Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A10X03		
Policy Title	Personalised External Aortic Root Support (PEARS) for surgical management of enlarged aortic root (adults)		
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Section K - Activity Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K.1.1 This policy recommends **not-routinely commissioning** personalised external aortic root support (PEARS) for: • patients with **Marfan syndrome**; • a subgroup of those with **bicuspid aortic valve disease** (BAVD); and • a proportion of patients having undergone **major cardiac correction** in infancy. **Marfan syndrome** has an estimated prevalence of 1 case per 3,000-5,000 people.[i, ii] There are therefore estimated to be between c. 8,500 and 14,250 adults in England with Marfan syndrome in 2014/15[iii].

		BAVD has an estimated prevalence of 1 case per 50-100 people[iv], resulting in c. 426,500 to 853,250 adults[v] in England in 2014/15[vi]. The **total prevalent adult population** across these conditions is therefore estimated to be c. 435,000 to 867,500 in England in 2014/15[vii].
	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 The population **eligible for treatment** is a subset of the prevalent population; those patients with an enlarged aorta (40-55mm) that is growing by more than 5mm a year. It is estimated that around 40-50 patients per year are expected to meet these criteria.[viii] Around half (20-25) of these are expected to have Marfan syndrome, 10-15 to have BAV and the remaining c.10 patients to have had cardiac correction surgery in infancy.
	K1.3 What age group is the treatment indicated for?	K1.3 The treatment is indicated for adults (defined as aged over 18).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Early clinical results for the PEARS procedure show patients had an age range of 16-58, with a median age of 33.[ix]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 Around 10-12 patients underwent a PEARS procedure in 2014/15.[x] The remaining 30-38 patients eligible for PEARS can be expected to currently be treated with: • β-Adrenergic–Blocking agents (c. 70%)[xi] that aim to lower blood pressure. These drugs are a life-long treatment, and do not preclude the need for surgical correction[xii]; • Angiotensin II receptor blockers (ARBs) or Losartan[xiii] (c. 15%[xiv]) to treat hypertension, diabetic nephropathy and congestive heart failure[xv]; or • A small proportion of patients may receive no medication in relation

		to their aortic dilation (c.15%[xvi]). It is expected that even if a patient undergoes a PEARS or a comparator procedure, they would still continue to take any medication listed above. To prevent aortic dissection, patients are recommended aortic surgery once the aortic diameter exceeds c. 45mm[xvii] (this is different to the eligibility criteria for PEARS, where patients must have an enlarged aorta (40-55m) that is growing by more than 5mm a year). The traditional surgical procedures that these patients would receive are the: 1. Bentall operation with either a mechanical or bioprosthetic valve[xviii]; or the 2. Valve-sparing root replacement (VSRR)
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	K1.6 No change to the future prevalence rate is anticipated. The prevalent population identified in K1.1 could grow in line with population growth and is estimated to be in the region of[xix]: • 442k to 880k in 2016/17 (year 1) • 445k to 886k in 2017/18 (year 2) • 454k to 904k in 2020/21 (year 5)
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	K1.7 In the 'do-nothing' it is estimated that activity would remain equal to that identified in K1.5.[xx]
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, no geographic differences in the prevalence were identified.[xxi] [xxii]
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely	K2.1 This policy proposes a **non-routine commissioning position**.

	commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 As Marfan syndrome is a hereditary condition, the prevalence in the population may not be affected by environmental factors. However, were there to be reductions in smoking rates in the prevalent population, then there could be fewer patients with larger aortic size.[xxiii]With a greater all-round awareness of the aortic dilation feature of the conditions, there could be more people that volunteer for early screening and therefore enter the patient population.[xxiv]
	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details	K2.3 The prevalence of Marfan syndrome does not vary with ethnicity or geography.[xxv]The prevalence of BAVD, however, is likely to vary with ethnicity.[xxvi]
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	K2.4 Under the policy, PEARS would not be routinely commissioned for the target population as identified in K1.2. In this case, the target population would still require a surgical procedure which is likely to be a comparator treatment as described in K1.5. For comparator treatments however there may be a slight delay in when the patients receive the surgery (given the difference in the eligibility criteria between PEARS and the comparators – see K1.5).
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 Current annual activity is identified in K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented	K3.2 Future PEARS activity is expected to be zero in future years given a non-routinely commissioned position.

