NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Commissioning Policy

Gastroelectrical Stimulation for Gastroparesis

August 2015

This commissioning policy applies to patients within:
South Worcestershire Clinical Commissioning Group (CCG)
Redditch & Bromsgrove Clinical Commissioning Group (CCG)
Wyre Forest Clinical Commissioning Group (CCG)

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Ratified by (name and date of Committee):	The Clinical Executive Teams of: NHS Redditch & Bromsgrove CCG – 02/09/2015 NHS South Worcestershire CCG – 08/09/2015 NHS Wyre Forest CCG – 08/09/2015
Date issued:	08/09/2015
Internal Review Date:	Documents will be reviewed as a minimum every 3 years. However, an earlier revision to the policy will be based on published updates to local and national evidence of effectiveness and cost effectiveness together with recommendations and guidelines from local, national and international clinical professional bodies. Date to Initiate Review: 08/09/2018
Lead Executive/Director	Ms Chris Emerson – Director of Commissioning
Name of originator/author:	Mrs Fiona Bates – Project Pharmacist Mrs Helen Bryant – Senior Commissioning Manager
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Contribution list

Key individuals involved in developing the document

Name	Designation

Circulated to the following individuals/groups for comments

Name	Date
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	

Review and Amendment Log

Version No	Type of Change	Date	Description of change
1.0	New Policy	Sept 15	Introduction of new policy

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Commissioning Summary

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed "the Commissioner" in this document):

Do not support the NHS funding of Gastric Nerve or Gastric Electrical Stimulation (also known as the Enterra ™ Therapy System) for the treatment of patients with intractable nausea and vomiting diagnosed as gastoparesis following failure of conservative and pharmacological therapies.

Definitions

1.1 ***Exceptional clinical circumstances*** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.

1.2 A ***Similar Patient*** refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Commissioner collaborates. The existence of one or more similar patients indicates that a policy position is required of the Commissioner.

1.3 An ***individual funding request (IFR)*** is a request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

1.4 An ***in-year service development*** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

Scope of policy:

2.1 This policy should be considered in line with all other Worcestershire Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients that the Worcestershire CCGs have responsibility for including:

- People provided with primary medical services by GP practices who are members of one of the CCGs or
- People usually resident in the area covered by the CCG's and not provided with primary medical services by any CCG.

2.3 For patients who do not meet the policy and where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "clinically exceptional circumstances", please refer to the Definitions section of this document.

2.4 This policy potentially applies to patients presenting with severe intractable nausea and vomiting, diagnosed as gastroparesis.

Background:

3.1. NHS principles have been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (termed "the Commissioners") consider all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. Where an NHS commissioned service is provided by the Independent Sector (a privately funded provider), any patient referred for NHS funded treatment MUST also comply with the Provider's exclusion criteria for treatment; for example, at time of referral (and treatment) they must:

- Be aged 18 or over
- Have a BMI of 40 or less
- Not have an incapacitating disease which is a constant threat to life
- Have had no previous adverse events or complications as a result of anaesthesia
- Not have an unstable mental condition, receiving psychiatric treatment

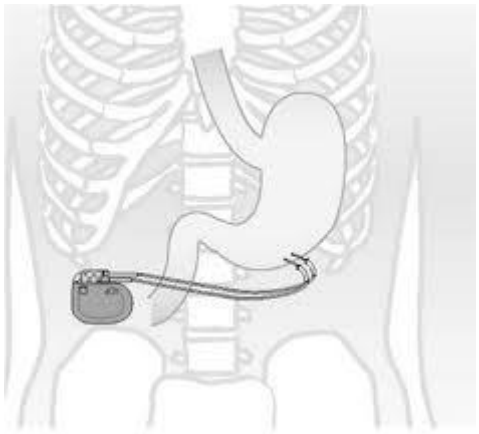
3.4. Gastroparesis is defined as a chronic disorder associated with delayed emptying of the stomach in the absence of mechanical obstruction. Symptoms associated with this include nausea, vomiting, abdominal distention and pain and bloating. This, in severe cases can lead to failure to maintain body weight, dehydration and metabolic disturbances which may require hospital admission and is associated with reduced quality of life.

