| Integrated Impact Assessment Report for Clinical Commissioning Policies | | | |
|---|---|---|---|
| **Policy Reference Number** | 1693 | | |
| **Policy Title** | Long term left ventricular assist device therapy for advanced heart failure (all ages)<br>Proposal **not for routine commission** (ref A3.1) | | |
| **Lead Commissioner** | Sarah Watson | **Clinical Lead** | Mr Steven Tsui |
| **Finance Lead** | Keith Moulds | **Analytical Lead** | N/A |

| Integrated Impact Assessment – Index | | |
|---|---|---|
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| 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 |
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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. | There is no direct epidemiological evidence about the size of this target population. Evidence is available from the North American INTERMACS registry and from other countries where LVAD destination therapy is funded. Expert opinion in the UK suggests that the best comparator is the United States, where the rate of destination LVAD implant is 4.2 per million population in 2015-16. Germany is a recognised outlier with a rate of 12 per million population.<br>From the US data 82.6% of patients were in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Profile 1-3, i.e. inotrope dependent. Applying the US rate to England suggests a steady state of 3.5 per million population destination therapy (DT) implants.<br>*Source: Policy Proposition section 6* |
| A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria. | 0<br>*Source: required*<br>Please specify<br>Policy proposition – not for routine commissioning |
| A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria. | **All ages**<br>Please specify<br>Click here to enter text. |
| A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria | Not relevant<br>*Source: required* |

<table>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Not relevant</u><br>If unevenly, estimate regional distribution by %:<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table>Source: Policy Proposition section 6<br>Please specify<br>Click here to enter text.</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>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?</td><td><u>Increasing</u><br><br>If other, Click here to enter text.<br>Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>Not known</u><br>Please specify<br>Click here to enter text.<br>Source: Policy Proposition section 6/other</td></tr>
<tr><td>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?</td><td><table><tr><td>YR2 +/-</td><td>0</td></tr><tr><td>YR3 +/-</td><td>0</td></tr><tr><td>YR4 +/-</td><td>0</td></tr></table></td></tr>
</table>

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| Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made. | <table><tr><td>YR5 +/-</td><td>0</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table><br>*Source: Service specification proposition section 3.1*<br><br>**Not relevant**<br>Click here to enter text. |
| **A3 Activity** | |
| A3.1 What is the purpose of new policy? | **Confirm non-routine commissioning position of an additional new treatment**<br>Please specify<br>Click here to enter text. |
| A3.2 What is the annual activity associated with the existing pathway for the eligible population? | Not known<br>*Source: required*<br>Please specify<br>Click here to enter text. |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population? | 190 patients<br>*Source: required*<br>Please specify<br>Click here to enter text. |
| 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 | Not known<br>*Source: required* |

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| applicable' and move to A4. | Please specify<br>Click here to enter text. |
| **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. | Optimal medical management (OMM) of heart failure involves drugs such as diuretics and inotropic agents. In addition to OMM, some patients may also have already undergone one or more of the following treatments before heart transplant or MCSD was considered: electrophysiological interventions such as pacemakers and implantable cardioverter defibrillators, revascularisation by percutaneous coronary angioplasty and stenting or coronary artery bypass grafting, valve replacement or repair, and temporary use of intra-aortic balloon pumps. These treatment options were reflected in the population characteristics of studies included in this review. The term OMM therefore included all the interventions above.<br>*Source:* *evidence review* |
| A4.2. What are the current treatment access and stopping criteria? | Patients with advanced heart failure would have progressed through treatment with optimal medical therapy, cardiac re-synchronisation therapy and non-transplant cardiac surgery if indicated before being considered for heart transplantation. For patients with advanced heart failure who are not heart transplant candidates, the alternative treatments available include: .<br>a) repeated hospital readmission for<br>a. intravenous therapy e.g. diuretics<br>b. intravenous inotropes (Level 2 or 3 care)<br>c. haemofiltration (Level 2 or 3 care)<br>b) palliative care until deat<br>*Source:* policy proposition section 3 |