	in the target population? Please provide details in accompanying excel sheet K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet	 K3.3 It is expected that the 10-12 patients in K1.7 who would have received PEARS in the 'do-nothing' would require either a Bentall or VSRR, as noted in K1.5. The criteria for receiving a comparator treatment is slightly different to that of PEARS. This is noted in K1.5.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity. K4.2. What are the current treatment access criteria? K4.3 What are the current treatment stopping points?	K4.1 N/A K4.2. N/A K4.3. N/A
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please	K5.1 See K1.5 K5.2 N/A

	indicate likely outcome for patient at each stopping point.	
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K6.1 N/A – no new pathway proposed K6.2 N/A – no new pathway proposed
K7 Treatment Setting	K7.1How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/Outpatient ○ Mental Health Provider: Inpatient /Outpatient ○ Community setting ○ Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.1 This is an acute inpatient procedure with an average hospital stay of 3-4 days. [xxvii] K7.2 No
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related	K8.1 N/A

	to the new patient pathway be recorded?	
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 N/A
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 N/A
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 N/A
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 N/A
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 N/A
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 N/A
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 N/A
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	K9.7 N/A

Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision) L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.1 Service currently delivered in three specialist cardiac centres in England: Royal Brompton and Harefield NHS Trust, St Guy's and St Thomas's NHS Trust and Oxford University Hospitals NHS Trust. L1.2 No change
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new policy change / restrict / expand the sources of referral? L2.3 Is the new policy likely to improve equity of access? L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.1 Patients with an enlarged aortic root are regularly monitored at specialist cardiac centres L2.2 No L2.3 Yes, through a consistent commissioning position across the country. L2.4 No.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed? L3.2 Is there a change in provider physical infrastructure required? L3.3 Is there a change in provider staffing required?	L3.1 No L3.2 No L3.3 No

	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 N/A
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 No
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices, and if so which?	M1.1 There is no tariff specifically for PEARS – this falls under the following national tariff: • EA17Z - Single Cardiac Valve Procedures[xxviii] with a tariff in 2014/15 of £9,286. Including an average market forces factor

		(MFF) for the three providers identified in L1.1 would result in a tariff price of £11,238. [xxix] This tariff would cover the cost of undertaking the procedure and any device used for the traditional surgical procedures (as described K1.5).
	M1.2 Is this treatment excluded from national prices?	M1.2 No
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	M1.3 There would be local price arrangement around the ExoVasc® implant, which is estimated to cost £6,500.[xxx] This is greater than the cost of a traditional device which is estimated to range between £949 and £2,889[xxxi]. *[Note: It has been noted by the policy working group that benefits from PEARS (such as reduced cost of operating theatre time and procedure, potential saving from no use of Cardio Pulmonary Bypass, and lower length of stay) help mitigate the additional costs associated with the device. The overall costs of the treatment – including the beddays, device cost and the procedure costs are therefore broadly consistent to that of traditional single cardiac valve procedures.]*
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes	M1.4 N/A
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 N/A
	M1.6 Do you envisage a prior approval / funding authorisation being required to	M1.6 N/A

