| Integrated Impact Assessment Report for Clinical Commissioning Policies | | | |
|---|---|---|---|
| **Policy Reference Number** | 1714 | | |
| Policy Title | Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation<br>Proposal for routine commission | | |
| Lead Commissioner | Carrie Gardner | Clinical Lead | Dr Mamta Buch |
| Finance Lead | Munieb Raban | Analytical Lead | Munieb Raban |

| Integrated Impact Assessment – Index | | |
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| About this Impact Assessment: instructions for completion and explanatory notes |
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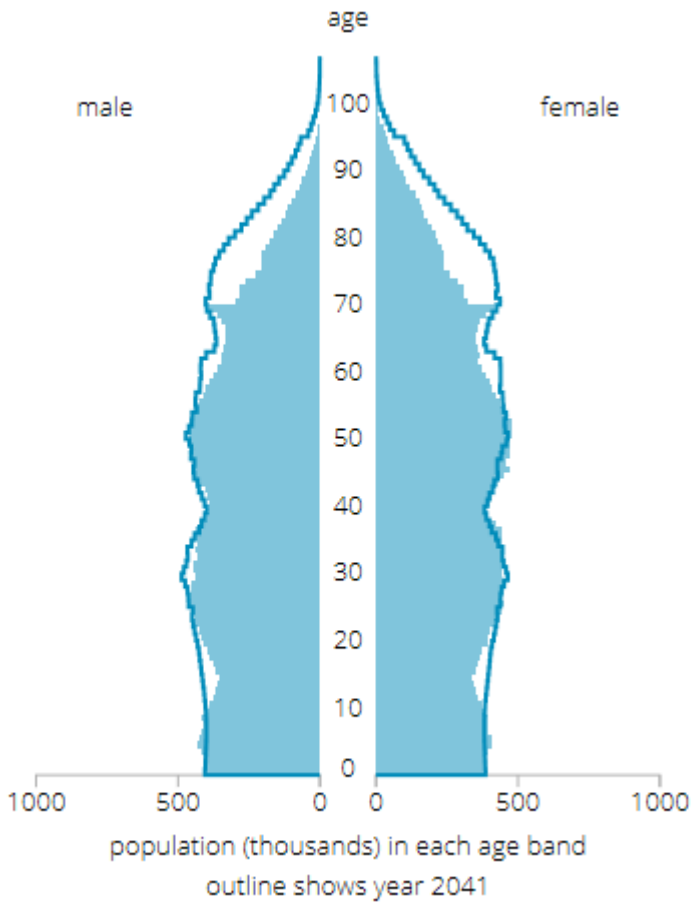
| • Each section is divided into themes.<br>• Each theme sets out a number of questions.<br>• All questions are answered by selecting a drop down option or including free text.<br>• Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.<br>• Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.<br>• 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. | Accurate epidemiological data for valvular heart disease (VHD) are limited, particularly for mitral regurgitation due to its different aetiologies. However a population-based study in the UK using echocardiographic screening in primary care (OxVALVE) showed the prevalence of moderate or severe left sided valve disease increasing to 18.7% in the over 75 years old. This study projected that the number of patients with heart valve disease will double by 2046, due to an increasingly elderly population. In a population of 53 million (England), 7.8% are aged over 75 years of age, giving a target population of 4 million. Of this group, approximately 8% have moderate-severe degenerative mitral regurgitation which equals a population of 320,000. 50% or 160,000 of these will have significant mitral prolapse. Of these, 25%, i.e. 40,000 patients will have anatomy suitable for invasive mitral valve intervention such as percutaneous mitral valve edge-to-edge leaflet repair. This patient population will encompass a broad group of clinical scenarios including absence of symptoms, both acute and elective presentations and co-morbidities. Whilst patients who are inoperable or of high surgical risk should be considered for percutaneous mitral valve edge-to-edge leaflet repair, there will be some patients for whom any intervention will be futile. It is probable that only 10% of this population, i.e. 4000 patients might be considered for percutaneous mitral valve edge-to-edge leaflet repair. It is estimated that approximately 10% of patients eligible for edge-to-edge leaflet repair would be referred. It may therefore be expected that approximately 400 patients might presently be considered for percutaneous mitral valve edge-to-edge leaflet repair such as MitraClip intervention in England on an annual basis. This may be expected to increase annually with improved referral networks and clinical awareness<br><br>*Source:* |

