Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1620		
Policy Title	Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension (all ages)		
Lead Commissioner	Sarah Watson	**Clinical Lead**	Joanna Pepke-Zaba
Finance Lead	Craig Charlton	**Analytical Lead**	Click here to enter text.

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Sections A – C	
Theme / Questions: Each section is divided into themes. Each theme sets out a number of questions.	**Responses / Comments:** All questions are answered by selecting a drop down option or including free text in line with the specified word limit. 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.	The incidence of CTEPH is estimated to be approximately 5 cases per million people per year. This implies around 300 new cases of CTEPH per annum in the UK, of whom approximately 60% will be treated with PEA, remaining 40% will be very heterogeneous group of patients from which it is estimated 34 will be eligible for BPA. Extrapolated for England it is estimated that 31 patients will be eligible for BPA *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	Not currently commissioned *Source: required*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** If other, specify Click here to enter text.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	The evidence review reports studies in patients with an average age varying between 59-70 years *Source: required*

<table>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u>
Analysis done by the HSS team shows a systematic component of geographic variation to be 3.15. An SVC value >20 demonstrates inequitable variation.

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</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>Constant</u>

If other, Click here to enter text.
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>No</u>

If yes, Click here to enter text.
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 treatment, according to the proposed policy 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><tr><td>YR5 +/-</td><td>0</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table>Source: Policy Proposition section 6/ other</td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	Confirm routine commissioning position of an additional new treatment If other, Click here to enter text.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	31 patients with an average treatment of 4-6 procedures *Source: required*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	Up to a maximum of 6 procedures per patient 155 procedures *Source: required*
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population?	272 patients *Source: required*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	PAH targeted therapies with Riociguat as first line treatment. Referral for lung transplantation should be considered *Source: required*
A4.2. What are the current treatment access and stopping criteria?	Distribution of thromboembolic disease too distal to be considered a suitable candidate for PEA *Source: required*
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?	a) 100% b) 0% c) 100% d) 100% e) 100% *Source: required*

A5 Comparator (next best alternative treatment) Patient Pathway	
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*	**Yes - additional comparator routinely commissioned** If yes, Riociguat *Source: required*
A5.2 What percentage of the total eligible population is estimated 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?	Total estimated eligible a) 100% b) 0% c) 100% d) 100% e) 100% *Source: required*
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?	a) 100% b) 62.5% c) 37.5% d) 100% e) 100% *Source: required*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Time limited** For time limited treatments, specify frequency and/or duration. The procedure is performed in stages and several sessions (4-6 per patient) are usually required *Source: Evidence review*

A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?	**Acute Trust: inpatient** If other Click here to enter text.
A7.2 What is the current number of contracted providers for the eligible population by region?	NORTH: 0 MIDLANDS & EAST: 0 LONDON: 0 SOUTH: 0
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**yes** If yes or not yet known, specify Proposition to commission from the expert centre for PEA surgery *Source: Policy proposition*

A8 Coding

A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	☒
Patient level contract monitoring	☒
Patient level drugs dataset	☐
Patient level devices dataset	☐
Devices supply chain reconciliation dataset	☐
Secondary Usage Service (SUS+)	☐
Mental Health Services DataSet (MHSDS)	☐
National Return**	☐
Clinical Database**	☒
Other**	☐

<table>
<tr><td></td><td>**If National Return, Clinical database or other selected, list here: Click here to enter text.</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>
Describe a suitable Identification Rule for the service or procedure:
OPCS4 code L13.5
NCBPS13X: E05-Congenital Heart Services
NCBPS23X: E02-Specialised Surgery in Children</td></tr>
<tr><td>A8.3 Does the service require the creation of a new specialised service line?</td><td><u>yes</u></td></tr>
</table>

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.	**Yes - other** If yes, specify Add into HSS contract monitoring
A9.2 **Excluded Drugs** For treatments which are tariff excluded drugs, specify the pharmacy monitoring required, for example reporting or use of prior approval systems.	*Select all that apply:* Drugs MDS ☐ Blueteq ☐ Other prior approval ☐ If other, Click here to enter text.
A9.3 **Business intelligence** Specify analytical information, monitoring and reporting requirements, including validation requirements, to ensure activity is not double charged through existing routes.	Same as PEA surgery activity
A9.4 **Contract monitoring** Specify contract monitoring to be undertaken by supplier managers, and any changes from current arrangements.	Monitoring to be added to PEA activity monitoring and reported as part of the annual PEA audit report
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text. If no, will one be developed? No
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?	**No** If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.

