

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	URN1618		
Policy Title	Keratoprosthesis for Corneal Blindness Proposal <u>for routine commission</u> (ref A3.1)		
Lead Commissioner	Nicola Symes	Clinical Lead	Stephen Kaye
Finance Lead	Peter Davies	Analytical Lead	Jacqueline Low

Integrated Impact Assessment – Index

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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- 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.
- 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.

There is no evidence directly available in England on the incidence and prevalence of patients with corneal blindness unsuitable for corneal transplant and/or a limbal stem cell transplant. Data has therefore been drawn from experience in the USA, NHS Blood and Transplant data on corneal transplants as well as clinical consensus.

Source: Policy Proposition section 6

A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.

Estimate 100 – 200

Source: See below

Please specify

The experience in the USA, where the prosthesis has been available for several years, the estimated need is 2 patients per year per million population, or about 110 patients per year in England.

NHS Blood and Transplant data on patients receiving multiple corneal grafts, which indicates there would be an expected number of 174 patients per year potentially requiring the keratoprosthesis based on them having 2 or more failed grafts.

Clinical Consensus of Consultant corneal specialists in England. A survey of corneal specialists in England identified that of those who responded an estimated patient population of 81 – 98 patients per annum may be suitable for treatment.

A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.

All ages

Please specify

	<p>This treatment may be suitable for all ages however it is very rare in children. In line with NHS BT data on corneal transplant, it is anticipated that less than 1% of patients would be under 18 years of age, with 74% being over the age of 50 years.</p>																										
<p>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</p>	<p>See below: <i>Source:</i> NHS BT Cornea Activity Report 2014-2015 http://www.odt.nhs.uk/uk-transplant-registry/annual-activity-report/</p> <p>Please specify</p> <p>It is anticipated that the age distribution would be in line with NHS BT Corneal transplant data for the UK as below:.. (*note: only a small subset of this total corneal transplant patient population would be considered suitable for this treatment, but the age profile is expected to be the same).</p> <table border="1" data-bbox="1093 719 1603 1029"> <thead> <tr> <th rowspan="2">Age group (years)</th> <th colspan="2">Transplant Recipients</th> </tr> <tr> <th>N</th> <th>%</th> </tr> </thead> <tbody> <tr> <td>0 - 17</td> <td>54</td> <td>(1)</td> </tr> <tr> <td>18 - 34</td> <td>505</td> <td>(13)</td> </tr> <tr> <td>35 - 49</td> <td>438</td> <td>(12)</td> </tr> <tr> <td>50 - 59</td> <td>362</td> <td>(10)</td> </tr> <tr> <td>60 - 69</td> <td>642</td> <td>(17)</td> </tr> <tr> <td>70-79</td> <td>993</td> <td>(26)</td> </tr> <tr> <td>80+</td> <td>785</td> <td>(21)</td> </tr> </tbody> </table>	Age group (years)	Transplant Recipients		N	%	0 - 17	54	(1)	18 - 34	505	(13)	35 - 49	438	(12)	50 - 59	362	(10)	60 - 69	642	(17)	70-79	993	(26)	80+	785	(21)
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<p>A1.5 How is the population currently distributed geographically?</p>	<p>Evenly</p> <p>If unevenly, estimate regional distribution by %:</p> <table border="1" data-bbox="1088 1219 1599 1382"> <tbody> <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> </tbody> </table>	North	enter %	Midlands & East	enter %	London	enter %																				
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	<table border="1" data-bbox="1079 97 1599 153"> <tr> <td data-bbox="1079 97 1435 153">South</td> <td data-bbox="1435 97 1599 153">enter %</td> </tr> </table> <p data-bbox="1079 161 1599 196"><i>Source: Policy Proposition section 6</i></p> <p data-bbox="1079 204 1294 239">Please specify</p> <p data-bbox="1079 247 2141 435">NHS BT Corneal transplant data for England suggests that a fairly even geographical distribution (rate per million population) anticipated for this treatment (*note: only a small subset of this total corneal transplant patient population would be considered suitable for this treatment but the geographical profile is expected to be the same).</p> <table data-bbox="1079 485 1675 655"> <thead> <tr> <th data-bbox="1079 485 1317 520">Region</th> <th data-bbox="1361 485 1503 544">Number of transplants</th> <th data-bbox="1532 485 1675 544">(per million population)</th> </tr> </thead> <tbody> <tr> <td data-bbox="1079 544 1317 571">North of England</td> <td data-bbox="1361 544 1413 571">955</td> <td data-bbox="1532 544 1606 571">(63.2)</td> </tr> <tr> <td data-bbox="1079 571 1317 598">Midlands and East</td> <td data-bbox="1361 571 1413 598">968</td> <td data-bbox="1532 571 1606 598">(59.1)</td> </tr> <tr> <td data-bbox="1079 598 1317 625">London</td> <td data-bbox="1361 598 1413 625">481</td> <td data-bbox="1532 598 1606 625">(56.3)</td> </tr> <tr> <td data-bbox="1079 625 1317 655">South of England</td> <td data-bbox="1361 625 1413 655">887</td> <td data-bbox="1532 625 1606 655">(62.0)</td> </tr> </tbody> </table> <p data-bbox="1079 708 2063 778">NHS BT Cornea Activity Report 2014-2015 http://www.odt.nhs.uk/uk-transplant-registry/annual-activity-report/</p>	South	enter %	Region	Number of transplants	(per million population)	North of England	955	(63.2)	Midlands and East	968	(59.1)	London	481	(56.3)	South of England	887	(62.0)
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A2 Future Patient Population & Demography																		
<p data-bbox="91 975 1059 1086">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?</p>	<p data-bbox="1079 975 1227 1010"><u>Constant</u></p> <p data-bbox="1079 1066 1532 1101">If other, Click here to enter text.</p> <p data-bbox="1079 1109 1599 1144"><i>Source: Policy Proposition section 6</i></p>																	
<p data-bbox="91 1201 1010 1278">A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</p>	<p data-bbox="1079 1201 1133 1236"><u>No</u></p> <p data-bbox="1079 1244 1294 1279">Please specify</p> <p data-bbox="1079 1287 1413 1323">Click here to enter text.</p> <p data-bbox="1079 1331 1682 1366"><i>Source: Policy Proposition section 6/other</i></p>																	