<table>
<tr><td>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</td><td>400 in year 1 rising to 442 in year 5<br>Source: Epidemiology and clinical experience of the procedure PRIOR to and during CtE plus ONS growth.</td></tr>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>Adults</u><br>18 years and over</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>18 and above relevant but mainly those over 60 years of age<br>Source:<br>The average age of participants was over 70 years old in all trials. The mean age of patients in the CtE programme was 76.2 years.</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u><br>If unevenly, estimate regional distribution by %:<br><table><tr><td>North</td><td></td></tr><tr><td>Midlands & East</td><td></td></tr><tr><td>London</td><td></td></tr><tr><td>South</td><td></td></tr></table><br>Source: The 2016 ONS population figures continue to show that there continues to be an increase in the aging population:<br><br>Please specify<br>The population of England is projected to grow by 4.1 million (7.5%) by mid-2024. The projected growth varies considerably by different age groups. The fastest-growing age group (people aged 65 and over) is projected to grow by 20.4% over 10 years and by nearly 60% over 25 years in England.</td></tr>
</table>




Source: Office for National Statistics National Population Projections: 2016-based statistical bulletin 2017

**A2 Future Patient Population & Demography**

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|---|---|
| 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? | **Increasing**<br>*Source: The 2016 ONS population figures continue to show that there continues to be an increase in the aging population.* |
| A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes? | **No** |
| 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?<br><br>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made. | YR2 +/- 8<br>YR3 +/- 8<br>YR4 +/- 9<br>YR5 +/- 9<br>YR10 +/-<br>*Source: Policy proposition and financial costing model*<br><br>**Yes**<br>Growth is in line with ONS population growth assumptions. We are aware that there is currently some build up of patients but as only three centres were commissioned as part of the CtE programme it is felt unlikely that there is full capacity in the system to identify, refer and then undertake the procedure in all eligible patients.<br>The finance model is based on 400 patients per annum from the outset to understand total potential impact. |

<table>
<tr><th colspan="2">A3 Activity</th></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Revise existing policy (expand or restrict an existing treatment threshold</u><br>Please specify<br>NHSCB/A09/PS/b Percutaneous mitral valve leaflet repair for mitral regurgitation<br>Dated April 2013. The aim is to improve the outcomes of patients who are assessed as very high risk for conventional mitral valve surgery.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>None<br>Please specify<br>Procedure is not currently routinely commissioned</td></tr>
<tr><td>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</td><td>It is estimated that each patient will require the activity in the table below with the number of patients being 400 in year 1 rising to 442 in year 5
<table>
<tr><th>Activity</th><th>Count</th></tr>
<tr><td>Mitral Clip Device</td><td>1</td></tr>
<tr><td>Outpatient First</td><td>1</td></tr>
<tr><td>Outpatient FU</td><td>4</td></tr>
<tr><td>Inpatient Spells (Insertion of Device)</td><td>1</td></tr>
<tr><td>Angio (Pre Op)</td><td>1</td></tr>
<tr><td>ECG (Pre Op)</td><td>1</td></tr>
<tr><td>Transthoracic Echocardiogram (Pre Op)</td><td>1</td></tr>
<tr><td>Transoesophageal Echocardiogram (Pre Op)</td><td>1</td></tr>
</table></td></tr>
<tr><td>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.</td><td>Not applicable</td></tr>
</table>

| **A4 Existing Patient Pathway** | |
|---|---|
| A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned:<br>• Treatment or intervention<br>• Patient pathway<br>• Eligibility and/or uptake estimates. | The current standard of care is mitral valve repair or replacement surgery. Some patients however will not be able to undergo surgery because of the risk caused by other health conditions. These patients will be treated with medication to try and control symptoms but medical therapy cannot alter the underlying valve disease process. |
| A4.2. What are the current treatment access and stopping criteria? | Not applicable |
| A4.3 What percentage of the total eligible population is expected to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | Not applicable |
| **A5 Comparator (next best alternative treatment) Patient Pathway**<br>(NB: comparator/next best alternative does not refer to current pathway but to an alternative option) | |
| A5.1 **Next best comparator**:<br>Is there another 'next best' alternative treatment which is a relevant comparator?<br>*If yes, describe relevant*<br>• *Treatment or intervention* | **No** |

