

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1740		
Policy Title	Selective internal radiation therapy (SIRT) in the treatment of chemotherapy refractory and intolerant, unresectable metastatic colorectal cancer (Adults) Proposal <u>for routine commission</u> (ref A3.1)		
Lead Commissioner	Kim Fell	Clinical Lead	Prof Ricky Sharma
Finance Lead	Craig Charlton	Analytical Lead	Craig Charlton

Integrated Impact Assessment – Index

Section A – Activity	Section B - Service	Section C – Finance
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile

About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact

A1 Current Patient Population & Demography / Growth

A1.1 Prevalence of the disease/condition.

Colorectal cancer (CRC) is the third most common cancer in the UK, with 40,755 new cases diagnosed in 2012, which is projected to rise to 58,119 cases annually by 2035. It is more common in people aged over 65 years (73.1% of new cases) and in males (55.4% of cases) than females. CRC is an important cause of death; there were 16,202 deaths in 2012 and this is expected to increase to almost 24,000 deaths annually by 2035.

Around 25% of people diagnosed with colorectal cancer will develop metastatic disease and this rises to over 50% of people diagnosed with colorectal cancers in time, though this can be several years following diagnosis.

In most cases, colorectal cancer spreads to the liver. Of these, only 10-20% of cases will be able to have surgical resection; the majority of metastatic CRC cases instead have chemotherapy. It is estimated that every year around 150 -200 people treated with chemotherapy for metastatic CRC will either become intolerant of the treatment or will have a cancer that is or becomes refractory to treatment. Of these, it is estimated that approximately 50 cases would be eligible for treatment with SIRT.

Source: Policy Proposition, Section 6

A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.

50

Source: SIRT Commissioning Through Evaluation Programme

A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	<u>Adults</u>
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	<p>CRC is more common in people aged over 65 years (73.1% of new cases) and in males (55.4% of cases) than females.</p> <p><i>Source: Policy Proposition, Section 6</i></p>
A1.5 How is the population currently distributed geographically?	<p><u>Evenly</u></p> <p><i>Source: Policy Proposition section 6</i></p>
A2 Future Patient Population & Demography	
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?	<p><u>Increasing</u></p> <p>In line with ONS growth projections.</p> <p><i>Source: Policy Proposition, Section 6</i></p>
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><u>Yes</u></p> <p>CRC is more common in people aged over 65 years (73.1% of new cases) and in males (55.4% of cases) than females.</p> <p><i>Source: Policy Proposition, Section 6</i></p>

A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?	YR2 +/-	1
	YR3 +/-	2
	YR4 +/-	2
	YR5 +/-	3
	YR10 +/-	6
	Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	
<u>Yes</u>		
A3 Activity		
A3.1 What is the purpose of new policy?	<u>Revise existing policy (expand or restrict an existing treatment threshold / Add an additional line of treatment / stage of treatment</u> Currently there is a not for routine commissioning policy statement in place.	
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	50 Currently, there is a not for routine commissioning policy statement in place. Patients have been treated as part of Commissioning Through Evaluation programme which is now closed to recruitment. It is estimated that 50 patients would be eligible for SIRT and currently these patients will be receiving best supportive care. Source: Policy Proposition, Section 6	

A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	50 <i>Source: Policy Proposition, Section 6</i>
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable.
A4 Existing Patient Pathway	
<p>A4.1 Existing pathway: Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates. 	<p>Metastatic CRC that has spread to the liver can be treated with: (i) surgery (resection); (ii) chemotherapy; (iii) ablation; (iv) radiotherapy; and (v) supportive care.</p> <p>Treatment choice largely depends on the extent of disease. Where metastatic disease is identified at an early stage with few secondary tumours having developed in the liver, then surgery is almost always the preferred treatment choice. However, most metastatic colorectal cancer is diagnosed at stage where surgery cannot be performed because the cancer is too advanced. Where this is the case, the most common treatment is chemotherapy.</p> <p>In some cases chemotherapy medicines either don't work or stop working, this is because the cancer develops resistance which is called refractory disease. For some people the side effects of chemotherapy treatments will be so significant that the treatment cannot be tolerated. In both cases, chemotherapy treatment is stopped. Further treatment options are very limited and usually aim to manage symptoms and any side effects of treatment as well as providing pain relief. This type of care is called best</p>

