

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B11X02		
Policy Title	Robotic assisted surgery for oesopha	ago-gastric cancers	
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	Section K - Activity Impact		
Theme	Questions	Comments (Include made and any issues	source of information and details of assumptions with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?		oses to not routinely commission robotic assisted sophago-gastric (OG) cancer.
			go-gastric cancers have an estimated ten year an 4 per 10,000 of the population. ⁱ This translates to a 00 in 2014/15. ⁱⁱ
			dence in England in 2014/15 can be estimated at or in the region of 12,800 new cases per year. ⁱⁱⁱ
	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	potentially be eligible	ble to undergo traditional surgery for OG cancer could for RAS. ^{iv} The number of patients that can undergo f the prevalent population. In 2014/15 the number of

	surgeries for OG cancer is estimated in the region of 2,300 (c. 10% of the prevalent population, or around 20% of the incident population). ^{v}
K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for adults (18 years or over).
K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Most patients requiring surgery are aged between 62 and 80. The median age of patients undergoing surgery is ~70 to 75 years. ^{vi} Moreover, there are almost twice as many stomach cancers diagnosed in men than in women. ^{vii}
K1.5 What is the current activity associated with currently routinely commissioned care for this group?	 K1.5 For the population that is eligible for RAS, the number of patients undergoing each of the following treatments in 2014/15 is estimated to be in the region of: ^{viii} Open Oesophagectomies: 720 Hybrid Oesophagectomies: 490 Minimally invasive Oesophagectomies: 190 Open Gastrectomies: 730 Minimally invasive Gastrectomies: 150 Robotic assisted surgery is currently performed in a small number of patients.^{ix}
K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	 K1.6 Prevalence is expected to increase in line with demographic growth rates.^x Therefore, future prevalence is estimated to be in the region of:^{xi} 21,000 in 2016/17 21,200 in 2017/18 21,600 in 2020/21 OG cancer has a high mortality rate,^{xii} and surgical intervention is typically
	indicated for earlier stage cancers. ^{xiii} Incidence figures are therefore more relevant in understanding possible demand.
	 Future incidence is expected to be in the region of: xiv 12,700 in 2016/17

F	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	 12,600 in 2017/18 12,500 in 2020/21 K1.7 The future activity for the eligible population set out in K1.2 is estimated to be in the region of: ^{xv} Open Oesophagectomies: 700 in 2016/17 660 in 2017/18 520 in 2020/21 Hybrid Oesophagectomies: 620 in 2016/17
		 740 in 2017/18 1,130 in 2020/21 Minimally invasive Oesophagectomies: 190 in 2016/17 190 in 2017/18 170 in 2020/21 Open Gastrectomies: 740 in 2016/17 720 in 2017/18 670 in 2020/21 Minimally invasive Gastrectomies: 170 in 2016/17 170 in 2016/17 170 in 2017/18 200 in 2020/21
	K1.8 How is the population currently distributed geographically?	 200 in 2020/21 K1.8 Ten year prevalence of stomach cancer is higher than the national average in northern England. The age standardised proportion (ASP) in England is 15.7 per 100,000, while in the North of England it is 22.6.^{xvi}

		Oesophagus cancer is more prevalent in the Avon, Somerset & Wiltshire (ASP: 16) as well as in the Yorkshire (ASP: 15.9) cancer networks relative to the England as a whole (ASP: 13.3). ^{xvii}
K2 Future Patient Population & Demography	K2.1 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?	K2.1 The policy moves to a non-routine commissioning position.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 Lifestyle factors such as smoking, obesity, and alcohol may affect the growth in the population. ^{xviii} As the population ages, this may also affect the growth of these cancers. ^{xix}
	K 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	K2.3 No evidence of any changes was identified.
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	K2.4 Under the policy to not routinely commission, there would be no net change from the do nothing position as set out in K1.6 to K1.7). This is because there would be no patients receiving RAS in either the 'do nothing' or the not routinely commissioned positions. ^{xx}
		The proposed policy establishes a 'not routinely commissioned' proposal for the relevant population (the specific cohort set out in K1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.