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| • *Patient pathway*<br>• *Actual or estimated eligibility and uptake* | |
| A5.2 What percentage of the total eligible population is estimated to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | Not applicable |
| **A6 New Patient Pathway** | |
| A6.1 What percentage of the total eligible population is expected to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | If not known, please specify<br>a) 100<br>b) 10<br>c) 10<br>d) 100<br>e) 100 |
| A6.2 Specify the nature and duration of the proposed new treatment or intervention. | **Time limited**<br>For time limited treatments, specify frequency and/or duration.<br>Percutaneous mitral valve edge-to-edge leaflet repair is a minimally invasive procedure for the treatment of mitral regurgitation (MR, leaking of the mitral valve). It is performed in the cardiac catheterisation laboratory/hybrid theatre under general anaesthesia with trans-oesophageal echocardiography (ultrasound imaging by placing a specialised probe in the oesophagus) and X-ray guidance. The |

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| | percutaneous leaflet repair system is based on a surgical technique described as the "Alfieri stitch" but instead of a stitch, a device (for example a clip) is attached to the mitral valve leaflets to reduce retrograde blood flow through the valve. Vascular access is via the femoral vein which leads to the right atrium and trans-septal puncture is performed to access the left atrium and place a guide catheter. The device is delivered via this guide catheter within a delivery system. The device can be manoeuvred in the left atrium to approach the mitral valve. In the case of the MitraClip device specifically, the arms of the clip open, the MitraClip is passed below the valve and then pulled back to grasp and bring together the segments of the two valve leaflets responsible for the leak. The reduction in MR is assessed and if necessary, the further adjustments in position may be made to improve the MR reduction. The device which is firmly attached to the valve leaflets is then detached from the delivery system which is withdrawn. |
| **A7 Treatment Setting** | |
| A7.1 How is this treatment delivered to the patient? | *Select all that apply:*<br>☐ Emergency/Urgent care attendance<br>☒ Acute Trust: inpatient<br>☐ Acute Trust: day patient<br>☒ Acute Trust: outpatient<br>☐ Mental Health provider: inpatient<br>☐ Mental Health provider: outpatient<br>☐ Community setting<br>☐ Homecare<br>☐ Other |

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| A7.2 What is the current number of contracted providers for the eligible population by region? | <table><tr><td>NORTH</td><td>0</td></tr><tr><td>MIDLANDS & EAST</td><td>0</td></tr><tr><td>LONDON</td><td>0</td></tr><tr><td>SOUTH</td><td>0</td></tr></table> The are no commissioned providers of the service |
| A7.3 Does the proposition require a change of delivery setting or capacity requirements? | **yes**<br>Please specify:<br>A national procurement intervention will be required to commission specialised/ tertiary cardiac centres to deliver the service. |
| **A8 Coding** | |
| A8.1 Specify the datasets used to record the new patient pathway activity.<br><br>*expected to be populated for all commissioned activity | *Select all that apply:*<br><table><tr><td>Aggregate Contract Monitoring *</td><td>☒</td></tr><tr><td>Patient level contract monitoring</td><td>☒</td></tr><tr><td>Patient level drugs dataset</td><td>☐</td></tr><tr><td>Patient level devices dataset</td><td>☒</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☒</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☒</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr></table> |

<table>
<tr><td></td><td>
<table>
<tr><td>Clinical Database**</td><td>☒</td></tr>
<tr><td>Other**</td><td>☐</td></tr>
</table>
**If National Return, Clinical database or other selected, please specify: Funding of £100k per year for a National Registry has been included in the Impact Assessment and finance model.
</td></tr>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>
Select all that apply:
<table>
<tr><td>OPCS v4.8</td><td>☒</td></tr>
<tr><td>ICD10</td><td>☒</td></tr>
<tr><td>Treatment function code</td><td>☒</td></tr>
<tr><td>Main Speciality code</td><td>☐</td></tr>
<tr><td>HRG</td><td>☒</td></tr>
<tr><td>SNOMED</td><td>☐</td></tr>
<tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>A8.3 Identification Rules for Drugs:<br>How are drug costs captured?</td><td>
<u>Not applicable</u><br>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:<br><br>
If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:
</td></tr>
</table>