<p>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?</p> <p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p>	<table border="1"> <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>	YR2 +/-	0	YR3 +/-	0	YR4 +/-	0	YR5 +/-	0	YR10 +/-	0	<p><i>Source: Service specification proposition section 3.1</i></p> <p>Yes Click here to enter text.</p>
YR2 +/-	0											
YR3 +/-	0											
YR4 +/-	0											
YR5 +/-	0											
YR10 +/-	0											
<p>A3 Activity</p>												
<p>A3.1 What is the purpose of new policy?</p>	<p><u>Confirm routine commissioning position of an additional new treatment</u> Please specify Click here to enter text.</p>											
<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>Current annual activity for this patients population would be limited to supportive outpatient ophthalmology care, up to 4 times per year <i>Source: PWG Clinical Consensus</i> Please specify Click here to enter text.</p>											
<p>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</p>	<p>Each patient would require an assessment, surgical procedure, overnight admission, medication and outpatient follow-up. <i>Source: PWG Clinical Consensus</i></p>											

	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 applicable' and move to A4.	The next best activity would be a repeat high risk corneal transplant with poor prognosis (including immunosuppression drugs), or blind registration and supportive outpatient ophthalmology care. <i>Source: PWG Clinical Consensus</i> Click here to enter text.
A4 Existing Patient Pathway	
A4.1 Existing pathway: Describe the relevant currently routinely commissioned: <ul style="list-style-type: none"> • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates. 	Supportive outpatients 4 times per year. First and follow-up outpatients. <i>Source: PWG Clinical Consensus</i>
A4.2. What are the current treatment access and stopping criteria?	Consultant to consultant referral – specialist ophthalmology (secondary to tertiary). Refer for corneal transplant if suitable, or refer back to secondary care for ongoing outpatient care. <i>Source: PWG Clinical Consensus</i>
A4.3 What percentage of the total eligible population is expected to: <ul style="list-style-type: none"> 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? 	If not known, please specify: Current treatment would be to maintain supportive outpatient follow-up. All patients would be eligible for supportive treatment, assumed 10% DNA rate. <ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 90% e) 90%