K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 Current annual activity is as described in K1.5; alternative surgical techniques (minimally invasive, open, or in some cases hybrid approaches) could be used.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet	K3.2 Should the policy be implemented, i.e. RAS would not be routinely commissioned, the activity would be the same as outlined in K1.7.
	K3.3 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	K3.3 Future activity is described in K1.7; alternative surgical techniques (minimally invasive, open, or in some cases hybrid approaches) could be used.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 Oesophago-gastric cancer is usually treated with surgery, chemotherapy or radiotherapy or sometimes a combination of all three. Existing surgical techniques include open and laparoscopic surgery.
	K4.2 What are the current treatment access criteria?	K4.2 The appropriate treatment will depend on the type of cancer, how far it has spread and the general health of the patient. For cancers where surgery is deemed appropriate, the approach to surgery is determined by the position of the tumour.
	K4.3 What are the current treatment stopping points?	K4.3 Surgery for oesophageal and gastric cancer is normally undertaken with curative intent although there are indications for palliative surgery for gastric cancer.

K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 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.	K5.1 Most patients with oesophago-gastric cancer have inoperable disease at the time of diagnosis and will require palliative and non-surgical treatment such as chemotherapy, radiotherapy or endoscopic intervention to relieve symptoms.
	K5.2 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.	K5.2 Treatment is stopped in the event of failure to control the disease.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy	K6.1-6.2 Not applicable as position is to not routinely commission.
	K6.2 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.	

K7 Treatment Setting	 K7.1How is this treatment delivered to the patient? Acute Trust: Inpatient/Daycase/Outpatient Mental Health Provider: Inpatient /Outpatient Community setting Homecare delivery 	K7.1 This treatment is delivered as an inpatient procedure under general anaesthetic. ^{xxi}
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i>	K7.2 No change anticipated.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 As the underlying treatment is delivered as an inpatient procedure, this will be recorded within the Secondary Uses Services (SUS) dataset. Furthermore, all surgeries for OG cancer are recorded in the National Oesophago-gastric Cancer Audit.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 The underlying procedures (oesophagectomy, gastrectomy) within SUS can be identified with a combination of ICD-10 and OPCS codes. ^{xxii}
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 – 9.7 Not applicable as position is to not routinely commission.

	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	
	K9.3 What analytical information /monitoring/ reporting is required?	
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	
	K9.7 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 L - Ser	vice Impact
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision)	L1.1 OG cancer resection surgery is only delivered in designated specialist centres by teams of appropriately trained surgeons.

	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change anticipated as position is to not routinely commission.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Patients are usually referred from primary care and emergency departments into secondary care and from secondary care to the specialist multidisciplinary team.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No change anticipated.
	L2.3 Is the new policy likely to improve equity of access?	L2.3-2.4 No impact anticipated.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 Not applicable as the position is to not routinely commission.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2-3.3 No changes anticipated.
	L3.3 Is there a change in provider staffing required?	
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4-3.6 Not applicable as the position is to not routinely commission.
	L3.5 Are there changes in the	

	support services that need to be in place? L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime	
	contractor) L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No change anticipated.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 Not applicable as the position is to not routinely commission.
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 No
	Section M - Fina	nce Impact
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 The underlying procedures (oesophagectomy, gastrectomy) are within tariff. ^{xxiii}

	M1.2 Is this treatment excluded from national prices?	M1.2 Partly. National prices apply to the main procedure but robotic consumables are excluded from national tariff.
	M1.3 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?	M1.3 Consumables for robotic assisted surgery are excluded from tariff. These are paid by NHS trusts. As there is limited experience with RAS for OG cancer, estimating the costs of such consumables is difficult. The cost of consumables for another robotic procedure (robotic assisted lung surgery) has been estimated in the region of around £1,500 per procedure (in addition to the tariff for the underlying procedure). ^{xxiv}
	M1.4 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	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 Not applicable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 Not applicable.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 There would be no revenue cost for RAS as the policy is to not routinely commission.
		Under the policy to not routinely commission, patients would continue to undergo comparator treatments, as set out in K3.2. The cost for treating patients with oesophagectomy or gastrectomy procedures is estimated at c. £4,500 based on the 2014/15 tariffs. ^{xxv}
		For reference, the additional cost of robotic surgery could be in the region of £1,500 for robotic consumables. ^{xxvi} This would be in addition to the