	support implementation of the new policy?	
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 The cost of a patient undergoing a PEARS procedure will comprise different components, which will depend on the following patient pathway: 1. Each patient receives a computerised tomography (CT) scan[xxxii] to map the precise anatomy of the patient's aorta. The cost of a CT scan can vary between £92 and £105.[xxxiii] 2. The average cost per patient per spell ranges from c.£14,000 to £18,000[xxxiv] 3. Each patient then receives a follow up MRI scan, around 6-8 weeks after the operation.[xxxv] The cost of an MRI scan varies between £164 and £224. The cost per patient in year one, is estimated to be between c. £14,256 and £18,329. However, given that PEARS is not routinely commissioned, the revenue cost will relate to the comparator procedures as defined in K1.5. The procedure cost is expected to be the broadly same as for PEARS given this falls under the same tariff. There could be minor differences in the overall costs due to length of stay (including critical care). However, overall the total per patient cost is broadly consistent to that of PEARS[xxxvi].
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 In the years following the procedure, patients may be seen annually for a 'check-up'.[xxxvii] This involves a similar MRI scan to that mentioned in M2.1 and would cost between £164 and £224 per patient per year.[xxxviii]
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	M3.1 The policy is to **not routinely commission** this treatment so the 10-12 patients who would have received PEARS in the 'do-nothing' scenario would receive a comparator treatment instead. As these are both funded by NHS England, and are assumed to be equal in

		cost[xxxix], this policy is expected to be broadly cost neutral. Taking the number of patients from K1.5 and the range of per patient costs identified in M2.2, the baseline expenditure on PEARS could be in the region of £143k - £220k excluding any follow-up.
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.2 N/A
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	M4.1 This policy is broadly cost neutral to other parts of the NHS[xl].
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2 This policy is broadly cost neutral to the NHS as a whole.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	M4.3 N/A
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 N/A
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified *e.g. decommissioning less clinically or cost-effective services*	M5.1 N/A
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No material financial risks have been identified.
	M6.2 Can these be mitigated, if so how?	M6.2 N/A

	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	M6.3 N/A
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature* M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.1 and M7.2 There is no published literature comparing the cost effectiveness of PEARS to other procedures.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs* M8.2 If so, confirm the source of funds to meet these costs.	M8.1 N/A M8.2 N/A

[i] Pyeritz, R. E., & Keane, M. G. (2008). Medical Management of Marfan syndrome.

[ii] The Marfan Foundation

[iii] This applies the prevalence rates to ONS (2012) population projections for 2014/15.

[iv] Losenno, K., Goodman, R. and Chu, M. (2012). Bicuspid Aortic Valve Disease and Ascending Aortic Aneurysms: Gaps in Knowledge. Cardiology Research and Practice, 2012, pp.1-16.

[v] Aged over 16 as discussed with the policy working group.

[vi] This applies the prevalence rate to the ONS (2012) population projections for 2014/15.

[vii] The number of patients that underwent cardiac correction surgery in infancy is difficult to estimate and therefore excluded from the prevalence estimates. This is based on discussions with the policy working group.

[viii] Based on discussions with the policy working group.

[ix] Pepper, J., John Chan, K., Gavino, J., Golesworthy, T., Mohiaddin, R. and Treasure, T. (2010). External aortic root support for Marfan syndrome: early clinical results in the first 20 recipients with a bespoke implant. JRSM, 103(9), pp.370-375.

[x] Based on discussions with the policy working group

[xi] This assumes that the survey data from the clinical trials for PEARs is representative of the target population as a whole. Treasure, T., Takkenberg, J., Golesworthy, T., Rega, F., Petrou, M., Rosendahl, U., Mohiaddin, R., Rubens, M., Thornton, W., Lees, B. and Pepper, J. (2014). Personalised external aortic root support (PEARS) in Marfan syndrome: analysis of 1-9 year outcomes by intention-to-treat in a cohort of the first 30 consecutive patients to receive a novel tissue and valve-conserving procedure, compared with the published results of aortic root replacement. Heart, 100(12), pp.969-975. Includes patients also receiving Angiotensin II receptor blockers (ARBs).