	Source: <i>r PWG Clinical Consensus</i>
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 Next best comparator: Is there another 'next best' alternative treatment which is a relevant comparator? <i>If yes, describe relevant</i> <ul style="list-style-type: none"> • <i>Treatment or intervention</i> • <i>Patient pathway</i> • <i>Actual or estimated eligibility and uptake</i> 	<u>Yes</u> If yes, The 'next best' comparator has been considered as a high-risk repeat corneal graft. Source: <i>PWG Clinical Consensus</i>
A5.2 What percentage of the total eligible population is estimated to: <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> a) 80% b) 20-30% c) 50-60% d) 80% e) 80% Source: <i>PWG Clinical Consensus</i>
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following 	If not known, please specify Click here to enter text. <ul style="list-style-type: none"> a) 80% b) 20-30%

<p>assessment</p> <p>c) Choose to initiate treatment</p> <p>d) Comply with treatment</p> <p>e) Complete treatment?</p>	<p>c) 50-60%</p> <p>d) 80%</p> <p>e) 80%</p> <p>Source: PWG Clinical Consensus</p>
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<p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p>	<p>Life long</p> <p>For time limited treatments, specify frequency and/or duration.</p> <p>One-off surgical procedure, with life-long outpatient follow-up, estimated as 4 times per year. This is the same frequency as existing supportive outpatient treatment.</p> <p>Source: PWG Clinical Consensus</p>
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A7 Treatment Setting

<p>A7.1 How is this treatment delivered to the patient?</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Emergency/Urgent care attendance</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: inpatient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Acute Trust: day patient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: outpatient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Homecare</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table>	Emergency/Urgent care attendance	<input type="checkbox"/>	Acute Trust: inpatient	<input checked="" type="checkbox"/>	Acute Trust: day patient	<input type="checkbox"/>	Acute Trust: outpatient	<input checked="" type="checkbox"/>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input type="checkbox"/>
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	<p>Please specify: Click here to enter text.</p>								
<p>A7.2 What is the current number of contracted providers for the eligible population by region?</p>	<table border="1" data-bbox="1088 245 1715 467"> <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> <p>There are no providers currently contracted for the treatment as outlined in the policy proposition. The process for identification of providers for this procedure is outlined in the commissioning plan associated with this policy proposition, but will be identified from existing centres commissioned for the provision of and experienced in corneal transplant.</p>	NORTH	0	MIDLANDS & EAST	0	LONDON	0	SOUTH	0
NORTH	0								
MIDLANDS & EAST	0								
LONDON	0								
SOUTH	0								
<p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p>No Please specify: Click here to enter text. <i>Source:</i> PWG Clinical Consensus</p>								
<p>A8 Coding</p>									
<p>A8.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1246 1850 1366"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input type="checkbox"/></td> </tr> </table>	Aggregate Contract Monitoring *	<input type="checkbox"/>	Patient level contract monitoring	<input type="checkbox"/>				
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<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Treatment function code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	OPCS v4.8	<input checked="" type="checkbox"/>	ICD10	<input checked="" type="checkbox"/>	Treatment function code	<input type="checkbox"/>	Main Speciality code	<input type="checkbox"/>	HRG	<input checked="" type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>			
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<p>A8.3 Identification Rules for Drugs: How are drug costs captured?</p>	<p><u>Not applicable</u> If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:</p>																	

