Anthem

Medical Policy

Subject: Lower Esophageal Sphincter Augmentation Devices for the Treatment of Gastroesophageal Reflux Disease (GERD)
Document #: SURG.00131 **Publish Date:** 09/27/2023
Status: Reviewed **Last Review Date:** 08/10/2023

Description/Scope

This document addresses the use of non-endoscopic devices intended for the treatment of gastroesophageal reflux disease (GERD), including the LINX® Reflux Management System (Johnson and Johnson, New Brunswick, NJ). Such devices are surgically implanted in the vicinity of the lower esophageal sphincter (LES) to support and augment the function of the LES, with the goal of decreasing or stopping gastroesophageal reflux. This document does not address transendoscopic therapies for the treatment of GERD.

Note: Please see the following related documents for additional information:

- SURG.00047 Transendoscopic Therapy for Gastroesophageal Reflux Disease, Dysphagia and Gastroparesis
- CG-SURG-101 Ablative Techniques as a Treatment for Barrett's Esophagus

Position Statement

Investigational and Not Medically Necessary:

Lower esophageal sphincter augmentation devices are considered **investigational and not medically necessary** for the treatment of gastroesophageal reflux disease (GERD) and for all other indications**.**

Rationale

LES augmentation devices are designed to address the limitations of fundoplication. The LINX Reflux Management System is a United States (U.S.) Food and Drug Administration (FDA) cleared LES augmentation device with the following labeled indication: "for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximal medical therapy for the treatment of reflux." The LINX device received FDA pre-market approval (PMA) on March 22, 2012. The device received approval for 4 years. Continued approval of the PMA was contingent upon the annual reporting of the number of devices sold and adverse events. In addition, the manufacturer was required to conduct two post-approval studies. These studies were requested to evaluate the long-term effectiveness of the device and incidence of adverse events. The first study, a 5-year extension of the PMA Investigational Device Exemption (IDE) cohort was published in 2016 (Ganz, 2016). The second, which is still underway, is a multi-center, prospective, new enrollment, observational study, also to be conducted over 5 years. Preliminary results, at 1-year follow-up, have been published (Louie, 2019). The peer-reviewed literature on LES augmentation devices is largely dominated by case series without a control group and non-randomized comparative trials (LINX vs medical therapy or Nissen fundoplication) with relatively short-term follow-up. These studies reported before and after results on safety and efficacy, including pH studies, resolution of GERD symptoms and quality of life (QOL) in individuals with uncomplicated GERD (Bonavina, 2008; Bonavina, 2010; Ganz, 2013; Ganz, 2015; Lipham, 2012; Rona, 2018; Schwameis, 2014; Smith 2014).

A relatively large uncontrolled case series was published by Ganz and colleagues (2013), reporting the results of 98 subjects who received the LINX device. Subjects were followed for 3 years and complete data was available for 85 subjects (87%). Those eligible had a minimum of a 6-month history of GERD, a partial response to proton pump inhibitors (PPIs), and a pathologic esophageal acid exposure; they did not have a hiatal hernia greater than 3 cm, grade C or D esophagitis according to the Los Angeles classification, body mass index (BMI) greater than 35, Barrett's esophagus or a motility disorder. Individuals enrolled served as their own control. No intraoperative complications were reported. The primary endpoint of at least a 50% reduction in esophageal acid exposure was achieved in 67% of subjects. Serious adverse events were seen in 6 subjects; 3 required removal of the device due to persistent dysphagia that subsequently resolved, 1 required removal for intermittent vomiting that did not resolve following device removal, and 2 subjects required hospitalization due to vomiting, which resolved with conservative therapy. An additional 2 subjects had their devices removed, 1 due to persistent reflux symptoms and the other for persistent chest pain. The authors did not include these 2 subjects in the adverse events population, and the reason for this is unclear. The most frequent adverse event was dysphagia, which occurred in 68% of subjects and was noted in 11% of subjects at 1 year, 5% at 2 years and 4% at 3 years. Esophageal dilation was conducted in 19 subjects, with 16 reporting subsequent improvement. Esophagitis, which was noted in 40% of subjects at baseline, was reported to be 12% at year 1 and 11% at year 2; results of this measure were not provided for year 3. The development of new grade A esophagitis was reported in 4 subjects at 2 years and 2 subjects reported the inability to belch or vomit at the 3-year endpoint. No erosions or device migrations were reported. FDA pre-market approval was based on this study.

