Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1771		
Policy Title	Selective internal radiation therapy (SIRT) for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma (ICC) (Adults) Proposal **not for routine commission** (ref A3.1)		
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Finance Lead	Craig Charlton	**Analytical Lead**	Craig Charlton

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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.

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Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Intrahepatic cholangiocarcinoma (ICC) is a rare primary liver cancer which arises from the epithelial cells of the bile ducts. ICCs can originate from either small intrahepatic ducts (peripheral cholangiocarcinomas) or large intrahepatic ducts proximal to the bifurcation of the right and left hepatic ducts. The majority of cholangiocarcinomas (>90 percent) are adenocarcinomas and squamous cell carcinoma comprise most of the remaining cases. The 5 year survival rate for resectable ICC is between 20 and 40%; the 5 year survival rate for metastasised unresectable ICC is approximately 2% (Cancer Research UK 2015). *Source: Policy Proposition, Section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	0 - The Policy Proposition recommends that the treatment should not be routinely available. *Source: Policy Proposition, Section 1*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults**
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	The incidence of ICC increases with age, with the majority of people diagnosed aged between 70 and 80 years. *Source: Policy Proposition, Section 6*
A1.5 How is the population currently distributed geographically?	**Evenly**

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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?	**Other - detail below** This policy is for not routine commissioning and the treatment is not currently commissioned. *Source: Policy Proposition, Section 1*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**Not applicable.**
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? Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	**Not applicable**.
A3 Activity	
A3.1 What is the purpose of new policy?	**Confirm non-routine commissioning position of an additional new treatment**

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A3.2 What is the annual activity associated with the existing pathway for the eligible population?	Estimated 15 -20 patients per year. *Source: Commissioning through Evaluation (CtE) - SIRT* The CtE Programme closed to recruitment in early 2016.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	Not applicable – this policy is for not routine commissioning. *Source: Policy Proposition*
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.	Total 15-20 patients per year. *Source: Commissioning through Evaluation (CtE) - SIRT*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	ICC can be treated with surgery where there is potential for cure and is the treatment of choice. However, the majority of cases are diagnosed at a stage where the cancer is too advanced for surgery to be effective. Where this is the case, palliative (non-curative) treatment is offered to manage symptoms and prolong life, including chemotherapy, surgical procedures (such as bile duct bypass, stent insertion), and best supportive care. While chemotherapy has been demonstrated to be an effective palliative treatment, sometimes the chemotherapy medicines either don't work or stop working, this is because the cancer develops resistance to the medicine 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. At this stage, further treatment options are usually limited to best supportive

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	care. *Source: Policy Proposition, Section 3*
A4.2. What are the current treatment access and stopping criteria?	Not applicable – this policy is for not routine commissioning. *Source: Policy Proposition*
A4.3 What percentage of the total eligible population is expected to: 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?	Not applicable – this policy is for not routine commissioning. *Source: Policy Proposition*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**<u>Yes</u>** Best Supportive Care *Source: Policy Proposition, Section 3*
A5.2 What percentage of the total eligible population is estimated	Not applicable - this policy is for not routine commissioning.

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to: 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?	
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: 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?	Not applicable - this policy is for not routine commissioning.
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Not applicable - this policy is for not routine commissioning.
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	Not applicable - this policy is for not routine commissioning.
A7.2 What is the current number of contracted providers for the eligible population by region?	Not applicable - this policy is for not routine commissioning.

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A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** This is a not routinely commissioned policy proposition. *Source: Policy Proposition, Section 1*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity.	Not applicable – this treatment is not currently available and the policy is for not routine commissioning.
A8.2 Specify how the activity related to the new patient pathway will be identified.	Not applicable – this treatment is not currently available and the policy is for not routine commissioning.
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**Not applicable**
A8.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Not applicable**
A9 Monitoring	
A9.1 **Contracts**	**None**

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Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	This policy is for not routine commissioning.
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?	**Not applicable**
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Not applicable**
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**Not applicable**
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?	**Not applicable**
Section B - Service Impact	
B1 Service Organisation	

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<table>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Not applicable – this policy is for not routine commissioning.</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u>

This treatment is not currently available and the policy is not for routine commissioning.</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u>

This treatment is not currently available and the policy is for not routine commissioning.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>

This treatment is not currently available and the policy is for not routine commissioning</td></tr>
</table>

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B2.3 Is the new policy likely to improve equity of access?	**No impact** This treatment is not currently available and the policy is for not routine commissioning. *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** This treatment is not currently available and the policy is for not routine commissioning. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** This treatment is not currently available and the policy is for not routine commissioning.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** t
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**

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B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
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	**No change**
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	**Not applicable** – this treatment is not currently available and the policy is for not routine commissioning.
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based	**No**

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commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	
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	Not applicable.
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 %)	Not applicable.
C1.5 **Activity Costs covered by Local Tariff**	Not applicable.

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<table>
<tr><td>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.</td><td></td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Not applicable.</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td>Not applicable.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>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?</td><td><table><tr><td>YR1</td><td>£0</td></tr><tr><td>YR2</td><td>£0</td></tr><tr><td>YR3</td><td>£0</td></tr><tr><td>YR4</td><td>£0</td></tr><tr><td>YR5</td><td>£0</td></tr></table>
No</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in</td><td><u>Cost neutral</u></td></tr>
</table>

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relation to the relevant pathway.	This treatment is not currently commissioned. The CtE programme closed to recruitment in early 2016 and this is a not routinely commissioned policy proposition. Therefore there is no change in the cost for this cohort of patients.
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.	Budget impact for CCGs: **Cost neutral** Budget impact for providers: **Cost neutral** This treatment is not currently commissioned. The CtE programme closed to recruitment in early 2016 and this is a not routinely commissioned policy proposition
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral** See Section C3.1.

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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?	Not applicable.
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.	Not applicable.
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	

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C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**<u>There is no published evidence of cost-effectiveness</u>** No studies were identified which reported the cost-effectiveness of SIRT with yttrium-90 in this ICC population. *Source: Evidence Review*
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	Not applicable.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**<u>No</u>**
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable.

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