	<p>supportive care or palliative care.</p> <p><i>Source: Policy Proposition, Section 3</i></p>
A4.2. What are the current treatment access and stopping criteria?	See section A4.1.
<p>A4.3 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? 	<ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 100% <p><i>Source: Policy Proposition, Section 3</i></p>
<p>A5 Comparator (next best alternative treatment) Patient Pathway</p> <p>(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>	
<p>A5.1 Next best comparator:</p> <p>Is there another 'next best' alternative treatment which is a relevant comparator?</p> <p><i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> • <i>Treatment or intervention</i> • <i>Patient pathway</i> • <i>Actual or estimated eligibility and uptake</i> 	<p><u>Yes</u></p> <p>Best Supportive Care</p> <p><i>Source: Policy Proposition, Section 3</i></p>
A5.2 What percentage of the total eligible population is estimated to:	

<ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? 	<ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 100% <p><i>Source: Policy Proposition, Sections 3 and 6</i></p>		
A6 New Patient Pathway			
<p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? 	<ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 100% <p><i>Source: Policy Proposition, Sections 3 and 6</i></p>		
<p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p>	<p><u>One off</u></p> <p><i>Source: Policy Proposition, Section 3</i></p>		
A7 Treatment Setting			
<p>A7.1 How is this treatment delivered to the patient?</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="1086 1316 1637 1374">Emergency/Urgent care attendance</td><td data-bbox="1637 1316 1713 1374"><input type="checkbox"/></td></tr> </table>	Emergency/Urgent care attendance	<input type="checkbox"/>
Emergency/Urgent care attendance	<input type="checkbox"/>		

	<table border="1"> <tr> <td>Acute Trust: inpatient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Acute Trust: day patient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Homecare</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table>	Acute Trust: inpatient	<input checked="" type="checkbox"/>	Acute Trust: day patient	<input type="checkbox"/>	Acute Trust: outpatient	<input type="checkbox"/>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input type="checkbox"/>	
Acute Trust: inpatient	<input checked="" type="checkbox"/>																	
Acute Trust: day patient	<input type="checkbox"/>																	
Acute Trust: outpatient	<input type="checkbox"/>																	
Mental Health provider: inpatient	<input type="checkbox"/>																	
Mental Health provider: outpatient	<input type="checkbox"/>																	
Community setting	<input type="checkbox"/>																	
Homecare	<input type="checkbox"/>																	
Other	<input type="checkbox"/>																	
<p>A7.2 What is the current number of contracted providers for the eligible population by region?</p>	<p>Not applicable – currently a not for routine commissioning policy statement is in place and the Commissioning Through Evaluation Programme has now ceased. If approved, an implementation plan will need to be developed.</p>																	
<p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p><u>Yes</u></p> <p>Treatment was previously delivered as part of a Commissioning Through Evaluation Programme which has now ceased.</p>																	
<p>A8 Coding</p>																		
<p>A8.1 Specify the datasets used to record the new patient pathway activity.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input checked="" type="checkbox"/></td> </tr> </table>		Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>														
Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>																	

<p>*expected to be populated for all commissioned activity</p>	<table border="1"> <tr> <td>Patient level contract monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table> <p>**Clinical Database – Radiotherapy Treatment Dataset (RTDS)</p>	Patient level contract monitoring	<input checked="" type="checkbox"/>	Patient level drugs dataset	<input type="checkbox"/>	Patient level devices dataset	<input type="checkbox"/>	Devices supply chain reconciliation dataset	<input type="checkbox"/>	Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>	Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>	National Return**	<input type="checkbox"/>	Clinical Database**	<input checked="" type="checkbox"/>	Other**	<input type="checkbox"/>
Patient level contract monitoring	<input checked="" type="checkbox"/>																		
Patient level drugs dataset	<input type="checkbox"/>																		
Patient level devices dataset	<input type="checkbox"/>																		
Devices supply chain reconciliation dataset	<input type="checkbox"/>																		
Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>																		
Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>																		
National Return**	<input type="checkbox"/>																		
Clinical Database**	<input checked="" type="checkbox"/>																		
Other**	<input type="checkbox"/>																		
<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Treatment function code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input type="checkbox"/></td> </tr> </table>	OPCS v4.8	<input checked="" type="checkbox"/>	ICD10	<input checked="" type="checkbox"/>	Treatment function code	<input type="checkbox"/>	Main Speciality code	<input type="checkbox"/>	HRG	<input checked="" type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>				
OPCS v4.8	<input checked="" type="checkbox"/>																		
ICD10	<input checked="" type="checkbox"/>																		
Treatment function code	<input type="checkbox"/>																		
Main Speciality code	<input type="checkbox"/>																		
HRG	<input checked="" type="checkbox"/>																		
SNOMED	<input type="checkbox"/>																		
Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>																		
<p>A8.3 Identification Rules for Drugs: How are drug costs captured?</p>	<p><u>Not applicable</u></p>																		