<table>
<tr><th colspan="2">Section B - Service Impact</th></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)</td><td>The service is not currently provided
Source: Click here to enter text.</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>Yes</u>

If yes, specify:
Proposal to commission from HSS PEA service in Papworth
Source: required</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>Implement a lead provider model</u>

If other, specify:
Click here to enter text.</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>
If other, specify:
Click here to enter text.</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>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>

Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve</td><td><u>Increase</u></td></tr>
</table>

equality of access and/or outcomes?	*Source: Equalities Impact Assessment (NB this can only be a source if the improved access is for a protected demographic?)*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Service organisation action** Specify action required: Service has expertise in managing patient group and facilities for surgery. Will need to factor additional capacity into cardiology job plans and cath lab time.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: full capacity will take a while to grow but procedures could start immediately. Not the national population is agreed to be c27 patients.
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** If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** If yes, specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	**No** If yes, specify: Click here to enter text.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No** If yes, specify: Click here to enter text.

<table>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>

If yes, specify:
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>

If yes, specify:
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>Increase</u>

If yes, complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future State expected range</td><td>*</td></tr>
<tr><td>North</td><td>0</td><td>0</td><td>C</td></tr>
<tr><td>Midlands & East</td><td>0</td><td>1</td><td>C</td></tr>
<tr><td>London</td><td>0</td><td>0</td><td>C</td></tr>
<tr><td>South</td><td>0</td><td>0</td><td>C</td></tr>
<tr><td>Total</td><td>0</td><td>1</td><td>C</td></tr>
</table>
*select P=provisional or C=confirmed</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table>
<tr><td>Publication and notification of new policy</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☐</td></tr>
<tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr>
<tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr>
<tr><td>Any qualified provider</td><td>☐</td></tr>
<tr><td>National Commercial Agreements e.g. drugs,</td><td>☐</td></tr>
</table></td></tr>
</table>

	devices ☐ Procurement ☐ Other ☐ If other, 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** If yes, specify: Click here to enter text.
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 Is this treatment paid under national prices?	**No** If yes, specify HRG and tariff Click here to enter text.
C1.2 Is this treatment excluded from national prices?	**Yes**
C1.3 Is this covered under a local price arrangement? NB: Local pricing may be subject to commercial confidentiality and must not be disclosed.	**Yes** If yes, state: Range £6k Midpoint £6k Certainty **High**
C1.4 Is a new price proposed?	**Yes** If yes, specify how this has been derived, validated and tested? From provider information testes against national prices where possible

<table>
<tr><td></td><td>and patient level information</td></tr>
<tr><td>C1.5 If VAT is payable, is it included in the proposed price?</td><td><u>Not payable</u>

If yes – in part, specify:
Click here to enter text.</td></tr>
<tr><td>C1.6 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?</td><td><u>No</u>

If yes, specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated net cost per patient to NHS England, in years 1-5, including follow-up where required?

NB: Net cost takes account of the impact of the new proposal compared to the existing pathway and any comparators.
A4 sets out the existing pathway.
A5 sets out any relevant comparator pathway.
A6.2 sets out the nature of the proposed treatment (one off / ongoing etc).
Inputs summary sets out key input assumptions.</td><td><table><tr><td>YR1</td><td>£39k</td></tr><tr><td>YR2</td><td>£39k</td></tr><tr><td>YR3</td><td>£39k</td></tr><tr><td>YR4</td><td>£39k</td></tr><tr><td>YR5</td><td>£39k</td></tr></table></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.</td><td><u>Cost pressure</u></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>Click here to enter text.</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 agreed, and calculated?</td><td>Click here to enter text.</td></tr>
</table>

C3.4 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, are CCGs aware of the values to be transferred?	Choose an item.
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**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure**
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** If yes specify: 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.	From within specialised commissioning recurrent allocation envelope.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	Not considered material
C6.2 How can these risks be mitigated?	Click here to enter text.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case,	Worked up based on clinical input and known patient data

<table>
<tr><td>worst case and most likely total cost scenarios?</td><td></td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>Click here to enter text.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What evidence is available that the treatment is cost effective?</td><td><u>No published evidence available</u></td></tr>
<tr><td>C7.2 What issues or risks are associated with this assessment? e.g. quality or availability of evidence</td><td>Select all that apply:<table><tr><td>Some uncertainty about number of eligible patients</td><td>☐</td></tr><tr><td>Some uncertainty about estimates of uptake</td><td>☐</td></tr><tr><td>Some uncertainty about future drug prices</td><td>☐</td></tr><tr><td>Potential for legal challenge</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>

If yes, specify type and range:
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>