3.5. Gastroparesis is commonly associated with diabetes but can also arise idiopathically (chance), post gastric surgery, in anorexia nervosa and abdominal migraine. Other diagnoses which are associated with this condition include: long term medications (opiates and antidepressants), multiple sclerosis, parkinsons disease, scleroderma and amyloidosis.

3.6. Gastroparesis is managed initially conservatively and then medically before any surgical interventions are considered.

- Conservative measures include dietary modification with nutritionist/dietetic support. Hydration and nutrition input may be required with recurrent vomiting and reduced oral intake which can result in micronutrient and vitamin deficiencies, hypokalaemia, metabolic alkalosis and dehydration; supplementation should be provided orally via liquidised or homogenised meals as tolerated.
- Medical management follows on from conservative management and consists of the use of prokinetic drugs which increase the rate of gastric emptying and antiemetics based on their efficacy in controlling non- specific nausea and vomiting.
- Invasive procedures are options in more severe and intractable cases.

3.7. Gastroelectrical stimulation has been suggested as a potential treatment option for individuals with intractable gastroparesis. The treatment involves the insertion of electrodes, which are fixed to the muscle of the lower stomach. The connector end of each lead is then attached to the neurostimulator. When the neurostimulator is turned on, electrical impulses are delivered via the electrodes. The aim of gastroelectrical stimulation is reduced symptoms and enhanced gastric emptying.



Gastro Electrical Stimulator in situ

3.8 Gastroelectrical stimulation is currently only offered by one NHS provider in England who estimates that 8 patients per year for the population of England would require this treatment. Evidence from a large US population based study[1] suggests that 2.7% of potential gastroparesis cases fulfil diagnostic criteria. The age adjusted incidence of gastroparesis was 2.4 per 100,000 person years for men and 9.8 per 100,000 person years for women. In age adjusted prevalance of definite gastroparesis there was 9.6 per 100,000 persons for men and 38 per 100,000 persons for women. Crudely extrapolating these figures to relate to the Worcestershire population results in an incidence of 1 patient with gastroparesis.

3.9 The United States Food and Drug Admninistration authority (FDA) has given Enterra™ Humanitarian Use Device (HUD) status. This is given to devices intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The HUD provision provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting small populations.

Relevant National Guidance and Facts

4.1. The National Institute for Health and Care Excellence (NICE) published updated interventional procedure guidance 489 (IPG489) Gastroelectrical stimulation for gastroparesis in May 2014[2]. This guidance states:

- Current evidence on the safety and efficacy of gastroelectrical stimulation is adequate to support the use of this procedure with normal arrangements for consent and for clinical governance, consent and audit.
- Clinicians wishing to undertake gastroelectrical stimulation for gastroparesis should inform patients during the consent process that some patients do not get any benefit from it.
- Patients should be provided with detailed written information about risk of complications which can be serious and include device removal.
- Patient selection and follow up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders and procedures done by surgeons working in these units.

4.2. The NHS Commissioning Board published a Clinical Commissioning policy statement: Gastroelectrical stimulation in April 2013[3]. Since this time, commissioning of GES has become the responsibility of CCGs. The NHSE policy covered use of GES delivered by the Enterra™

therapy system for intractable nausea and vomiting caused by idiopathic or diabetic gastroparesis and stated:

- "Gastric stimulation/gastroelectrical stimulation is not routinely funded for use in intractable nausea and vomiting from idiopathic gastroparesis"

Note: This policy and the associated statement were written prior to the publication of the recent NICE IPG guidance. The previous NICE IPG guidance for GES was negative.