	<p>Click here to enter text.</p> <p>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:</p> <p>Click here to enter text.</p>
<p>A8.4 Identification Rules for Devices: How are device costs captured?</p>	<p><u>Already covered by an existing category of HCTED and commissioned via the Zero Cost Model</u></p> <p>If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).</p> <p>Click here to enter text.</p> <p>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.</p> <p>Click here to enter text.</p>
<p>A8.5 Identification Rules for Activity: How are activity costs captured?</p>	<p><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>Click here to enter text.</p> <p>If activity costs are already captured please specify whether this service needs a separate code. No</p> <p>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.</p> <p>Click here to enter text.</p> <p>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.</p>

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.	<u>Yes - population of clinical databases</u> Please specify Click here to enter text.						
A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model) 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.	<i>Select all that apply:</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Drugs or Device MDS</td> <td style="text-align: center; padding: 2px;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 2px;">Blueteq</td> <td style="text-align: center; padding: 2px;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 2px;">Other prior approval</td> <td style="text-align: center; padding: 2px;"><input type="checkbox"/></td> </tr> </table> Please specify: Click here to enter text.	Drugs or Device MDS	<input type="checkbox"/>	Blueteq	<input checked="" type="checkbox"/>	Other prior approval	<input type="checkbox"/>
Drugs or Device MDS	<input type="checkbox"/>						
Blueteq	<input checked="" type="checkbox"/>						
Other prior approval	<input type="checkbox"/>						
A9.3 Business intelligence Is there potential for duplicate reporting?	<u>No</u> If yes, please specify mitigation: Click here to enter text.						
A9.4 Contract monitoring Is this part of routine contract monitoring?	<u>Yes</u> If yes, please specify contract monitoring requirement: Click here to enter text.						
A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention?	<u>No</u> 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?						

	Click here to enter text.
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?	<u>No</u> If yes, specify how performance monitoring data will be used for this purpose. 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.)	Specialised ophthalmology Services for adults are currently organised through a range of specialised and tertiary centres. <i>Source: required</i>
B1.2 Will the proposition change the way the commissioned service is organised?	<u>No</u> Please specify: Click here to enter text. <i>Source: required</i>
B1.3 Will the proposition require a new approach to the organisation of care?	<u>No change to delivery of care</u> Please specify: Click here to enter text.
B2 Geography & Access	
B2.1 Where do current referrals come from?	<u>Select all that apply:</u> <hr/>

	<table border="1" data-bbox="1086 97 1599 336"> <tr> <td data-bbox="1086 97 1512 156">GP</td> <td data-bbox="1512 97 1599 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 156 1512 215">Secondary care</td> <td data-bbox="1512 156 1599 215"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 215 1512 274">Tertiary care</td> <td data-bbox="1512 215 1599 274"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 274 1512 336">Other</td> <td data-bbox="1512 274 1599 336"><input type="checkbox"/></td> </tr> </table> <p data-bbox="1086 336 2157 472">Please specify: Click here to enter text.</p>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of referral?	<p data-bbox="1086 472 2157 655"><u>No impact</u> Please specify: Click here to enter text.</p>								
B2.3 Is the new policy likely to improve equity of access?	<p data-bbox="1086 655 2157 882"><u>Increase</u> Please specify: There is currently no access to this service. <i>Source: Equalities Impact Assessment</i></p>								
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<p data-bbox="1086 882 2157 1109"><u>Increase</u> Please specify: Click here to enter text. <i>Source: Equalities Impact Assessment</i></p>								
B3 Implementation									
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<p data-bbox="1086 1249 2157 1422"><u>Contract action</u> Please specify: Regional Specialised Commissioning Teams will be responsible for liaising</p>								

	with providers within their region to determine the centres that will be approved for undertaking this procedure, to ensure that they are able to comply with the requirements specified for this procedure.
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	<u>No - go to B3.4</u> If yes, specify the likely time to implementation: Enter text
B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?	<u>No - go to B3.4</u> If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	<u>No</u> Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	<u>No</u> Please specify: Click here to enter text.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<u>No</u> Please specify: Click here to enter text.
B3.7 Are there changes in the support services that need to be in place?	<u>No</u> Please specify: Click here to enter text.
B3.8 Is there a change in provider and/or inter-provider governance	<u>No</u>