A8.4 Identification Rules for Devices: How are device costs captured?	<u>Not applicable</u>
A8.5 Identification Rules for Activity: How are activity costs captured?	<u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u> NCBPS01W SPECIALIST CANCER SERVICES: LIVER CANCER
A9 Monitoring	
A9.1 Contracts Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	<u>None</u>
A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model) For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.	Not applicable.
A9.3 Business intelligence Is there potential for duplicate reporting?	<u>No</u>
A9.4 Contract monitoring	<u>Yes</u>

Is this part of routine contract monitoring?	
A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention?	<u>No</u>
A9.6 NICE reporting Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	<u>No</u>
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	There were 10 participating centres involved in the SIRT Commissioning Through Evaluation Programme, which closed in June 2017. If approved, an implementation plan will need to be developed to support this policy proposition.
B1.2 Will the proposition change the way the commissioned service is organised?	<u>Yes</u> The service is not currently commissioned and a not for routine commissioning policy statement is in place. However, infrastructure and experience will be in place at the participating centres involved in the Commissioning Through Evaluation Programme
B1.3 Will the proposition require a new approach to the organisation of care?	<u>Implement a network model to support appropriate selection of treatment</u>

B2 Geography & Access									
B2.1 Where do current referrals come from?	<p>Select all that apply:</p> <table border="1"> <tr> <td>GP</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Tertiary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of referral?	<u>Increase</u>								
B2.3 Is the new policy likely to improve equity of access?	<u>Increase</u> <i>Source: Equalities Impact Assessment</i>								
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<u>Increase</u> <i>Source: Equalities Impact Assessment</i>								
B3 Implementation									
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<u>Provider selection action</u> If the policy is approved, an implementation plan will needed to be developed including a provider selection process.								

B3.2 Time to implementation: Is a lead-in time required prior to implementation?	<u>Yes - go to B3.3</u>
B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?	<u>Yes</u>
B3.4 Is a change in provider physical infrastructure required?	<u>No</u> Infrastructure will be in place at the participating centres involved in the Commissioning Through Evaluation Programme.
B3.5 Is a change in provider staffing required?	<u>No</u> See above
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<u>Yes</u> A multidisciplinary team (MDT) approach must be in place to ensure appropriate patient selection and treatment. The specialised MDT must meet the relevant standards and offer the full range of liver-directed treatment options for the indications agreed, offering genuine choice between clinically suitable options. All cases must be discussed at an appropriate MDT with liver surgery representation. Centres should have adequate MDT, radio-pharmacy and Interventional Radiology capacity to support 10-20 cases per annum. Procedures should be performed in an interventional radiology suite that is equipped with cone-beam CT. There should be a SIRT nurse co-ordinator to provide individual expert advice and support for the whole SIRT patient pathway.

B3.7 Are there changes in the support services that need to be in place?	<p><u>Yes</u></p> <p>See section B3.6.</p>																
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<p><u>No</u></p>																
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	<p><u>Not yet known</u></p>																
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="1084 727 1883 783">Publication and notification of new policy</td> <td data-bbox="1883 727 1998 783"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 783 1883 839">Market intervention required</td> <td data-bbox="1883 783 1998 839"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 839 1883 935">Competitive selection process to secure increase or decrease provider configuration</td> <td data-bbox="1883 839 1998 935"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 935 1883 1031">Price-based selection process to maximise cost effectiveness</td> <td data-bbox="1883 935 1998 1031"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1031 1883 1086">Any qualified provider</td> <td data-bbox="1883 1031 1998 1086"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1086 1883 1142">National Commercial Agreements e.g. drugs, devices</td> <td data-bbox="1883 1086 1998 1142"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1142 1883 1198">Procurement</td> <td data-bbox="1883 1142 1998 1198"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1198 1883 1254">Other</td> <td data-bbox="1883 1198 1998 1254"><input checked="" type="checkbox"/></td> </tr> </table>	Publication and notification of new policy	<input checked="" type="checkbox"/>	Market intervention required	<input type="checkbox"/>	Competitive selection process to secure increase or decrease provider configuration	<input checked="" type="checkbox"/>	Price-based selection process to maximise cost effectiveness	<input checked="" type="checkbox"/>	Any qualified provider	<input type="checkbox"/>	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>	Procurement	<input type="checkbox"/>	Other	<input checked="" type="checkbox"/>
Publication and notification of new policy	<input checked="" type="checkbox"/>																
Market intervention required	<input type="checkbox"/>																
Competitive selection process to secure increase or decrease provider configuration	<input checked="" type="checkbox"/>																
Price-based selection process to maximise cost effectiveness	<input checked="" type="checkbox"/>																
Any qualified provider	<input type="checkbox"/>																
National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>																
Procurement	<input type="checkbox"/>																
Other	<input checked="" type="checkbox"/>																