A total of 85 individuals from the original trial were available for inclusion in the 5-year extension trial mandated by the FDA's 2012 pre-market approval (Ganz, 2016). Enrollees were evaluated for changes in QOL, reflux control, use of PPIs and side effects. Predetermined post-approval efficacy endpoints included the following: at least 50% of individuals achieving at least a 50% reduction in the Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) score without the use of PPIs, and at least a 50% reduction in at least 60% of participants in the dose of PPI. Both endpoints were achieved; 83% had a reduction in GERD-HRQL (95% confidence interval [CI], 73 to 91%) and 89% reduced their daily use of PPI (95% CI, 81 to 95%). Over the course of the 5-year follow-up, no device erosions, migrations or malfunctions were reported. A total of 76.5% (26 of 34) experienced healing of the esophagus during the study period and 10% who did not have esophagitis developed it (5 of 48). All study participants reported the ability to belch and vomit and there was no significant change from baseline in the proportion of enrollees who reported bothersome swallowing. Constipation and nausea/vomiting were reduced (p=0.008, p=0.003, respectively). The rate of device removal was 7% (n=7) over the 5-year study period. A total of 6 of the removals were described above in the original trial and the 1 subsequently occurring removal was due to an additional case of persistent dysphagia; 3 individuals received Nissen fundoplication following device removal. A limitation of this study is the lack of a randomly assigned control group receiving standard of care (PPIs or Nissen fundoplication), study sponsorship, and a 15% loss to follow-up at 5 years. While similar improvements in GERD-symptoms were reported at 1 year of follow-up in the additional FDA-mandated, 5-year, post-approval study, the same limitations are present in this cohort of 200 individuals in which 2.5% (n=5) have already experienced complications necessitating device removal (Louie, 2019).

Results from another large, prospective case series conducted at a single center were published by Bonavina and colleagues (2013). A total of 100 participants were enrolled. The median follow-up period was also 3 years (range, 378 days - 6 years) and during that

time no device complications such as erosion or migration were reported but 3 participants had their device removed for persistent GERD, and painful or difficult swallowing. Statistically improved outcomes after device placement included total acid exposure time ($p<0.001$) and GERD QOL scores ($p<0.001$). In addition, daily dependence on PPIs was no longer necessary in 85% of the study participants. Limitations of this study design included a small sample size, lack of a randomized control group and a relatively short follow-up period for an implanted device.

Several small studies were published in 2014 with short (6 months or less) follow-up periods which preclude the ability to draw safety and efficacy conclusions from their data. Louie and colleagues (2014) reported results of a small, retrospective case-control study evaluating 66 consecutive participants who were treated with the LINX device, with an indirect comparison to a retrospective population of those undergoing a laparoscopic Nissen fundoplication. At 6 months follow-up, there were no significant differences between the two groups in terms of symptoms of heartburn, regurgitation, cough, aspiration, chest pain, throat clearing, QOL and hoarseness; both groups reported significant improvements in these measures compared to baseline values. This study's limitations included the retrospective study design, small sample size, and short follow-up. Results of another prospective observational study were published by Reynolds and colleagues (2014). A total of 67 participants were implanted with the LINX device. Median follow-up was limited to only 5 months and there was no control group in this small cohort. Schwameis and colleagues (2014) published prospective observational data from 23 subjects that received the LINX device and were followed for just 4 weeks postoperatively.

In 2014, a larger prospective, multi-center, observational study was conducted by Riegler and colleagues. A total of 202 individuals had LES augmentation devices (LINX) implanted and 47 had laparoscopic fundoplication performed. The fundoplication group was of advanced age, had a higher frequency of large hiatal hernias and Barrett's esophagus, compared to the LES augmentation device group ($p<0.001$). Improvement in severity of regurgitation ($p=0.014$), discontinuation of PPIs ($p=0.009$), excessive gas and abdominal bloating ($p<0.001$), and ability to vomit if need be ($p<0.001$), were significantly better in the LES augmentation device group versus the fundoplication group. Although the study outcomes appear to favor LES augmentation, limitations of the trial include the lack of randomization, poorly matched controls, observational design and the 249 participants were recruited across 22 medical centers in four countries. Furthermore, the follow-up of only 1 year is inadequate to definitely determine the safety and efficacy of an implanted device.

Lipham and colleagues (2014) conducted a safety analysis of the LINX device. Safety of the first 1000 individuals implanted with the LINX device was reported. Retrospective data regarding adverse events was obtained from the published medical literature, the Manufacturer and User Facility Device Experience (MAUDE) database, and information provided by the device manufacturer. The median time since device implantation was under 1 year (274 days). A total of 111 adverse events occurred in 82 individuals at 26 medical centers. The rate of adverse events was as follows: 0.1% intra/perioperative complications; 1.3% readmission rate; 5.6% esophageal dilation; 3.4% reoperation to remove device; and 0.1% device erosion. Dysphagia was cited as the most common reason for device removal (2.2%). Informally tracked data was only available for a portion of individuals who required device removal. A total of 10 of 36 individuals had a fundoplication procedure performed at the time of device removal or later. Median time to removal was 94 days (range, 6-1302). With one exception, all readmissions occurred within 90 days following surgery, and readmission was primarily due to dysphagia, pain, nausea, and vomiting. There were no device migrations, and 1 individual (0.1%) experienced erosion of the device into the esophageal lumen. While the MAUDE database purports safety of the LINX, the study's limitations, such as retrospective design, short duration since device implantation and the potential for pertinent safety data to be underreported, impact the reliability of conclusions drawn.