[xii] Milewicz, D. (2005). Treatment of Aortic Disease in Patients With Marfan Syndrome. Circulation, 111(11), pp.e150-e157

[xiii] Based on discussions with the policy working group

[xiv] This assumes that the survey data from the clinical trials for PEARs is representative of the target population as a whole (Treasure et al, 2014). Includes patients also receiving Beta-Blockers.

[xv] Milewicz, D. (2005). Treatment of Aortic Disease in Patients With Marfan Syndrome. Circulation, 111(11), pp.e150-e157.

[xvi] This assumes that the survey data from the clinical trials for PEARs is representative of the target population as a whole (Treasure et al, 2014).

[xvii] Based on discussions with the policy working group.

[xviii] Also known as the total root replacement

[xix] Demographic growth rates are sourced from ONS (2012), Population projections. The demographic growth rate for adults is applied.

[xx] Based on discussions with the policy working group. It was discussed that in the 'do nothing' activity would remain at the current levels.

[xxi] Grimes, S., Acheson, L., Matthews, A. and Wiesner, G. (2004). Clinical consult: Marfan syndrome. Primary Care: Clinics in Office Practice, 31(3), pp.739-742.

[xxii] No evidence to suggest any particular geographical distribution in patients with BAVD across England was found.

[xxiii] 'A long smoking history, especially with chronic obstructive pulmonary disease, should prompt earlier intervention because smoking causes elastin fragmentation, and both smoking and chronic obstructive pulmonary disease correlate with larger aortic size and faster aortic expansion rate' Milewicz, D. (2005). Treatment of Aortic Disease in Patients With Marfan Syndrome. Circulation, 111(11), pp.e150-e157.

[xxiv] Based on discussions with the policy working group.

[xxv] Pyeritz, R. E., & Keane, M. G. (2008). Medical Management of Marfan syndrome.

[xxvi] Novaro, G., Houghtaling, P., Gillinov, A., Blackstone, E. and Asher, C. (2013). Prevalence of Mitral Valve Prolapse and Congenital Bicuspid Aortic Valves in Black and White Patients Undergoing Cardiac Valve Operations. The American Journal of Cardiology, 111(6), pp.898-901.

[xxvii] As discussed with the policy working group.

[xxviii] Based on information received from the policy working group

[xxix] This is sourced from the 2014/15 national tariff and a MFF uplift of c.21% has been applied. From 2015/16 onwards, this is expected to be c. £11,058, based on an efficiency factor of -3.5% and inflation rate of 1.9%.

[xxx] Computer aided design is used to create a model of the aorta, which is subsequently used to make a bespoke external polymer mesh support. The total cost of the ExoVasc® implants per procedure is £6,500 as two sleeves are made.-- based on discussions with the policy working group.

[xxxi] Based on information received from the policy working group.

[xxxii] Based on discussions with the policy working group.

[xxxiii] This assumes that the scans are of one area. The tariffs for CT scans vary dependent on the number of areas and whether the scan is with or without contrast. This includes a market forces factor (MFF) uplift of c.21%; the average across the 3 providers of PEARS, an efficiency factor of -3.5% and an inflation uplift of 1.9%.

[xxxiv]This is based on information received from the policy working group and includes the cost of the procedure in M1.3 (which includes the device) and any critical care bed days.

[xxxv] Based on discussions with the policy working group.

[xxxvi] Based on discussions with the policy working group.

[xxxvii] Based on discussions with the policy working group.

[xxxviii] This is the average MRI scan on one area from the 14/15 national tariff. This includes a market forces factor (MFF) uplift of c.21%; the average across the 3 providers of PEARS, an efficiency factor of -3.5% and an inflation uplift of 1.9%.

[xxxix] Based on discussions with the policy working group The cost to providers, however, is borne in different areas; PEARS has a greater device cost but requires less time in theatre and has a lower length of stay.

[xl] As the costs of undertaking PEARS or a comparator treatment are assumed to be equal (based on discussions with the policy working group).