		baseline cost for the underlying procedure of c. £4,500.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 In years following the treatment, follow-up costs for patients receiving treatment are assumed to be the same as for the comparator treatments (i.e. open, hybrid or minimally invasive surgeries).xxvii
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	M3.1 Cost neutral, as the policy is to not routinely commission RAS, and there is no identified activity for RAS in the 'do-nothing' scenario (see K1.5).
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	M4.1 Cost neutral for the reasons given in M3.1.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2 Cost neutral for the reasons given in M3.1.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 None identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g. decommissioning less</i> <i>clinically or cost-effective services</i>	M5.1 Not applicable.

M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 Not applicable.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? e.g. NICE appraisal, clinical trials or peer reviewed literature	M7.1 No cost effectiveness studies were identified.
	M7.2 What issues or risks are associated with this assessment? e.g. quality or availability of evidence	M7.2 Not applicable as no cost effectiveness studies were identified.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs,</i> <i>periodical costs</i>	M8.1 Not applicable.
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

ⁱ Based on a reported ten year prevalence in England of 8,566 for 'Oesophagus' and 10,793 for 'Stomach' in 2006 [Source: NCIN (2006). "One, Five and Ten Year Cancer Prevalence by Cancer Network, UK, 2006"]. This number is grown by demographic growth rates to arrive at a 2014/15 figure and based on the population of England in 2014/15. [Source: ONS (2012). Population projections].

" See endnote i for the calculations.

iii Based on 12,880 reported diagnoses in 2012, which is grown with historic incidence growth rates over 2007 and 2012 to arrive at 2014/15 figures [Source: ONS (2012). Registrations of newly diagnosed cases of cancer (3rd digit): site and sex, England, 1995 to 2012].

^{iv} Based on discussions with the policy working group.

^v Based on 2,782 oesophagectomies and 1,806 gastrectomies undertaken in England and Wales between the two years 2011 and 2012 [Source: Healthcare Quality Improvement Partnership (2014). "National Oesophago-gastric Cancer Audit 2014."]. These numbers are adjusted to cover only the population of England [Based on ONS (2013). "Population Estimates for England and Wales, Mid-2012."]; and it is assumed that the number of surgeries was the same in 2011 and 2012. Furthermore, past figures from 2007-2009 are used to estimate growth rates of each type of OG surgery (see endnote xv), which are applied to estimate 2014/15 figures. [Source: The NHS Information Centre (2010). "National Oesophago-gastric Cancer Audit 2010."].Percentages are rounded.

^{vi} Healthcare Quality Improvement Partnership (2014). "National Oesophago-gastric Cancer Audit 2014." The interquartile range for the age of those receiving Oesophagectomy is 62 to 76 and for Gastrectomy 69 to 80.

vii Based on: ONS (2012). Registrations of newly diagnosed cases of cancer (3rd digit): site and sex, England, 1995 to 2012.

viii Based on figures reported in the 2014 National Audit and grown with relative growth rates obtained when comparing these figures to those listed in the 2010 National Audit (also see endnote v). Figures rounded.

^{ix} Based on discussions with the policy working group. It was not possible to establish the number of patients undergoing RAS, however it was noted this number is minimal.

^x Based on discussions with the policy working group. Prevalence is expected to increase with an ageing population.

xi Growth rates based on demographic growth of the population of England: ONS (2012). Population forecasts.

xii Cancer Research UK. Oesophago-gastric cancer. [Online] Available at http://www.cancerresearchuk.org/cancer-

info/prod_consump/groups/cr_common/@nre/@hea/documents/generalcontent/cr_079690.pdf [Accessed: 20/11/2015]. Five-year survival rates noted at between 3.7% and 15.6% as noted in Coupland V.(2012) Incidence and survival of oesophageal and gastric cancer in England between 1998 and 2007, a population-based study. Biomed Central Cancer. Vol 12. [Online] Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3274437/ [Accessed: 13/01/2016].

xiii Based on discussions with the policy working group. The policy proposition outlines the patient pathway.

xiv Incidence growth rates based on: ONS (2012). Registrations of newly diagnosed cases of cancer (3rd digit): site and sex, England, 1995 to 2012. The CAGR over the last 5 years of data (2007 to 2012) is c. -0.37%.