In 2015, the first comparative study was published by Sheu and colleagues. This small clinical trial was conducted at a single institution and enrolled 24 matched case-control participants into one of two study arms; LINX ($n=12$) and fundoplication ($n=12$). Matching was based on age, gender, GERD severity, body mass index and hiatal hernia size. The average follow-up period was 7 months and although several outcome measures differed between the two study arms, only differences in one measure reached statistical significance; 50% ($n=6$) of LES augmentation device recipients experienced persistent, severe dysphagia that required post-operative endoscopic dilation, while none from the fundoplication arm required such intervention. Endoscopic dilation resolved all but 1 case of severe dysphagia from the LES augmentation device arm. From this relatively small, comparative study authors concluded that although the interventions performed similarly in the immediate peri-operative period, post-operative dysphagia after LES augmentation device implantation was more severe, longer in duration and more frequently required intervention compared to fundoplication.

Reynolds and colleagues (2015a) published the results of a single-institution, retrospective, non-randomized controlled trial of 50 subjects who underwent treatment with the LINX device compared to 50 propensity-matched subjects who received laparoscopic Nissen fundoplication. At 1 year after surgery, the authors reported that both groups had similar GERD Health Related QOL scores ($p=0.897$) and PPI use ($p=0.355$). There were no differences in the number of subjects reporting mild gas and bloating ($p=1.000$); however, no LINX group subjects reported severe gas and bloating while the fundoplication group reported a 10.6% incidence ($p=0.022$). The ability to belch (8.5% vs. 25.5%; $p=0.028$) or vomit (4.3% vs. 21.3%; $p=0.004$) was significantly lower in the LINX group compared to the fundoplication group. The clinical significance of this is unclear. The incidence of postoperative dysphagia and the number of subjects requiring dilation was similar between the groups ($p=0.766$ and $p=0.554$, respectively). Post-operative complications within 30 days occurred in 2 fundoplication subjects and no LINX subjects. No device removals or erosions were reported at 1 year for the LINX group. This study demonstrated good results for the LINX group compared to fundoplication; however, its study design does not allow any conclusions regarding non-inferiority due to the small study population and retrospective design.

This same group (Reynolds, 2015b) reported the results of another single-institution retrospective non-randomized controlled trial of 52 subjects who underwent treatment with the LINX device compared to 67 subjects who received Nissen fundoplication. The authors reported that complete data at follow-up was available for 92% (48/52) of LINX subjects and 88% (59/67) of fundoplication subjects. At the 1-year follow-up, the mean GERD-HRQL was 4.3 for LINX group compared to, 5.1 for fundoplication subjects ($p=0.47$) and 85 % of LINX subjects compared to 92 % of fundoplication subjects were free from use of PPIs ($p=0.37$). Fewer gas bloat symptoms were reported in the LINX group compared to the fundoplication group (23% vs. 53 %; $p\leq0.01$) as was the inability to belch (10% vs. 36%; $p\leq0.01$) and vomit (4% vs. 19%; $p\leq0.01$). Mild-to-moderate dysphagia was reported in 46% of LINX subjects and 56% of fundoplication subjects, and severe dysphagia was reported in no LINX subjects and 5% of fundoplication subjects ($p=0.25$). The number of subjects requiring dilation for persistent dysphagia was similar between groups (9 LINX subjects and 8 fundoplication subjects, $p=0.22$). At 30 days, 2 complications were reported, both in the LINX group. The first complication involved intractable vomiting which was resolved with inpatient hydration and care. The second involved an impacted food bolus requiring endoscopic removal.

This group published a third retrospective non-randomized controlled trial in 2015 (Warren, 2015). Unlike the prior studies discussed above, this study involved data from three high-volume institutions and involved 201 subjects who underwent treatment with the LINX device compared to 214 subjects who received Nissen fundoplication. The subjects included in the fundoplication group all met inclusion criteria for LINX placement, but were excluded for various factors. A subgroup of 254 subjects, 169 from the LINX group and 185 from the fundoplication group, had full 1-year follow-up data. The authors reported that the LINX group subjects had lower BMI ($p=0.05$), were less likely to have preoperative dysphagia ($p=0.008$), had lower DeMeester scores ($p=0.03$), had lower rates of Barrett's esophagus ($p=0.001$), were less likely to have hiatal hernia ($p=0.001$), and when hiatal hernia was present, the LINX

subjects had significantly less severe Hill grades versus the fundoplication group. A total of 4 subjects were reported to have major 30-day post-operative comorbidities, with 1 LINX subject having gastroesophageal junction obstruction requiring removal of a crural stitch. The other 3 were in the fundoplication group and included 1 subject with gastroesophageal junction obstruction requiring revision surgery and 2 retroesophageal abscesses associated with the placement of biological mesh. Device removal was required in 2 LINX subjects due to recurrence of hiatal hernia. One of these subjects was reverted to fundoplication at 13 months due to continued symptoms. This subject was later reported to require additional treatment at 20 months for dysphagia. This subject was found to have esophageal erosion with magnetic beads in the esophageal lumen. The device was removed and a full recovery was reported at 90 days. Both groups had significant improvements in GERD-HRQL, with no differences between groups (p=0.17). While the overall rate of dysphagia was similar, the LINX group was reported to have a higher rate of mild dysphagia (p=0.20).