required? (e.g. ODN arrangements / prime contractor)	Please specify: Click here to enter text.																								
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	<p><u>Increase</u> <i>Please complete table:</i></p> <table border="1" data-bbox="1088 325 2013 770"> <thead> <tr> <th>Region</th> <th>Current no. of providers</th> <th>Future State expected range</th> <th>Provisional or confirmed</th> </tr> </thead> <tbody> <tr> <td>North</td> <td>0</td> <td></td> <td><u>P</u></td> </tr> <tr> <td>Midlands & East</td> <td>0</td> <td></td> <td><u>P</u></td> </tr> <tr> <td>London</td> <td>0</td> <td></td> <td><u>P</u></td> </tr> <tr> <td>South</td> <td>0</td> <td></td> <td><u>P</u></td> </tr> <tr> <td>Total</td> <td>0</td> <td>3-8</td> <td><u>P</u></td> </tr> </tbody> </table> <p>Please specify: Click here to enter text.</p>	Region	Current no. of providers	Future State expected range	Provisional or confirmed	North	0		<u>P</u>	Midlands & East	0		<u>P</u>	London	0		<u>P</u>	South	0		<u>P</u>	Total	0	3-8	<u>P</u>
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London	0		<u>P</u>																						
South	0		<u>P</u>																						
Total	0	3-8	<u>P</u>																						
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 963 1998 1385"> <tbody> <tr> <td>Publication and notification of new policy</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Market intervention required</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Competitive selection process to secure increase or decrease provider configuration</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Price-based selection process to maximise cost effectiveness</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Any qualified provider</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>National Commercial Agreements e.g. drugs, devices</td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	Publication and notification of new policy	<input checked="" type="checkbox"/>	Market intervention required	<input type="checkbox"/>	Competitive selection process to secure increase or decrease provider configuration	<input type="checkbox"/>	Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>	Any qualified provider	<input checked="" type="checkbox"/>	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>												
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	Procurement	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
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 Please specify: Click here to enter text.
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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	<i>Select all that apply:</i>	
	Drugs	Not separately charged – part of local or national tariffs <input checked="" type="checkbox"/>
		Excluded from tariff – pass through <input type="checkbox"/>
		Excluded from tariff - other <input type="checkbox"/>
	Devices	Not separately charged – part of local or national tariffs <input type="checkbox"/>
		Excluded from tariff (excluding ZCM) – pass through <input checked="" type="checkbox"/>
		Excluded from tariff (excluding ZCM) – other <input type="checkbox"/>
Via Zero Cost Model <input type="checkbox"/>		

	<table border="1"> <tr> <td rowspan="7" style="text-align: center;">Activity</td> <td>Paid entirely by National Tariffs</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>Paid entirely by Local Tariffs</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Partially paid by National Tariffs</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Partially paid by Local Tariffs</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Part/fully paid under a Block arrangement</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Part/fully paid under Pass-Through arrangements</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Part/fully paid under Other arrangements</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Activity	Paid entirely by National Tariffs	<input checked="" type="checkbox"/>	Paid entirely by Local Tariffs	<input type="checkbox"/>	Partially paid by National Tariffs	<input type="checkbox"/>	Partially paid by Local Tariffs	<input type="checkbox"/>	Part/fully paid under a Block arrangement	<input type="checkbox"/>	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>	Part/fully paid under Other arrangements	<input type="checkbox"/>
Activity	Paid entirely by National Tariffs		<input checked="" type="checkbox"/>													
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	Part/fully paid under Other arrangements	<input type="checkbox"/>														
<p>C1.2 Drug Costs 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. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>Not Applicable. Expected drug costs and antimicrobial eye drops are not excluded from tariff so there is no additional pass through payment to commissioners.</p>															
<p>C1.3 Device Costs 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. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>Expected £2,094 per device (exclusive of VAT and shipping)</p> <p>Anticipate 110 devices per year - Total device cost £230,340 per annum</p>															
<p>C1.4 Activity Costs covered by National Tariffs List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>	<p>HRG Codes, descriptions and tariffs used:</p> <table border="0"> <tr> <td>Outpatient Ophthalmology – first treatment</td> <td>TNC 130</td> <td>£</td> <td>139</td> </tr> <tr> <td>Outpatient Ophthalmology – follow up</td> <td>TNC 130</td> <td>£</td> <td>53</td> </tr> <tr> <td>Very Complex, Cornea or Sclera Procedures, with CC Score 2+ (For proposed procedure)</td> <td>HRG BZ60A</td> <td>£</td> <td>2,981</td> </tr> </table>	Outpatient Ophthalmology – first treatment	TNC 130	£	139	Outpatient Ophthalmology – follow up	TNC 130	£	53	Very Complex, Cornea or Sclera Procedures, with CC Score 2+ (For proposed procedure)	HRG BZ60A	£	2,981			
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Very Complex, Cornea or Sclera Procedures, with CC Score 2+ (For proposed procedure)	HRG BZ60A	£	2,981													

