e., Reza Band™, Reflux Band®).

Comparators

The following practice is currently being used to treat GERD: lifestyle medication, medication such as proton pump inhibitor (PPI) and laparoscopic fundoplication.

Outcomes

The general outcomes of interest are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. Follow-up at 3 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Observational Studies

Yadlapati et al in 2022 completed a single-arm study to review if using an upper esophageal sphincter compression device as an adjunct to proton pump inhibition for laryngopharyngeal reflux reduces reflux events. Thirty-one individuals completed the trial. Phase 1 of the trial included the administration of a double dose of PPI for 4 weeks. In Phase 2 of the trial had individuals continued PPI therapy and wore the external upper esophageal sphincter device at night. Symptom response was tracked with the reflux symptoms index (RSI). There were 17 responders (55%) and 14 non-responders. The baseline, mean RSI score was (24.1 (10.9)). RSI for Phase 1 (PPI alone) decreased from 21.9 (9.7); $p = 0.06$ when compared to Phase 2 (Device + PPI) to 15.5 (10.3); $p < 0.01$. Symptom response was met in 11/31 individuals (35%). Individuals who achieved symptom response had a BMI that was lower (24.2 kg/m2 (4.1) vs 28.6 (5.3); $p = 0.02$), and baseline salivary pepsin was higher when compared to those who did not achieve symptom response 145.0 ng/mL vs. 34.6 ng/mL, p=0,01). Additionally on manometry individuals with symptom response typically had a lower separation between the LES and crural diaphragm. Individuals are less likely to have relief of symptoms are those who have abdominal obesity, a large hiatal hernia, and reflex with an associated cough for those who use “PPI therapy and/or an external UES compression device”. At the 3-month follow-up, 14 individuals (67%) were utilizing UES compression device; seven discontinued for intolerance (4, 57%), poor symptom control (2, 29%), and rash (1, 14%). Limitations of this study included the lack of a concurrent control group, risk of imprecision due to small sample size, and unclear durability of effects due to lack of long-term follow-up.

In 2016 Slivers et al conducted a single arm, study assessing the safety and effectiveness of the UES Assist Device in individuals with extraesophageal reflux (EER). Ninety-five individuals with an RSI of 13 or more were included study. The individuals wore the UES Assist Device for 4 weeks. When compared to baseline [25.6 (21.0-30.0)], the median RSI at 2- and 4-weeks [12.5 (8.0-20.0) and 10.0 (5.8-16.5) was reduced. Adverse outcomes were generally mild and included hoarseness, throat clearing, excess mucus, difficult swallowing, coughing, lump in throat, heart burn. Limitations of this study included the lack of a concurrent control group, risk of imprecision due to small sample size, and unclear durability of effects due to lack of long-term follow-up.

Section Summary: Upper Esophageal Sphincter Assist Device

The evidence includes 2 single-arm studies for an upper esophageal sphincter assist device. Although both studies showed improvement in RSI score the longest reported follow up was at three months. At that time only 67% (14 of the 31) were wearing the UES. RCTs are needed that evaluate health outcomes in larger patient populations with longer follow up to support the safety and efficacy of these devices.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery

In 2019, an update to the 2013 joint guidelines were published by the American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE/ASM/Obesity Society) regarding the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient. Recommendations regarding which patients should be offered bariatric surgery indicated the following:

- "Patients with the following comorbidities and BMI $\geq$ 35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; GERD; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life." (Grade C, Weak Recommendation)

American Gastroenterological Association (AGA)

In June of 2023 the AGA provided an update on the Diagnosis and Management of Extraesophageal Gastroesophageal Reflux Disease: Expert Review

- "Alternative treatment methods to acid suppressive therapy (e.g., lifestyle modifications, alginate containing antacids, external upper esophageal sphincter compression device, cognitive behavioral therapy, neuromodulators) may serve a role in management of [extraesophageal reflux (EER)] symptoms" (p. 1415).
- "Shared decision-making should be performed before referral for anti-reflux surgery for EER when the patient has clear, objectively defined evidence of GERD. However, a lack of response to PPI therapy predicts lack of response to anti-reflex surgery and should be incorporated into the decision process."

In March of 2022 the American Gastroenterological Association (AGA) issued updated guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease which included the following recommendations:

Table 2: Surgical and Endoscopic Options for GERD

Recommendation	GRADE Quality of Evidence	GRADE Strength of Recommendation
We recommend antireflux surgery performed by an experienced surgeon as an option for long-term treatment of patients with objective evidence of GERD. Those who have severe reflux esophagitis (LA grade C or D), large hiatal hernias, and/or persistent, troublesome GERD symptoms who are likely to benefit most from surgery.	Moderate	Strong
We recommend consideration of RYGB as an option to treat GERD in obese patients who are candidates for this procedure and who are willing to accept its risks and requirements for lifestyle alterations.	Low	Conditional

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	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
	1013T	Laparoscopy, surgical, implantation or replacement of lower esophageal sphincter neurostimulator electrode array and neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver, including cruroplasty and/or electronic analysis, when performed
	1014T	Laparoscopic revision or removal, lower esophageal sphincter neurostimulator electrodes
	1015T	Revision or removal, lower esophageal sphincter neurostimulator pulse generator or receiver
	1016T	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter neurostimulator pulse generator/transmitter; intraoperative, with programming

Codes	Number	Description
	1017T	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter neurostimulator pulse generator/transmitter; subsequent, without reprogramming
	1018T	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter neurostimulator pulse generator/transmitter; subsequent, with reprogramming
HCPCS		
	E1399	Durable medical equipment, Miscellaneous
Type of Service	Device/ Surgery	
Place of Service	Outpatient / Inpatient	

POLICY HISTORY

Date	Reason	Action
March 2026	Annual Review	Policy Renewed
March 2025	Interim Review	Policy Renewed
December 2024	Annual Review	Policy Renewed
December 2023	Annual Review	Policy Revised, Content split into additional policies 07.01.99 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD), 01.01.38 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)
October 2022	Annual Review	Policy Revised
October 2021	Annual Review	Policy Revised

Date	Reason	Action
October 2020	Annual Review	Policy Revised
November 2019	Annual Review	Policy Revised
October 2018	Annual Review	Policy Revised
October 2017	Annual Review	Policy Revised
October 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised
July 2013	Annual Review	Policy Renewed
August 2012	Annual Review	Policy Renewed
December 2010	Interim Review	Policy Revised

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

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