Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	**D12X03**		
Policy Title	**Argus II retinal prosthesis**		
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Section A - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 1This policy proposes a non-routine commissioning position for Argus II Retinal Prosthesis. Retinitis pigmentosa (RP) is the leading cause of inherited blindness, affecting 1 in 3,500 people. The annual incidence of 6 per million suggests a total of 318 new cases in England per year.	
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 The proposed policy is non-routine commissioning of this treatment. It is estimated that 10 patients in England per annum could be eligibility for this treatment following clinical selection criteria for the procedure and patient choice.	
	A1.3 What age group is the treatment indicated for?	A1.3 The existing research trials have been conducted on adults with an age range from 28 to 77 years, (average 58 years).	

	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 The existing research trials have been conducted on adults with an age range from 28 to 77 years, (average 58 years).
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 n/a this treatment is not routinely commissioned.
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 No future changes in the prevalence of retinal pigmentosa has been identified.
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	A1.7 The policy proposes that Argus II for retinal pigmentosa is not routinely commissioned
	A1.8 How is the population currently distributed geographically?	A1.8 There is a national population distribution for identified for patients with retinal pigmentosa.
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	A2.1 The policy proposes that Argus II retinal prosthesis is not routinely commissioned.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased	A2.2 Retinal pigmentosa is a degenerative eye condition that causes progressive loss of vision. The disease is often inherited. No specific factors have been identified for a growth in this identified patient population, or disease prevalence.

	survival).	
	A 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.	A2.3 No specific factors have been identified for a change in this identified patient population.
	A2.4 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?	A2.4 The policy proposes that Argus II retinal prosthesis is not routinely commissioned therefore there are no anticipated increase or decrease in patients accessing treatment.
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	A3.1 The policy proposes that Argus II retinal prosthesis is not routinely commissioned therefore it is not anticipated that there will be any activity.
	A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	A3.2 The policy proposes that Argus II retinal prosthesis is not routinely commissioned therefore it is not anticipated that there will be any activity.
	A3.3 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.	A3.3 There is currently no NHS treatment for patients with end stage Retinal Pigmentosa. As per A1.2 it is estimated that 10 patients in England per annum could be eligibility for this treatment following clinical selection criteria for the procedure and patient choice.
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or	A4.1 No currently commissioned pathway. There is currently no NHS treatment for patients with end stage Retinal Pigmentosa.

	include a figure to outline associated activity.	
	A4.2. What are the current treatment access criteria?	A4.2 There is currently no NHS treatment for patients with end stage Retinal Pigmentosa.
	A4.3 What are the current treatment stopping points?	A4.3 There is currently no NHS treatment for patients with end stage Retinal Pigmentosa.
A5 Comparator (next best alternative treatment) Patient Pathway	A5.1 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.	A5.1 n/a There is currently no NHS treatment for patients with end stage Retinal Pigmentosa.
	A5.2 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.	A5.2 n/a There is currently no NHS treatment for patients with end stage Retinal Pigmentosa.
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	A6.1 The policy proposes that Argus II retinal prosthesis is not routinely commissioned.
	A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the	A6.2 The policy proposes that Argus II retinal prosthesis is not routinely commissioned.

	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.	
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery	A7.1 The policy proposes that Argus II retinal prosthesis is not routinely commissioned.
	A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	A8.1 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
A9 Monitoring	A9.1 Do any new or	A9.1 n/a The policy proposes that Argus II

	revised requirements need to be included in the NHS Standard Contract Information Schedule?	retinal prosthesis is not routinely commissioned
	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned. The NICE Interventional procedure guidance (519) for Insertion of an epiretinal prosthesis for retinitis pigmentosa, issued June 2015 recommended that due to limited evidence this procedure should only be used in the context of research, and encouraged further research on this technology.
	A9.7 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*	A9.7 n/a
Section B - Service Impact		

Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 This service is currently not routinely commissioned.
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 n/a this service is not currently routinely commissioned.
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B2.3 Is the new policy likely to improve equity of access?	B2.3 Equity of access will remain the same, as there is no change to current policy.
	B2.4 Is the new policy likely to improve equality of access / outcomes?	B2.4 Equality of access/outcome will remain the same as there is no change to current policy.
B3 Implementation	B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	B3.1 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.3 Is there a change in provider staffing required?	B3.3 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned

	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.5 Are there changes in the support services that need to be in place?	B3.5 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
	B3.8 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)	B3.8 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned
Section C - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment	C1.1 n/a this treatment is not routinely

	paid under a national prices*, and if so which?	commissioned
	C1.2 Is this treatment excluded from national prices?	C1.2 n/a this treatment is not routinely commissioned
	C1.3 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?	C1.3 n/a this treatment is not routinely commissioned
	C1.4 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?	C1.4 n/a this treatment is not routinely commissioned
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 n/a this treatment is not routinely commissioned
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 n/a this treatment is not routinely commissioned
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned. Treatment based on per patient cost has been estimated to be £93,734.
	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned.

C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.1 cost neutral. The policy proposes that Argus II retinal prosthesis is not routinely commissioned. C3.2 n/a
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. C4.3 Where this has not been identified, set out the reasons why this cannot be measured. C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.1 cost neutral. The policy proposes that Argus II retinal prosthesis is not routinely commissioned. C4.2 cost neutral. The policy proposes that Argus II retinal prosthesis is not routinely commissioned. C4.3 n/a C4.4 n/a
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*	C5.1 n/a
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy? C6.2 Can these be mitigated, if so how?	C6.1 none identified. The policy proposes that Argus II retinal prosthesis is not routinely commissioned. C6.2 n/a

	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.3 n/a
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	C7.1 None identified. The policy proposes that Argus II retinal prosthesis is not routinely commissioned. The NICE Interventional procedure guidance (519) for Insertion of an epiretinal prosthesis for retinitis pigmentosa, issued June 2015 recommended that due to limited evidence this procedure should only be used in the context of research, and encouraged further research on this technology.
	C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.2 The NICE Interventional procedure guidance (519) for Insertion of an epiretinal prosthesis for retinitis pigmentosa, issued June 2015 identified limitations with the quality and quantity with the current evidence on the safety and efficacy of insertion of an epiretinal prosthesis for retinitis pigmentosa.
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	C8.1 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned.
	C8.2 If so, confirm the source of funds to meet these costs.	C8.2 n/a The policy proposes that Argus II retinal prosthesis is not routinely commissioned.