In 2013, The American Society for Gastrointestinal Endoscopy (ASGE) published a Technology Review on “Magnets in the Gastrointestinal Tract.” In reference to the LINX device, the conclusion states, “Long-term data about the safety and efficacy of the Linx device are needed.” The review contains no recommendation to use the LINX device or similar technology at this time. In the same year, the American College of Gastroenterology (ACG) released updated guidelines on the Diagnosis and Management of GERD, which included the following statement in reference to the LINX device, “More data are required before widespread usage can be recommended” (ACG, 2013).

In 2017, Skubleny and colleagues conducted a systematic review and meta-analysis of LINX compared to fundoplication as a treatment for GERD. In total, three primary studies were identified of 688 individuals; 237 had undergone Nissen fundoplication and 415 received the LINX device. The LINX device was found to be statistically better than fundoplication in preserving individuals’ ability to belch (95.2 vs. 65.9%, p<0.00001) and ability to emesis (93.5 vs. 49.5%, p<0.0001). There was no statistically significant difference found between LINX and fundoplication in gas/bloating (26.7 vs. 53.4%; p=0.06), postoperative dysphagia (33.9 vs. 47.1%; p=0.43) and PPI elimination (81.4 vs. 81.5%; p=0.68). While the outcomes are promising, the trials of LINX included in the analysis are described elsewhere in this guideline and thus reflect the previously mentioned limitations including inadequate length of follow-up (only 12-month follow-up data included) and no head-to-head comparison with the gold standard, Nissen fundoplication, thus comparability between recipients of LINX versus fundoplication remains poorly understood.

Another meta-analysis by Chen and colleagues (2017) similarly examined the differences in LINX and fundoplication as a treatment for GERD. This analysis included four trials of 624 participants. While the LINX device had a shorter operative time (p=0.001) and length of stay (p=0.005), no statistically significant differences were found in individuals’ ability to belch or vomit, PPI use, or severe dysphagia. Those who received the LINX device were found to have less incidences of gas or bloating (Risk Ratio [RR]=0.71; 95% CI, 0.54-0.94; p=0.02). Given the previously mentioned limitations regarding data on the LINX device and divergent outcomes in this meta-analysis and Skublenv and colleagues analysis (2017; described above), further research is warranted regarding the safety and efficacy of the LINX device relative to fundoplication.

Similarly, Aiolfi and colleagues (2018) published results of a systematic review and meta-analysis comparing the efficacy and safety of the LINX device compared to Nissen fundoplication and Toupet fundoplication. Overall, 686 individuals who underwent placement of the LINX device and 525 who underwent laparoscopic fundoplication were included from seven observational cohort studies. Dysphagia necessitating endoscopic dilatation was reported in 9.3% of LINX implantations and 6.6% of those who underwent fundoplication (Odds Ratio [OR], 1.56; 95% CI: 0.61-3.95; p=0.119). The pooled OR of gas/bloat symptoms, ability to vomit, and ability to belch were 0.39 (95% CI: 0.25 to 0.61; p<0.001), 10.10 (95% CI: 5.33 to 19.15; p<0.001), and 5.53 (95% CI: 3.73 to 8.19; p<0.001), respectively. Reoperation rates were not significantly different and there are no reported outcomes on the rates of migration of the LINX device. The postoperative GERD-HRQL survey results were similar (p=0.101) between the two interventions. Although authors conclude that both procedures are safe and effective, the limitations of the previously described meta-analyses remain, there are no randomized trials included in this analysis and follow-up is inadequate at just 1 year post-procedure.

In March 2017, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee (TAVAC) conducted an updated Safety and Effectiveness Analysis for the LINX Reflux Management System and concluded:

With regards to safety:

- Safety analyses suggest the LINX procedure was associated with few serious adverse events and no reported mortality.
- The most common anticipated side effect was acute dysphagia.
- The reported rate of erosion is in the range of 0.1% to 0.2%. The published literature on erosions suggests that the device can be safely removed endoscopically or laparoscopically without serious adverse outcomes.
- Some devices require removal, most often for recurrent GERD or persistent and/or severe dysphagia.
- No new patterns of failure or complications have been reported in long-term follow-up.
- Longer-term follow-up supports the FDA conclusion that the device is safe.

With regards to efficacy, the panel concludes:

- LINX implant results in pH normalization, improved quality of life, and complete cessation of regular PPI use on a consistent basis. The ability to belch and vomit is maintained following implantation of LINX, and de novo moderate-severe gas-bloat is uncommon.
- When compared to laparoscopic fundoplication, rates of success in alleviating GERD symptoms and dysphagia are similar following LINX. Bloating side effects may be lower.
- Longer-term follow-up data demonstrates that the LINX Reflux Management System is effective in the management of GERD.

Despite SAGES conclusions, controlled studies, preferably prospective and randomized in design, which directly compare LINX with either fundoplication or maximal medical therapy, in those who would be considered candidates for LINX, are warranted.