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| 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? | If not known, please specify Click here to enter text.<br>a) 0<br>b) 0<br>c) 0<br>d) 0<br>e) 0<br>*Source: policy proposition- not routinely commissioned* |
| **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*<br>• *Patient pathway*<br>• *Actual or estimated eligibility and uptake* | **No**<br>If yes, Click here to enter text.<br>*Source: required* |
| 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? | Total estimated eligible<br>a) enter %<br>b) enter %<br>c) enter %<br>d) enter %<br>e) enter %<br>*Source: required* |
| | |

<table>
<tr><th colspan="2">A6 New Patient Pathway</th></tr>
<tr><td>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?</td><td>If not known, please specify Click here to enter text.<br>a) 0<br>b) 0<br>c) 0<br>d) 0<br>e) 0<br>Source: policy proposition – not routinely commissioned</td></tr>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Not applicable</u><br>For time limited treatments, specify frequency and/or duration.<br>Click here to enter text.<br>Source: required</td></tr>
<tr><th colspan="2">A7 Treatment Setting</th></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Select all that apply: Not applicable<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☐</td></tr><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☐</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr></table></td></tr>
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| | Homecare ☐<br>Other ☐<br>Please specify:<br>Click here to enter text. |
| A7.2 What is the current number of contracted providers for the eligible population by region? | NORTH number<br>MIDLANDS & EAST number<br>LONDON number<br>SOUTH number<br><br>Not applicable |
| A7.3 Does the proposition require a change of delivery setting or capacity requirements? | **No**<br>Please specify:<br>Policy proposition – not routinely commissioned |
| **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: Not applicable*<br>Aggregate Contract Monitoring * ☐<br>Patient level contract monitoring ☐<br>Patient level drugs dataset ☐<br>Patient level devices dataset ☐ |

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| | <table><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><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:<br>Click here to enter text. |
| A8.2 Specify how the activity related to the new patient pathway will be identified. | *Select all that apply:Not applicable*<br><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> |
| A8.3 **Identification Rules for Drugs:**<br>How are drug costs captured? | **<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>Click here to enter text.<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 |

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| | been discussed with the pharmacy lead:<br>Click here to enter text. |
| A8.4 **Identification Rules for Devices:**<br>How are device costs captured? | **Not applicable**<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><br>If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. |
| A8.5 **Identification Rules for Activity:**<br>How are activity costs captured? | **Not applicable**<br>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).<br><br>If activity costs are already captured please specify whether this service needs a separate code. Choose an item.<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><br>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item. |
| **A9 Monitoring** | |

<table>
<tr><td>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.</td><td><u>None</u><br>Please specify<br>Click here to enter text.</td></tr>
<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: Not applicable<br><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>Please specify: Click here to enter text.</td></tr>
<tr><td>A9.3 Business intelligence<br>Is there potential for duplicate reporting?</td><td><u>No</u><br>If yes, please specify mitigation:<br>Click here to enter text.</td></tr>
<tr><td>A9.4 Contract monitoring<br>Is this part of routine contract monitoring?</td><td><u>No</u><br>If yes, please specify contract monitoring requirement:<br>Click here to enter text.</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>Click here to enter text.<br>If no, will one be developed?<br>Click here to enter text.</td></tr>
<tr><td>A9.6 NICE reporting</td><td><u>No</u></td></tr>
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| Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy? | If yes, specify how performance monitoring data will be used for this purpose.<br>Click here to enter text. |
| **Section B - Service Impact** | |
| **B1 Service Organisation** | |
| B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.) | Tertiary centres<br>*Source: required* |
| B1.2 Will the proposition change the way the commissioned service is organised? | **No**<br>Please specify:<br>Click here to enter text.<br>*Source: required* |
| B1.3 Will the proposition require a new approach to the organisation of care? | **No change to delivery of care**<br>Please specify:<br>Click here to enter text. |
| **B2 Geography & Access** | |
| B2.1 Where do current referrals come from? | *Select all that apply:*<br>GP ☐<br>Secondary care ☒<br>Tertiary care ☒ |

