

## Clinical Commissioning Policy Collaborative – Brief Technology Assessment

### AREA: Non-routine Surgical Interventions For Gastro- Oesophageal Reflux Disease (GORD)

<b>Background</b>	<p>The management of gastro-oesophageal reflux disease (GORD) includes life-style changes (such as avoidance of aggravating foods, excess alcohol, weight reduction, smoking cessation, raising the head of the bed), drug treatment (antacids, H2 receptor antagonists, proton pump inhibitors) and in some cases surgery. Patients who have refractory symptoms, develop complications despite medication or experience intolerance to medication may be considered for routine anti-reflux surgery (usually laparoscopic fundoplication).</p> <p>There is some uncertainty about the benefit (long term clinical efficacy and, in some cases, patient safety) of some surgical procedures for GORD. The purpose of this statement is to provide clarification about the commissioning of the following non-routine procedures:</p> <ul style="list-style-type: none"> <li>• Endoscopic radiofrequency ablation* (eg. Stretta)</li> <li>• Laparoscopic insertion of a magnetic titanium ring (eg. Linx)</li> <li>• Endoluminal gastroplication (eg. Esophyx)</li> <li>• Electrical stimulation of the lower oesophageal sphincter (eg. Endostim)</li> <li>• Anti-reflux prosthesis (ARP) (eg. Angelchik)</li> </ul> <p>Please note:</p> <ol style="list-style-type: none"> <li>i. *Endoscopic Radiofrequency Ablation for the treatment of Barrett's oesophagus with biopsy proven low grade dysplasia is available as a recognised treatment for this condition (NICE IPG 496, BSG 2017).</li> <li>ii. The list of non-routine procedures within this statement is not considered exhaustive. The commissioning statement applies to all non-routine procedures and will be reviewed and updated in line with the publication of new or revised evidence.</li> </ol>
<b>Evidence to support the Technology</b>	<p>NICE Clinical Guideline 184 <b>Gastro-oesophageal reflux disease and dyspepsia in adults</b>: investigation and management. (Updated October 2019) advises that laparoscopic fundoplication should be considered for people who have:</p> <ul style="list-style-type: none"> <li>• A confirmed diagnosis of acid reflux and adequate symptom control with acid suppression therapy, but who do not wish to continue with this therapy long term</li> <li>• A confirmed diagnosis of acid reflux and symptoms that are responding to a PPI, but who cannot tolerate acid suppression therapy.</li> </ul> <p>The NICE Interventional Procedures programme has considered the following interventions and determined, based on the available evidence, that these procedures should only be used with special arrangements for clinical governance, consent and audit or research:</p> <p><b>Endoscopic radiofrequency ablation</b> – IPG 461 August 2013 - The evidence on safety is adequate in the short and medium term but there is uncertainty about longer-term outcomes. With regard to efficacy, there is evidence of symptomatic relief but objective evidence on reduction of reflux is inconclusive.</p>

	<p><b>Laparoscopic insertion of a magnetic titanium ring</b> – IPG 585 July 2017 - There are no major safety concerns. There is limited evidence of short-term efficacy, but the evidence of long-term efficacy is inadequate in quality and quantity.</p> <p><b>Endoluminal gastroplication</b> – IPG 404 July 2011 - The evidence raises no major safety concerns. Evidence from a number of RCTs shows a degree of efficacy in terms of reduced medication requirement in the short term, but changes in other efficacy outcomes are inconsistent and there is no good evidence of sustained improvement in oesophageal pH measurements.</p> <p>The NICE IPG review of <b>Electrical stimulation of the lower oesophageal sphincter</b> – IPG 540 December 2015 – states that current evidence on the safety and efficacy is limited in quantity and quality and should therefore only be used in the context of research.</p> <p>NICE has also published guidance on other Interventional Procedures with special arrangements for clinical governance, consent and audit or research.</p> <p>A C-shaped silicon ring fitted as an Anti-Reflux Prosthetic (ARP) device (Angelchik) introduced in 1979 is no longer used due its high rate of complications and dysphagia.</p>
<p><b>Future Pathways of Care</b></p>	<p>Across Herefordshire and Worcestershire none of the non-routine interventions have been undertaken routinely. The existing pathway of care will therefore not change as these alternative interventions are not recommended for local commissioning. The CCG Commissioning Statement will be reviewed and updated in line with any new evidence arising as a result of audit or research.</p>
<p><b>Financial implications arising from new pathway of care</b></p>	<p>Information on the cost of each surgical procedure has not been sourced. The pathway of care has not changed and therefore there are no financial implications arising from this review.</p>
<p><b>Implications</b></p>	<p>The routine commissioning of the reviewed non-routine surgical procedures for the treatment of gastric reflux, would be associated with the following implications and/or issues:</p> <ul style="list-style-type: none"> <li>• Insufficient national policy, guidance or high quality evidence to confidently confirm that these procedures are effective, safe or cost-effective for treating gastric reflux, especially over a long-term basis</li> <li>• Lack of a clearly defined cohort of patients who would be likely to benefit from these procedures i.e. inability to establish eligibility criteria</li> <li>• Unknown impact of undertaking these procedures on existing pathways i.e. referral processes, post-surgical clinical care, ongoing management</li> </ul>
<p><b>CCPC Recommendations</b></p>	<ol style="list-style-type: none"> <li>1. The routine use of any non-routine surgical procedure for Gastro-oesophageal Reflux Disease, with uncertainty relating to efficacy and safety, is not supported in Herefordshire and Worcestershire.</li> <li>2. The Clinical Commissioning Policy Collaborative will reconsider this position should new evidence or national advice become available.</li> </ol>
<p><b>Approved by Herefordshire and Worcestershire Joint Commissioning Collaborative</b></p> <p><b>05/02/2020</b></p>	<p><b>Date to Initiate Review: April 2023</b></p> <p>Documents will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made in light of published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies.</p>