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| A8.4 **Identification Rules for Devices:**<br>How are device costs captured? | **Already covered by an existing category of HCTED but not commissioned via the Zero Cost Model**<br>If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).<br>Percutaneous valve repair and replacement devices |
| How are activity costs captured? | **Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool**<br>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).<br>NCBPS13F - Cardiology: PPCI And Structural Heart Disease Complex Invasive Cardiology<br><br>If activity costs are already captured please specify whether this service needs a separate code. **No**<br><br>If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.<br>No<br>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. **No** |
| **A9 Monitoring** | |
| A9.1 **Contracts**<br>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. | **Yes - population of clinical databases**<br>Submission of data to National Registry (to be established). |

<table>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)<br>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.</td><td>Select all that apply:<table><tr><td>Drugs or Device MDS</td><td>☒</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table></td></tr>
<tr><td>A9.3 Business intelligence<br>Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring<br>Is this part of routine contract monitoring?</td><td><u>Yes</u><br>If yes, please specify contract monitoring requirement:<br>Activity will be reported in line with Schedule 6 of the NHS Standard Contract</td></tr>
<tr><td>A9.5 Dashboard reporting<br>Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u><br>If yes, specify how routine performance monitoring data will be used for dashboard reporting.<br>If no, will one be developed?<br>Data will be collected through a National Registry</td></tr>
<tr><td>A9.6 NICE reporting<br>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?</td><td><u>No</u></td></tr>
<tr><td colspan="2">Section B - Service Impact</td></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
</table>

<table>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>The service is not routinely commissioned<br>Source: Clinical Commissioning Policy Statement: Percutaneous mitral valve leaflet repair for mitral regurgitation April 2013 Reference: NHSCB/A09/PS/b</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>Yes</u><br>Please specify:<br>Providers will be selected to provide the service when commissioned.</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><br>Please specify:<br>Service delivery will be through current specialised cardiac interventional services. A lead in period may be required to build capacity to deliver the service and increase awareness and education of health professionals in primary and secondary care.</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></td></tr>
</table>

| | |
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| B2.3 Is the new policy likely to improve equity of access? | **No impact**<br><br>*Source: Equalities Impact Assessment* |
| B2.4 Is the new policy likely to improve equality of access and/or outcomes? | **No impact**<br>Please specify:<br>The new policy is likely to improve treatment options and therefore outcomes for patients at very high risk for conventional mitral valve surgery.<br>*Source: NHSCB/A09/PS/b Clinical Commissioning Policy Statement: Percutaneous mitral valve leaflet repair for mitral regurgitation*<br>*Dated April 2013* |
| **B3 Implementation** | |
| B3.1 Will commissioning or provider action be required before implementation of the proposition can occur? | **Procurement action**<br>Please specify:<br>There are currently no commissioned providers; a national procurement intervention will be required to commission centres to deliver the service. |
| B3.2 **Time to implementation:**<br>Is a lead-in time required prior to implementation? | **Yes - go to B3.3**<br>If yes, specify the likely time to implementation: 12 months |
| B3.3 **Time to implementation:**<br>If lead-in time is required prior to implementation, will an interim plan for implementation be required? | **Yes**<br>If yes, outline the plan:<br>An interim plan will be required. The criteria for this will need to be decided but may be based on the requirements of the CtE programme. |

<table>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u><br>Please specify:<br>The procedure can be delivered within current tertiary and specialised cardiac facilities</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>Yes</u><br>Please specify:<br>There may be a requirement to increase staff to deliver the new procedure</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u><br>Please specify:<br>All the specialities within a tertiary cardiac and cardiac surgery centre in line with current specialised cardiac service specifications.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u><br>Please specify:<br>Services are not currently commissioned</td></tr>
<tr><td>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</td><td><u>Increase</u><br>Please complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future<br>State expected range</td><td>Provisional or confirmed</td></tr>
<tr><td>North</td><td>0</td><td>2</td><td><u>P</u></td></tr>
</table></td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| Midlands & East | 0 | 2 | P |
| London | 0 | 2 | P |
| South | 0 | 2 | P |
| Total | 0 | 8 | P |

Please specify:

The intervention is not routinely commissioned. As there were only three centres in the CtE programme this would not provide equitable geographic access; interim future locations are therefore likely to be selected from current specialised tertiary cardiac centres who have experience of both providing the procedure and the service or similar interventions.