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|---|---|
| | Other ☐<br>Please specify:<br>Click here to enter text. |
| B2.2 What impact will the new policy have on the sources of referral? | **No impact**<br>Please specify:<br>Click here to enter text. |
| B2.3 Is the new policy likely to improve equity of access? | **No impact**<br>Please specify:<br>Click here to enter text.<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>Click here to enter text.<br>*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**<br>Please specify:<br>Click here to enter text. |
| B3.2 **Time to implementation:**<br>Is a lead-in time required prior to implementation? | **No - go to B3.4**<br>If yes, specify the likely time to implementation: Enter text |

<table>
<tr><td>B3.3 Time to implementation:<br>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</td><td>Choose an item.<br>If yes, outline the plan:<br>Click here to enter text.</td></tr>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u><br>Please specify:<br>Click here to enter text.</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u><br>Please specify:<br>Click here to enter text.</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>Click here to enter text.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u><br>Please specify:<br>Click here to enter text.</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>Click here to enter text.</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>No change</u><br>Please complete table:<table><tr><td>Region</td><td>Current no. of providers</td><td>Future State expected</td><td>Provisional or confirmed</td></tr></table></td></tr>
</table>

| | | | |
|---|---|---|---|
| | | range | |
| North | 0 | 0 | C |
| Midlands & East | 0 | 0 | C |
| London | 0 | 0 | C |
| South | 0 | 0 | C |
| Total | 0 | 0 | C |

Please specify:

Not routinely commissioned policy

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

*Select all that apply: Not applicable*

| | |
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| 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:

Click here to enter text.

**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**<br>Please specify:<br>Click here to enter text. |

## 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: Not applicable*

| | | |
|---|---|---|
| **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 | ☐ |
| | Part/fully paid under a Block arrangement | ☐ |
| | Part/fully paid under Pass-Through arrangements | ☐ |
| | Part/fully paid under Other arrangements | ☐ |

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| 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. | Not applicable |
| 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. | Not applicable |
| 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 %) | Not applicable |
| 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. | Not applicable |
| C1.6 **Other Activity Costs not covered by National or Local Tariff**<br>Include descriptions and estimates of all key costs. | Not applicable |
| C1.7 Are there any prior approval mechanisms required either during implementation or permanently? | **No**<br>Please specify: Click here to enter text. |

| **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?<br><br>Are there any changes expected in year 6-10 which would impact the model? | YR1: 0<br>YR2: 0<br>YR3: 0<br>YR4: 0<br>YR5: 0<br><br>If yes, please specify:<br>No |
| **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. | **Cost neutral**<br>Please specify:<br>Click here to enter text. |
| C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured. | Click here to enter text. |
| 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:<br>**No impact on CCGs**<br>Budget impact for providers:<br>Choose an item.<br>Please specify:<br>Click here to enter text. |
| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole. | **Cost neutral**<br>Please specify:<br>No change to current commissioning position |
| C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured | Click here to enter text. |
| C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders? | **No**<br>Please specify:<br>Click here to enter text. |
| **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 | |
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| C6.1 What are the material financial risks to implementing this policy? | There are no financial risks to implementing this policy |
| 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? | **Published evidence indicates the treatment is not cost-effective**<br>Please specify:<br>The evidence review referenced three cost effectiveness studies identified were based on outcomes at 2 years modelled over a lifetime (approximately 5 years). The model will have estimated a projected survival as well as QoL (including the impact of adverse events on QoL) based on indirect data from more than one study, and based on assumptions beyond the period of observed data. There was a wide variation in the estimated quality adjusted life years (QALY) and life years gained (LYG) over a lifetime. Despite the weakness of the models, the estimated ICER was consistently high in all studies (£91,299 to £162,388 per QALY). This is not surprising as the LYGs are associated with numerous and serious adverse events which in turn reduce quality of life for the patient and increase the ongoing cost of care. |

<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><br>If yes, specify type and range:<br>Click here to enter text.</td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Click here to enter text.</td></tr>
</table>