In 2018, a large, retrospective study was conducted to evaluate the rate of device migration in 9453 individuals who were implanted with the LINX device from 2007 through 2017. Data was reviewed from the manufacturer as well as the MAUDE database. Over the study period, a total of 29 cases of erosion were reported with a median time to occurrence of 26 months, the majority occurred between 1 and 4 years following device placement; the study did not report the proportion of device recipients who had the device implanted for 5 or more years, if any. Smaller devices were more likely to experience erosion; the rate of erosion was 4.93% in the 12-bead devices and 0 occurrences occurred in the larger devices (16 to 17 beads). Notably, the 12-bead device, which was associated with 18/29 (62%) of erosions, is no longer available for implantation. All 29 devices that necessitated removal were explanted without complication and 24 individuals returned to baseline within 2 months; 4 continued to have mild dysphagia. From this large, retrospective study the rate of device migration was determined to be 0.3% after 4 years. Efficacy of resolution of GERD-related symptoms was not evaluated in this study (Alicuben, 2018). A similar but smaller study published in 2017 (n=3283) also investigated outcomes of LINX implantation in individuals from the MAUDE database. The median duration of implant was just 1.4 years. No

deaths, life-threatening events, perforations or device malfunctions were reported and the overall removal rate was 2.7% (89/3283). The rate of erosion was 0.15% and no devices reportedly migrated. Only safety, not efficacy was reported in this retrospective study (Smith, 2017).

In 2018, an expert panel was convened to assess management options for individuals with GERD refractory to PPIs. A total of 14 esophagologists applied the RAND/UCLA Appropriateness Method to evaluate management options in the context of nine hypothetical scenarios of individuals with GERD refractory to medical therapy. According to the publication, "An appropriate intervention is one in which the expected health benefit exceeds the expected negative consequences by a sufficiently wide margin that the procedure is worth doing, exclusive of cost." The appropriateness of laparoscopic fundoplication, the LINX device, transoral incisionless fundoplication, radiofrequency energy delivery and pharmacologic/behavioral therapy were each evaluated in the context of the hypothetical scenarios. The majority of panelists agreed that the LINX device would be an inappropriate management strategy in seven of the nine scenarios. An 'equivocal rating with disagreement' (15% agreement) was given in the setting of breakthrough acid (elevated esophageal acid exposure [EAE] > 6.0%) with large hiatal hernia (> 3 cm) in this scenario, and the majority (77%) agreed that implantation of the LINX device would be appropriate in the setting of breakthrough acid (EAE > 6.0%) with a small/absent hiatal hernia ($\leq$ 3 cm). Despite the majority agreement amongst panelist members in the setting of breakthrough acid and absence of a large hiatal hernia, no evidence is provided in support of the practice management decisions and 50% (n=7) panelists report having received industry support from the manufacturer of the LINX management system, 2 of which are consultants for the company (Yadlapati, 2018). Randomized control trials with long-term follow-up and unbiased, evidence-based recommendations are warranted to consider implantation of the LINX device over fundoplication, the established gold standard of treatment for refractory GERD.

In 2018, a randomized clinical trial was conducted comparing the LINX procedure to PPI therapy. In total, 152 individuals with persistent moderate-to-severe GERD, despite once-daily PPI therapy, were prospectively enrolled and randomized 2:1 to receive twice-daily PPI therapy (20 mg omeprazole BID; n=102) or the LINX device (n=50). Eligible participants were 21 years of age or older and actively seeking alternative, surgical therapy for refractory GERD following at least 8 weeks of once-daily PPI. Additional inclusion criteria included a BMI of < 35, abnormal pH testing, normal esophageal motility, and absence of hiatal hernia > 3 cm, Barrett's Esophagus or LA Classification Grade C or D esophagitis. At 6 months following randomization, endpoints assessed included QOL surveys related to GERD, and participants underwent 24-hour impedance-pH testing by a blinded laboratory assessment. The primary endpoint was the percentage of participants in each study arm that achieved elimination of moderate-to-severe GERD at 6 months. In the intention-to-treat population, 89% (42/50) of those in the LINX arm achieved resolution of GERD-related symptoms whereas only 10% (10/102) of those in the medical therapy arm achieved resolution ($p<0.001$). Impedance-pH testing was shown to control reflux significantly better in the LINX arm than the medical therapy arm ($p<0.001$). A total of 15 participants (32%) reported dysphagia in the LINX arm, 9 (19%) of which were reportedly mild, 4 (9%) were moderate and 2 (4%) experienced severe dysphagia. No devices were removed by the end of 6 months (Bell, 2019). Safety and efficacy of the LINX device at just 6 months is an inadequate length of follow-up to fully assess an implantable device.