4.3 Healthcare Improvement Scotland published a technologies scoping report Number 5 in 2012[4]. This report was undertaken in response to the following question:

In patients with severe medically refractory gastroparesis (such as those requiring nutritional support), how effective and cost effective is gastric electrical stimulation (EnterraTM device) in reducing symptoms, reducing requirement for nutritional support or hospitalisation and improving quality of life, when compared with medical or alternative surgical management?

The report concludes:
The evidence base for GES consists mainly of uncontrolled observational studies. GES is associated with statistically significant reductions in symptom frequency and severity, reduced need for hospital admissions and improved quality of life for patients with severe medically refractory gastroparesis. Around 10% of patients require device removal.
While there is evidence of symptom reduction with gastric electrical stimulation, there is a lack of cost effectiveness evidence.

Evidence Review

5.1 The evidence review revealed few studies involving gastroelectrical stimulation. Evidence was collated from the new NICE interventional procedure guidance 489 on gastroelectrical stimulation and the related interventional procedure overview document[5]. NHS England commissioning policy statement (published April 2013 but no longer in use) and the Healthcare Improvement Scotland technologies scoping report.

Efficacy

5.2 The NICE IPG details a number of studies supporting the efficacy of gastroelectrical stimulation including a meta-analysis of 3 studies including 58 patients with idiopathic gastroparesisis treated by GES reporting improvement in total symptom severity score. Another meta-analysis of 7 studies including 378 patients with diabetic, idiopathic or post-surgical gastroparesis treated by GES reported a statistically significant improvement in gastric emptying at 4 hours. Further analysis showed that improvement was significant in diabetic and idiopathic gastroparesis but not in post-surgical.

5.3 In a systematic review of 364 patients, a meta-analysis of 8 studies involving 184 patients treated with gastroelectrical stimulation for gastroparesis reported a reduction in need for nutritional support (44% to 11% at follow up). There was also a significant improvement in Short form 36 scores (a validated way of measuring quality of life across 8 domains).

5.4 A randomised control trial of 32 patients with idiopathic gastroparesis reported reduced weekly vomiting frequency and improvement in gastroparesis symptoms, gastric emptying and days of hospitalisation, but the latter is not quantified.

5.5 The published NICE IPG reports positive feedback arising from 50 questionnaires given to patients between the ages of 16 and 88 years, about the gastroelectrical stimulation procedure, how their stomachs now empty and all stated they would have the procedure again; recommending it to another patient with the condition. However limited information is detailed as to the sample size of questionnaires and any negative feedback is not listed.

5.6 The Health Improvement Scotland technology scoping report looked at mainly uncontrolled observational studies including the study mentioned in 5.4. They concluded that

gastroelectrical stimulation (GES) was associated with a statistically significant reduction of symptom frequency and severity, reduced need for hospital admissions and improvement of quality of life for patients. However this is not quantified.

5.7 The NHS Commissioning Board policy on gastroelectical stimulation (GES) cited the same studies mentioned above (5.2 & 5.3) concluding that with gastroelectrical stimulation there was a significant reduction from baseline in patient reported symptoms severity scores relating to nausea and vomiting. In addition, gastric emptying at four hours was significantly improved from baseline and there were improvements in quality of life (SF36), as well as reduced requirements for enteral or parenteral feeding.

5.8 A more recent paper "Gastric Electrical Stimulations with the Enterra System: A Systematic Review" has been published in June 2015 by Lal et al from the University of Liverpool/ Aintree University Hospital. The review involved assessment of 21 eligible papers. The quality of the studies was variable with variation in outcome measures and follow-up methodology. Included studies suggested significant reductions in symptom severity reporting over the study period, but improvements in gastric emptying time were variable and rarely correlated with symptom improvement. The review concludes "*The evidence in support of GES is limited and heterogeneous in quality. While current evidence has shown a degree of efficacy in these patients, high-quality, large clinical trials are needed to establish the efficacy of this therapy and to identify the patients for whom this therapy is inappropriate. A consensus view on essential preoperative assessment and postoperative measurement is needed* ".

