Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B11X01		
Policy Title	Gastroelectrical Stimulation for Gastroparesis		
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Section A - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 This policy proposes to **not routinely commission** GES for gastroparesis. The prevalence is difficult to estimate due to inconsistencies between definitions, and is not reliably reported in the literature. Women appear to be disproportionately susceptibly to gastroparesis. Studies suggest that diabetic gastroparesis affects about 20% to 50% of patients with type 1 diabetes and up to 30% of patients with type 2 diabetes, especially those with long-standing disease.	

	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 Currently, in the region of 20 cases per year have been funded via CCGs. No cases have been approved by NHS England via the Individual Funding Request / Clinically Critically Urgent process. It is not possible to determine a patient population alternative to this activity level, given the challenges in defining the condition.
	A1.3 What age group is the treatment indicated for?	A1.3 This treatment, if commissioned, would be commissioned for adults (18 years and over).
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 Most people requiring this intervention will be over 18. No median range is quoted in the literature.
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 This intervention is not routinely commissioned, though in the region of 20 cases have been approved for funding by CCGs.
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 There is a high prevalence of gastroparesis in patients with diabetes and the number of cases appears to be increasing due in part to the rise in the incidence of diabetes (O'Grady et al 2009)
	A1.7 What is the associated projected growth in activity (prior to applying the new	A1.7 The policy introduces a non-routine commissioning position. However, given analysis of the activity data the activity model

	policy) in 2,5 and 10 years?	assumes flat growth, i.e., 20 cases per year.
	A1.8 How is the population currently distributed geographically?	A1.8 There is no data reporting this, given the challenges in defining the disease.
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	A2.1 The policy moves to a non-routine commissioning position.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 Diabetes may affect the growth in the population, though there is not an accepted definition of the disease.
	A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	A2.3 No evidence of any changes was identified.
	A2.4 What is the resulting expected net increase or decrease in	A2.4 There would be no activity if the policy is implemented, though it is the case that some exceptional

	the number of patients who will access the treatment per year in year 2, 5 and 10?	cases may still be funded through IFR/CCU.
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	A3.1 Currently, it would appear that a small number of providers are delivering this activity with CCG funding. This appears to be approximately 20 cases per year.
	A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	A3.2 GES will not be routinely commissioned, therefore the activity will be ‘zero’, not factoring in any activity funded via IFR.
	A3.3 What will be the comparative activity for the ‘Next Best Alternative’ or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	A3.3 Alternative techniques are, dietary changes, feeding tube insertion and surgery
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	A4.1 Dietary changes, anti-emetic medication, insertion of feeding tube, and in severe cases surgery to connect the stomach to the second part of the small intestines.

	A4.2. What are the current treatment access criteria?	A4.2 Treatment will depend on the severity of the condition ranging from dietary changes to Surgery.
	A4.3 What are the current treatment stopping points?	A4.3 Curative or reduction in the following symptoms: • feeling full very quickly when eating; • nausea (feeling sick) and vomiting; • loss of appetite; • weight loss; • bloating; • abdominal pain or discomfort; and heartburn.
A5 Comparator (next best alternative treatment) Patient Pathway	A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	A5.1 See sections A3 and A4.
	A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely	A5.2 See sections A3 and A4.

	success). If possible please indicate likely outcome for patient at each stopping point.	
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A6.1 – A6.2 Policy proposition is to not routinely commission the intervention, therefore the activity would be 'zero'.
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community	A7.1 If GES was commissioned, then the procedure would be delivered in an inpatient setting under GA.

	setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.2 No change anticipated.
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.1 – A8.2 The policy proposition does not alter the currently commissioned patient pathway, therefore this question is not applicable.
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? A9.2 If this treatment is a drug, what pharmacy monitoring is required? A9.3 What analytical information /monitoring/ reporting is required?	A9.1 – A9.4 Not applicable as position is to not routinely commission.

	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place? A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	
Section B - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 The service is delivered via a network of designated specialist centres

	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 No change anticipated as position is to not routinely commission.
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Patients are usually referred from primary care, emergency department into secondary care and from secondary care to the specialist multidisciplinary team.
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 No change anticipated
	B2.3 Is the new policy likely to improve equity of access?	B2.3- B2.4 No impact anticipated
	B2.4 Is the new policy likely to improve equality of access / outcomes?	
B3 Implementation	B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	B3.1 The policy should be implemented immediately, as the activity is not currently commissioned or funded by NHS England. It may be that this will not be fully resolved until new Information Rules come into force from April 2017.
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 – B3.6 No changes anticipated.

	B3.3 Is there a change in provider staffing required?	
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	
	B3.5 Are there changes in the support services that need to be in place?	
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 Currently it is the case that NHS England does not commission any providers to deliver this activity, this will not change with the implementation of the policy proposition. However, some CCGs have funded the procedure in a small (<10) number of providers. These arrangements will cease, following the implementation of the revised Information Rules.
	B3.8 How will the revised provision be secured by NHS England as the responsible	B3.8 Not applicable.

	commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 Not applicable.
Section C - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 – C1.3 The underlying procedure is a national tariff, however the cost of the device would be reimbursed separately. The code is AB07Z.
	C1.2 Is this treatment excluded from national prices?	C1.2 Not applicable
	C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	C1.3 Not applicable

	C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes? C1.5 is VAT payable (Y/N) and if so has it been included in the costings? C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.4 Not applicable
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1? C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.1 £11,855 is the revenue cost associated with the policy proposition. C2.2 £12,008 is the average cost per patient in future years.
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. C3.2 Where this has not been identified, set	C3.1 There is a small cost saving associated with this policy proposition – which will be realised as revised Information Rules are implemented. This is the cost of the device plus the cost of revisions and complications. C3.2 Not applicable

	out the reasons why this cannot be measured.	
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	C4.1 Cost neutral for other parts of the NHS.
	C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	C4.2 Cost saving for the NHS as a whole.
	C4.3 Where this has not been identified, set out the reasons why this cannot be measured.	C4.3 Not applicable
	C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.4 None identified
C5 Funding	C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. *e.g. decommissioning less clinically or cost-effective services*	C5.1 Non applicable.
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy?	C6.1 Not applicable

	C6.2 Can these be mitigated, if so how?	C6.2 Not applicable
	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.3 Not applicable
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	C7.1 No cost effectiveness studies were identified.
	C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.2 No cost effectiveness studies were identified.
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	C8.1 Not applicable
	C8.2 If so, confirm the source of funds to meet these costs.	C8.2 Not applicable