In 2020, Bell and colleagues published 1-year follow-up data from the above-mentioned randomized clinical trial. Overall, enrolled individuals remaining in the LINX arm (n=44) and those who crossed over to the LINX arm after PPI therapy (n=31) had similar outcomes. At study-end, study investigators reported 96% (72/75) of LINX device recipients achieved control of regurgitation, whereas only 8/43 study participants receiving PPIs-only (19%) reported similarly. A total of 61 of 75 (81%) in the LINX cohort reported improvements in GERD HRQL scores (>50%) and 68 (91%) achieved discontinuation of daily PPI use. The prevalence of dysphagia, bloating, and esophageal acid exposure time decreased significantly in the LINX cohort over the study period. Complete elimination of regurgitation was reported in 73% (n=51 of 75) after LINX implantation and 2% of PPI-only participants ($p<0.001$). No improvement in GERD HRQL or heartburn scores was seen in the PPI-only cohort. In this 1-year trial with randomized, cross-over design, implantation of the LINX device was not associated with adverse operative events such as device explants, erosions, or migrations. Long-term outcomes with sustained robust numbers and a comparator group that is comparable to the interventional arm is warranted. In this study, the PPI-only group was not eligible for LINX implantation due to reasonably controlled GERD with PPI's alone; as such, the PPI dose was dropped to the minimum therapeutic dose for the remaining 6 months of the study, likely reducing the therapeutic effect of PPI's being achieved in this cohort.

A retrospective study sought to characterize the incidence of postoperative dysphagia after placement of the LINX device for persistent GERD. In total, 380 individuals were enrolled and followed for an average of 11.5 months. At study-end, 88.5% were satisfied (at least a 50% improvement in the total GERD-HRQL score), 93.3% were no longer using PPIs, 76.2% had normalization of distal esophageal acid exposure, and the average GERD-HRQL score improved significantly from baseline (33.7 vs. 7.9; $p<0.001$). While reports of immediate postoperative dysphagia were relatively common (n=240; 63.2%), persistent dysphagia was reported in 59 subjects (15.5%; preoperative dysphagia was 35%; $p<0.001$). Esophageal dilation was performed in 116 subjects (31%); of these, only 46 (49.5%) experienced resolution of symptoms. A second dilation was performed in 55 (47.4%) subjects. Overall, after receipt of 1 to 5 dilations, just 78 (67%) of subjects responded to this intervention and 7 (1.8%) ultimately required device removal due to persistent dysphagia. An additional 7 subjects also underwent device removal for reasons unrelated to dysphagia. Interestingly, logistic regression suggests that absence of a large hiatal hernia resulted in a decreased likelihood of experiencing persistent dysphagia. Significant preoperative dysphagia and less than 80% peristaltic contractions of esophageal smooth muscle were related to an increased likelihood of persistent dysphagia. This study adds to the body of evidence demonstrating the relatively high frequency of persistent dysphagia following implantation of the LINX device and characterizes some of the potentially contributory risk factors. Further investigation is warranted in the setting of a prospective clinical trial, especially evaluating the impact of large hiatal hernias on clinical and HRQL outcomes as the results of this study are contradictory to previous findings (Ayazi, 2020b).

In 2020a, Ayazi and colleagues conducted another retrospective study of 553 individuals implanted with magnetic sphincter augmentation (MSA [i.e., LINX device]) and followed for 10 months. At study end, 92.7% no longer relied on PPIs, 84% of study participants reported a 50% or better improvement in GERD-HRQL scores and the mean baseline score was improved from a value of 33.8 to 7.2 ($p<0.001$). Normalization of esophageal acid exposure was achieved in 76.1% of MSA recipients.

In 2019, Guidozzi and colleagues published results of a systematic review which sought to evaluate clinical outcomes following LINX implantation in comparison with laparoscopic fundoplication. A meta-analysis was performed to characterize differences in postoperative PPI use, GERD-HRQOL, gas bloating, ability to belch, dysphagia, and reoperation. The study included 6 comparative studies of LINX versus fundoplication and 13 single-cohort studies. Following LINX implantation, 13.2% required postoperative PPI therapy, 7.8% dilatation, 3.3% device removal or reoperation, and 0.3% experienced esophageal erosion. There was no significant difference between postoperative PPI dependence, GERD-HRQOL score, dysphagia or reoperation. LINX implantation was associated with significantly less gas bloating (OR=0.34; 95% CI, 0.16–0.71) and a greater ability to belch (OR=12.34; 95% CI, 6.43–23.7). Authors conclude that, "There is an urgent need for randomized data directly comparing fundoplication with MSA for the treatment of GERD to truly evaluate the efficacy of this treatment approach."

In 2020, Bonavina and colleagues published a prospective observational trial that enrolled 631 individuals with GERD refractory to daily PPI use. Subjects and clinicians discussed antireflux surgical options and decided upon LINX or fundoplication on an individual basis. Clinicians reserved the liberty of switching the previously agreed upon procedure mid-operation if upon commencement it appeared anatomically complex or unsafe. Ultimately, 465 LINX devices were implanted and 166 fundoplications performed (62%