^{xv} Estimates for RAS growth are based on clinician discussions, and assume that without routine commissioning for RAS, RAS would not grow and continue to comprise a negligible number of surgeries. Based on historic data, hybrid techniques would become more common (growing from 21% to 42% of the eligible population), open surgery would decrease overall from around 63% to 44% of eligible patients, and minimally invasive techniques would decrease from 15% to 14% (these relative rates of change are

based on historic growth rates from the 2010 and 2014 National Audit and are applied over 5 years). Furthermore, a 'phasing' of 25% per year is assumed for these transformations.

The overall growth rate of surgeries is c 3% p.a..

^{xvi} These prevalence rates have been age standardised for geographical benchmarking and will therefore not align to the prevalence rates outlined in K1.1 which is the actual prevalence. Based on: NCIN (2006). "One, Five and Ten Year Cancer Prevalence by Cancer Network, UK, 2006."

^{xvii} These prevalence rates have been age standardised for geographical benchmarking and will therefore not align to the prevalence rates outlined in K1.1 which is the actual prevalence. Based on: NCIN (2006). "One, Five and Ten Year Cancer Prevalence by Cancer Network, UK, 2006."

^{xviii} Based on discussions with the policy working group.

xix NHS Choices (2014). Oesophageal cancer – Causes. [Online] Available from http://www.nhs.uk/Conditions/Cancer-of-the-oesophagus/Pages/Causes.aspx [Accessed: 11/11/2015]; and: NHS Choices (2015). Stomach cancer – Causes. [Online] Available from http://www.nhs.uk/Conditions/Cancer-of-the-oesophagus/Pages/Causes.aspx [Accessed: 11/11/2015]; and: NHS Choices (2015). Stomach cancer – Causes. [Online] Available from http://www.nhs.uk/Conditions/Cancer-of-the-stomach/Pages/Causes.aspx [Accessed: 11/11/2015]. The impact of future changes in these factors on growth has not been quantified.

xx This is consistent with the defined do nothing scenario, as there was no historic, other growth or other basis on which to predict the future growth of RAS.

^{xxi} NHS Choices (2015). Gastrectomy – Recovery. [Online] Available from <u>http://www.nhs.uk/Conditions/Gastrectomy/Pages/Recovery.aspx</u> [Accessed: 11/11/2015] and NHS Choices (2015). Gastrectomy – How it's performed. [Online] Available from http://www.nhs.uk/Conditions/Gastrectomy/Pages/How-it-is-performed.aspx [Accessed: 12/01/2016].

^{xxii} The ICD-10 codes are C15 for oesophagus and C16 for stomach cancer. The 3 most frequent OPCS codes (as identified within a SUS data extract for the years 2011/12 to 2015/16 for those with C16 or C15 codes within the first 3 ICD-10 positions) are: G449 -Unspecified other therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract, G031 - Total oesophagectomy and anastomosis of pharynx to stomach and G448 - Unspecified fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract.

^{xxiii} As there are many different underlying procedures, only the most relevant HRG codes are reported. These are FZ25 - *Therapeutic Endoscopic or Intermediate Stomach or Duodenum Procedures*, and FZ01 - *Complex Oesophageal Procedures 19 years and over* based on the OPCS codes G449, G448 and G031 (see endnote xxii), which were grouped to these HRG codes using the 2014/15 HRG grouper tool.

xxiv This estimate is based on the cost of robotic consumables for another type of surgery [robotic assisted lung resection surgery] undertaken in northern England.

xxv Based on average spell costs of the 20 most frequently undertaken procedures for the two indications stomach cancer and oesophagus cancer the first ICD-10 position (from a SUS data extract of the years 2011/12 to 2014/15 excluding OPCS codes relating to 'examinations' or 'rubber bands'). However, tariff costs could be higher or lower depending on case complexity of individual cases.

xxvi Based on a business case study from a hospital in northern England for robotic assisted lung resection surgery.

xxvii Based on discussions with the policy working group.