Safety

5.8 Reported complications of the procedure relate to the surgical nature of the insertion of the leads and neurostimulator. These potential complications include surgical site infection, migration of the leads and gastric perforation. The gastroelectrical stimulator had to be removed in 11% of cases as reported in the NICE IPG. The NICE IPG also reports a treatment failure rate of 26% due to failure to respond, device malfunction, damage to device.

Other

5.9 A double blind randomised controlled trial (Medico-economic Evaluation of Enterra™ therapy) now closed to recruitment, is examining both the clinical effectiveness and healthcare utilisation associated with GES in 220 patients with severe refractory symptoms over a 28 month study period. The full results are due in 2016 and will inform future policy development.

Patient Eligibility

6.1 The Commissioner does not support the routine NHS funding of Gastric stimulation / gastroelectrical stimulation (also known as, but not inclusive of, the Enterra ™ Therapy System, Medtronic, Minneapolic, MN, USA) for use in intractable nausea and vomiting from idiopathic or diabetic gastroparesis, including those patients in whom failure of conservative and pharmacological therapies has occurred.

Supporting Documents

1. Gastroparesis: Eitiology, clinical manifestations and diagnosis. Camileri, M. et al. Up to date: http://www.uptodate.com/contents/gastroparesis-etiology-clinical-manifestations-and-diagnosis (accessed May 2014) updated Oct 2013.

2. National institute for Health and Clinical Excellence Inverventional Procedure Guidance 489: Gastroelectrical stimulation for gastroparesis. Issued May 2014, http://guidance.nice.org.uk/ipg489.

3. NHS Commissioning Board Clinical Commissioning Policy Statement: Gastroelectrical stimulation. April 2013 Reference NHSCB/B11/PS/a

4. Healthcare Improvement Scotland. Technologies scoping report. Number 5. Edinburgh. 2012.http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/earlier_scoping_reports/technologies_scoping_report_5.aspx
5. National Institute for health and care excellence Interventional procedures programme. Overview of gastroelectrical stimulation for gastroparesis. December 2013.
6. Worcestershire: Individual Funding Request Operating Procedures
7. NHS England Policy: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements
8. NHS England Policy: Use of cost-effectiveness, value for money and cost effectiveness thresholds
9. NHS England Policy: Prior Approval
10. NHS England Policy: Individual funding requests

Equality Impact Assessment

Organisation	Worcestershire CCGs		
Department	Commissioning	Name of lead person	Fiona Bates
Piece of work being assessed	Commissioning Policy: Gastroelectrical Stimulation (GES) for Gastroparesis		
Aims of this piece of work	To define if and when GES should be offered to patients		
Date of EIA	04/02/2015	Other partners/stakeholders involved	CCPC (with PPI)
Who will be affected by this piece of work?	Individuals with intractable nausea and vomiting given a diagnosis of gastroparesis		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	Women appear to be disproportionally affected by gastroparesis with incidence and prevalence reported as almost 4 times greater than that for men.	Yes
Race	No known differences	No
Disability	Diabetic patients are more likely to be affected by gastroparesis but the majority of diabetic patients do not have a disability and so this is irrelevant.	No
Religion/ belief	No evidence of a link between religion and gastroparesis	No
Sexual orientation	No known differences	No
Age	No known differences	No
Social deprivation	Gastroparesis may be a complication of surgery, notably weight loss surgery, the incidence of which is greater in more deprived areas.	Yes
Carers	There is no evidence that being a carer has an impact on gastroparesis.	No
Human rights	Will this piece of work affect anyone's human rights?	No

Equality Impact Assessment Action Plan

Strand	**Issue**	**Action required**	**How will you measure the outcome/impact**	**Timescale**	**Lead**
The decision has been made that at the current time Gastroelectrical stimulation is not feasible for Worcestershire. Therefore there will be no suggestion actions in relation to the assessment.					