	<p>Complex, Cornea or Sclera Procedures, with CC Score 0-1 (For next best alternative procedure) HRG BZ61B £ 2,342</p> <p>Annual Volume Assumptions: 110 patients suitable and treated per year with new device Each patient receives 1 outpatient first treatment Each patient has 1 surgical procedure Each patients receive 4 follow-up outpatients <i>per year</i></p>
<p>C1.5 Activity Costs covered by Local Tariff 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.</p>	Not applicable
<p>C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.</p>	Not applicable
<p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>	<p>No Please specify: Click here to enter text.</p>
<p>C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.</p>	
<p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>	<p>No Please specify: Click here to enter text.</p>

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.	<p><u>Cost pressure</u> Please specify: Year 1 £229,500 Year 2 £229,500 Year 5 £229,500</p> <p>The cost to NHS England is device cost only, as outpatient and treatment costs are currently funded by CCGs.</p>
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not Applicable
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.	<p>Budget impact for CCGs: <u>Cost pressure</u> Budget impact for providers: <u>Cost neutral</u> Please specify: Outpatient and Treatment costs are funded by CCGs. A cost pressure of up to £20,900 is anticipated for CCG due to the higher tariff applied to this procedure. These costs have been partly off-set by a</p>

	reduction in high risk corneal transplants
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u>Cost pressure</u> Please specify: Year 1 £250,400 Year 2 £250,400 Year 5 £250,400</p>
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?	<p><u>No</u> Please specify: Click here to enter text.</p>
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.	CPAG prioritisation
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this	There are no significant financial risks, due to the financial and activity

policy?	modelling completed.						
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?	The financial scenarios modelled were do nothing, next best alternative and policy proposition. The most likely patient numbers requiring treatment and backlog were generated from expected rates per million population and existing data on corneal transplants. (see A 1.2 above)						
C6.4 What scenario has been approved and why?	'Most likely' has been approved as a realistic patient cohort requiring treatment.						
C7 Value for Money							
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	<u>There is no published evidence of cost-effectiveness</u> Please specify: Click here to enter text.						
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Available clinical practice data suggests the new treatment has</td> <td><input type="checkbox"/></td> </tr> </table>	Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment	<input checked="" type="checkbox"/>	Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>	Available clinical practice data suggests the new treatment has	<input type="checkbox"/>
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Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>						
Available clinical practice data suggests the new treatment has	<input type="checkbox"/>						

	the potential to improve value for money	
	Other data has been identified	<input type="checkbox"/>
	No data has been identified	<input type="checkbox"/>
	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>
	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
<p>Please specify: Treatment costs are anticipated to be in line with existing tariff for complex corneal transplant, however device cost is additional.</p>		
<p>C8 Cost Profile</p>		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	<p>No If yes, specify type and range: Click here to enter text.</p>	
C8.2 If yes, confirm the source of funds to meet these costs.	<p>Not Applicable</p>	

Appendix 1: PATIENT PATHWAY