B4 Place-based Commissioning

B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)

No

Section C - Finance Impact
C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	<input checked="" type="checkbox"/>
	Excluded from tariff – pass through	<input type="checkbox"/>
	Excluded from tariff - other	<input type="checkbox"/>
Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
	Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>
	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>
	Via Zero Cost Model	<input type="checkbox"/>
Activity	Paid entirely by National Tariffs	<input type="checkbox"/>
	Paid entirely by Local Tariffs	<input type="checkbox"/>
	Partially paid by National Tariffs	<input checked="" type="checkbox"/>
	Partially paid by Local Tariffs	<input checked="" type="checkbox"/>
	Part/fully paid under a Block arrangement	<input type="checkbox"/>
	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>

	<div> <div></div> <div>Part/fully paid under Other arrangements</div> <div><input type="checkbox"/></div> </div>
C1.2 Drug Costs Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable.
C1.3 Device Costs Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable.
C1.4 Activity Costs covered by National Tariffs List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	<p>Work Up procedure :YR54A-C Percutaneous Transluminal Embolisation of Peripheral Blood Vessel. Elective 2018/19 National Tariff £2,849 to £4,921. The weighted average tariff is £3,056</p> <p>Treatment Procedure: YR57Z Percutaneous, Chemoembolisation or Radioembolisation of Lesion of Liver. Elective 2018/19 National Tariff £3,394</p>
C1.5 Activity Costs covered by Local Tariff List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	<p>Policy identifies three distinct elements to treatments</p> <p>Unbundled Radiotherapy: SC28Z Deliver a Fraction of Interstitial Radiotherapy. Local Tariff based on CtE £14,288. This includes the cost of the microspheres which are c£8,000+VAT.</p>

	It is expected that the unbundled cost will reduce prior to implementation.		
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable.		
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	<u>No</u>		
C2 Average Cost per Patient			
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required? Are there any changes expected in year 6-10 which would impact the model?	YR1	£21,448	
	YR2	£21,448	
	YR3	£21,448	
	YR4	£21,448	
	YR5	£21,448	
C3 Overall Cost Impact of this Policy to NHS England			
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	<u>Cost pressure</u> Year 1 £1,093.8k Year 2 £1,093.8k		

	Year 5 £1,136.7k
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable.
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Not applicable.
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	<p>Budget impact for CCGs: <u>Cost neutral</u></p> <p>Budget impact for providers: <u>Cost neutral</u></p>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u>Cost pressure</u></p> <p>Year 1 £1,093.8k Year 2 £1,093.8k Year 5 £1,136.7k</p>
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<u>Not applicable.</u>

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.	CPAG Prioritisation Funding
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	Not applicable.
C6.2 How can these risks be mitigated?	Not applicable.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable.
C6.4 What scenario has been approved and why?	Not applicable.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	<u>Published evidence is mixed and it is uncertain whether the treatment is cost-effective</u>

<p>C7.2 Has other data been identified through the policy proposition development relevant to the assessment of value for money?</p>	<table border="1"> <tr> <td data-bbox="1081 153 2056 244">Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td> <td data-bbox="2056 153 2148 244"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 244 2056 335">Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td> <td data-bbox="2056 244 2148 335"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 335 2056 426">Available clinical practice data suggests the new treatment has the potential to improve value for money</td> <td data-bbox="2056 335 2148 426"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 426 2056 485">Other data has been identified</td> <td data-bbox="2056 426 2148 485"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 485 2056 544">No data has been identified</td> <td data-bbox="2056 485 2148 544"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 544 2056 635">The data supports a high level of certainty about the impact on value</td> <td data-bbox="2056 544 2148 635"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 635 2056 726">The data does not support a high level of certainty about the impact on value</td> <td data-bbox="2056 635 2148 726"><input type="checkbox"/></td> </tr> </table>	Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment	<input type="checkbox"/>	Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>	Available clinical practice data suggests the new treatment has the potential to improve value for money	<input type="checkbox"/>	Other data has been identified	<input type="checkbox"/>	No data has been identified	<input checked="" type="checkbox"/>	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment	<input type="checkbox"/>														
Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>														
Available clinical practice data suggests the new treatment has the potential to improve value for money	<input type="checkbox"/>														
Other data has been identified	<input type="checkbox"/>														
No data has been identified	<input checked="" type="checkbox"/>														
The data supports a high level of certainty about the impact on value	<input type="checkbox"/>														
The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>														
<p>C8 Cost Profile</p>															
<p>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</p>	<p><u>No</u></p>														
<p>C8.2 If yes, confirm the source of funds to meet these costs.</p>	<p>Not applicable.</p>														