Nissen fundoplication, 31% Toupet fundoplication and 7% “other/unspecified” procedures). Both LINX and fundoplication resulted in improvements in total GERD-HRQL score (mean reduction in GERD-HRQL from baseline to 3 years: LINX 22.0 to 4.6 and fundoplication 23.6 to 4.9) and in satisfaction (GERD-HRQL satisfaction increase from baseline to 3 years: LINX 4.6% to 78.2% and fundoplication 3.7% to 76.5%). Both procedures preserved the ability to belch at 3 years post-surgery for most study participants (97.6% vs 91.7% for LINX and fundoplication, respectively). A higher percentage of participants preserved the ability to vomit in the LINX group (91.2% vs 68.0%). From baseline to 3 years post-surgery, PPI usage declined similarly for both groups (LINX: 97.8% to 24.2% and fundoplication: 95.8% to 19.5%). The average procedure time was shorter for LINX implantation and complication rates were similarly low for both procedures (≤ 2%). Surgical intervention post procedure was 2.4% for the LINX group (11) and 1.9% (3/166) for the fundoplication group. Select measures were more favorable in the fundoplication cohort at varying time points throughout the study, such as less GERD interfering with sleep (5.5% vs 11.7% at 24 months) and lower use of PPIs (19.5% vs 24.2% at 36 months). In this trial, the fundoplication cohort’s comparability was not optimal with participants in that cohort reporting substantially lower HRQL and worse symptoms from GERD at baseline, further complicating head-to-head comparison of the interventions. Long-term studies of gold standard Nissen fundoplication’s (versus a variety of fundoplication techniques) to LINX implantation in a randomized cohort trial is warranted.

In 2020, Ferrari and colleagues published results from a single-center, retrospective, single-arm study. Analysis was performed in a cohort of 124 individuals followed for 6 to 12 years. GERD, use of PPIs, and esophageal pH monitoring parameters were compared to subjects’ own preoperative data. Positive outcome of the LINX procedure was defined as ≥ 50% improvement in GERD HRQL score from baseline and discontinuation of PPIs. The average GERD-HRQL score significantly improved from 19.9 to 4.01 ($p<0.001$), and PPIs were discontinued by 79% of the cohort. Normalization of pH was achieved in 89% of study participants. Independent predictors of a favorable outcome were less than 40 years old at the time of device implantation (OR 4.17) and baseline GERD-HRQL score > 15 (OR 4.09). The need for prospective, long-term, comparative study remains.

Between January 2013 and January 2020 an estimated 30,000 LINX devices were implanted worldwide. DeMarchi (2021) and colleagues published results of all surgical device explants from the Manufacturer and User Facility Device Experience (MAUDE) and Ethicon’s complaint databases. Overall, the 7-year cumulative risk of removal was 4.81% (95% CI, 4.31-5.36%) and erosion was 0.28% (95% CI, 0.17-0.46%). Device size was significantly associated with removal ($p<0.0001$), with smaller sizes being more likely to be explanted. The primary reasons for device removal were dysphagia/odynophagia (47.9%) and persistent GERD (20.5%). This study did not include efficacy or comparative data.

A systematic review included 35 studies comprised of 2511 subjects who received the LINX device for refractory GERD. While PPI cessation rates neared 100%, the incidence of dysphagia ranged from 6% to 83% with 8% resulting in dilation. While authors conclude that the LINX device has potential, the study also acknowledged the gap in long-term results (Schizas, 2020).

In 2021, Zhuang and colleagues conducted a systematic review and meta-analysis to determine the efficacy and safety of MSA using the LINX device. The authors searched for studies comparing the efficacy of MSA compared to PPIs or fundoplication. A total of 14 studies, including 3 RCTs, comprised of 1138 participants met the criteria for inclusion. Overall, MSA showed superior symptom control relative to PPI (GERD-HRQL improvement = 81% vs 8%; respectively) with a lower risk of gas-bloat syndrome (RR=0.69, 95% CI, 0.51-0.93, $p=0.01$) and better reserved ability to belch (RR=1.48, 95% CI, 0.76-2.86, $p=0.25$) compared with fundoplication. The authors conclude that although MSA demonstrated efficacy and a favorable safety profile, “[w]ell-designed randomized trials that compare the efficacy of MSA with other therapies are needed.”

In 2022, the American Gastroenterological Association (AGA) published a,*Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review.* The update outlines the AGA’s expert opinion on a personalized approach to the diagnosis and management of GERD. The review states:

> The Best Practice Advice statements presented here were developed from expert review of existing literature combined with extensive discussion and expert opinion to provide practical advice. Formal rating of the quality of evidence or strength of recommendations was not the intent of this clinical practice update.

Best Practice Advice # 12 in the update states:

> In patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients.

Bell (2019), previously described, is the only clinical research study cited to support the best practice advice statement.

In 2023, the AGA published a clinical practice update,*Diagnosis and Management of Extraesophageal Gastroesophageal Reflux Disease (GERD)*, with the following recommendation:

> In patients unresponsive to acid suppression, the presence of heartburn and a high burden of acid reflux (acid exposure time >12%) may predict response to surgery. Studies are needed to make meaningful conclusions about magnetic sphincter augmentation or endoscopic therapies for GERD (Chen, 2023).

The need for robust, long-term, randomized trials with head-to-head comparison of LINX to Nissen fundoplication remain. At present, the published evidence remains insufficient to definitively determine that implantation of the LINX device results in improved net health outcomes in individuals with refractory GERD.