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

*Select all that apply:*

| | |
|---|---|
| Publication and notification of new policy | ☒ |
| Market intervention required | ☒ |
| Competitive selection process to secure increase or decrease provider configuration | ☐ |
| Price-based selection process to maximise cost effectiveness | ☐ |
| Any qualified provider | ☐ |
| National Commercial Agreements e.g. drugs, devices | ☒ |
| Procurement | ☒ |
| Other | ☐ |

Please specify:

Future provision will be secured through procurement. The device will need to be included in the HCTED programme.

| **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 | ☐ |
| | Excluded from tariff – pass through | ☐ |
| | Excluded from tariff - other | ☐ |
| **Devices** | Not separately charged – part of local or national tariffs | ☐ |
| | Excluded from tariff (excluding ZCM) – pass through | ☒ |
| | Excluded from tariff (excluding ZCM) – other | ☐ |
| | Via Zero Cost Model | ☒ |
| **Activity** | Paid entirely by National Tariffs | ☒ |
| | Paid entirely by Local Tariffs | ☐ |
| | Partially paid by National Tariffs | ☐ |
| | Partially paid by Local Tariffs | ☐ |

<table>
<tr><td></td><td><table>
<tr><td></td><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table></td></tr>
<tr><td>C1.2 Drug Costs<br>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.<br>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Not applicable</td></tr>
<tr><td>C1.3 Device Costs<br>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.<br>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>£19,800 (including VAT)</td></tr>
</table>

<table>
<tr><td>C1.4 Activity Costs covered by National Tariffs<br>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</td><td>A full list of applicable HRGs are included in the finance spreadsheet, an overview of the costs covered by tariff are in the table below:<br><table><tr><th>Activity</th><th>Cost (£)</th></tr><tr><td>TBC</td><td>£TBC</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>C1.5 Activity Costs covered by Local Tariff<br>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>Not applicable</td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff<br>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><u>No</u></td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
</table>

<table>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?<br><br>Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR1</td><td>£TBC</td></tr><tr><td>YR2</td><td>£TBC</td></tr><tr><td>YR3</td><td>£TBC</td></tr><tr><td>YR4</td><td>£TBC</td></tr><tr><td>YR5</td><td>£TBC</td></tr></table><br>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 relation to the relevant pathway.</td><td><u>Cost pressure</u><table><tr><td>YR1</td><td>£TBC</td></tr><tr><td>YR2</td><td>£TBC</td></tr><tr><td>YR5</td><td>£TBC</td></tr></table></td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not applicable</td></tr>
<tr><td>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?</td><td>Not applicable</td></tr>
</table>

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| **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:<br>**Cost saving**<br>Reduced emergency admissions for heart failure<br>Value £TBC<br>Budget impact for providers:<br>**Cost neutral**<br>Please specify: |
| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole. | **Cost pressure**<br>Please specify:<br>Value £TBC |
| 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? | **No**<br>Please specify: |
| **C5 Funding** | |
| C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. | The funding will be from within the CPAG Prioritisation reserve. |

| | |
|---|---|
| decommissioning less clinically or cost-effective services. | |
| **C6 Financial Risks Associated with Implementing this Policy** | |
| C6.1 What are the material financial risks to implementing this policy? | There is a risk that the requirement for a gradual building of capacity has been over estimated and that the anticipated numbers will present within a shorter timeframe i.e. immediately, due to a build up of eligible patients in the system already. There is also a risk that the number of eligible patients will be greater than anticipated. |
| C6.2 How can these risks be mitigated? | It is not clear how real this risk is as numbers in the CtE were less. However numbers could potentially be subject to a cap (either providers or activity) over the first few years. Additionally by careful assessment and screening processes for patients and by the strict application of commissioning criteria to select patients who will benefit the most from the intervention. Inclusion of the device in the national HCTED programme will enable device costs to be managed. |
| C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios? | Click here to enter text. |
| C6.4 What scenario has been approved and why? | Click here to enter text. |
| **C7 Value for Money** | |
| C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review? | Please specify:<br>To be completed once the CtE Economic results have been published |

<table>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☒</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr>
</table></td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u></td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Not applicable</td></tr>
</table>