Background/Overview

GERD is related to inadequate functioning of the LES (the muscle separating the esophagus from the stomach), which allows the reverse flow of stomach acid into the esophagus, resulting in the symptoms of heartburn. While some degree of heartburn is normal, frequent heartburn occurring more than 2-3 times a week typically requires treatment. Frequent heartburn, which may be accompanied by other symptoms such as regurgitation of stomach acid, chest or stomach pain, pain or difficulty swallowing, the feeling of a lump in the throat, or recurrent pneumonia, are factors that distinguish GERD from normal heartburn. If left untreated, GERD may lead to esophageal ulcers, narrowing of the esophagus (stricture), difficulty swallowing (dysphagia), lung and throat inflammation, and transition of the lining of the esophagus to resemble that of the stomach (Barrett’s esophagus). Barrett’s esophagus has been identified as a potential precursor to esophageal cancer.

The initial treatment of GERD is typically medical therapy with PPIs that function to decrease the production of stomach acid, but do not address the underlying pathophysiology of an incompetent LES. Individuals whose symptoms persist despite maximal doses of PPIs may be considered candidates for surgical therapy, although recent data suggests this is a highly select group of individuals who should be cautiously identified only after extended trials of medical management. In a large randomized trial of 366 veterans with PPI refractory heartburn, only 78 were ultimately eligible for randomization of treatment with surgery or medical therapy (Spechler, 2019). The standard surgical procedure for refractory GERD is a Nissen fundoplication, which seeks to recreate the barrier function of the

sphincter by wrapping a portion of the stomach around its proximal end. Different fundoplication techniques are available, and vary in the circumference of the wrapping. However, the challenge of a fundoplication procedure is to create an effective barrier to reflux without creating obstructive symptoms. Fundoplication procedures are associated with well-known obstructive symptoms, including bloating or the inability to vomit or belch, collectively known as the gas-bloat syndrome.

LES augmentation devices are often considered less invasive than fundoplication and the design is thought to enhance preservation of the natural function of the LES. The LINX device consists of a “necklace” of magnetic beads that are laparoscopically implanted around the esophagus at the gastroesophageal junction. In its resting state, the magnetic beads are closely approximated, thus preventing reflux. However, the pressure of a bolus of food can force the beads apart permitting passage into the stomach, thus, in contrast to a fundoplication, more closely mimicking the action of the inborn LES.

Definitions

Fundoplication: A surgical procedure designed to restore the barrier function of the LES. The most common type of fundoplication procedure is referred to a Nissen fundoplication, which is typically performed laparoscopically.

Gas-bloat syndrome: A recognized complication of a “too-tight” fundoplication procedure that inhibits the ability to belch or vomit, with accumulation of gas in the stomach.

Gastroesophageal reflux disease (GERD): A disease caused by chronic back-flow of acid from the stomach into the esophagus, causing heartburn and leading to irritation and possible damage to the lining of the esophagus.

Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL): Total scores range from 0 to 50, with higher scores indicating worse symptoms.

Los Angeles (LA) classification: Describes four grades of esophagitis severity (A to D), based on the extent of esophageal lesions known as "mucosal breaks."

Lower esophageal sphincter (LES): The sphincter muscle separating the esophagus and the stomach. This muscle serves as a barrier to prevent the reflux of acid into the esophagus. GERD is the result of an incompetent lower esophageal sphincter.

Proton pump inhibitors (PPIs): Group of pharmacological therapies indicated to reduce the production of gastric acid to treat GERD and peptic ulcers.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device
ICD-10 Procedure	
0DV44CZ	Restriction of esophagogastric junction with extraluminal device, percutaneous endoscopic approach [when specified as placement of LES sphincter augmentation device]
ICD-10 Diagnosis	
	All diagnoses, including but not limited to the following:
K21.00-K21.9	Gastro-esophageal reflux disease

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	08/12/2021	MPTAC review. Updated Scope, Rationale, and References sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale, Background/Overview and References sections. Updated Coding section with 10/01/2020 ICD-10-CM changes, added K21.00 replacing K21.0.
Reviewed	08/22/2019	MPTAC review. Updated Scope, Rationale and References sections.
Reviewed	09/13/2018	(MPTAC review. Updated Rationale and Reference sections.
Reviewed	11/02/2017	MPTAC review. Updated Coding, References and Website sections. Updated header language from “Current Effective Date” to “Publish Date.”
Reviewed	11/03/2016	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, Definitions, References and Website sections. Updated Coding section with 01/01/2017 CPT changes.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Revised	05/07/2015	MPTAC review. Clarified investigational and not medically necessary statement. Updated Rationale and Reference sections. Updated Coding section with 07/01/2015 CPT and HCPCS changes; removed C9737 deleted 06/30/2015.
Reviewed	08/14/2014	MPTAC review. Updated Rationale and Reference sections.
	01/01/2014	Updated Coding section with 01/01/2014 HCPCS changes.
Reviewed	08/08/2013	MPTAC review. Updated Rationale and Reference sections.
Reviewed	11/08/2012	MPTAC review. Updated Rationale and Reference sections.
New	05/10/2012	MPTAC initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.