

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	D12/S(HSS)/c
Service	Osteo-odonto-keratoprosthesis service for corneal blindness (Adults)
Commissioner Lead	<i>For local completion</i>
Provider Lead	<i>For local completion</i>

1. Scope
<p>1.1 Prescribed Specialised Service</p> <p>This service specification covers the provision of Osteo-odonto-keratoprosthesis service for corneal blindness (adults)</p> <p>1.2 Description</p> <p>Osteo-odonto-keratoprosthesis (OOKP) is a highly specialist surgical intervention that can restore meaningful vision to patients suffering from end stage corneal blindness, and for whom conventional corneal surgery is not possible for reasons such as severe ‘dry eyes’ that causes heavy scarring of the cornea. OOKP is only contemplated in patients where no other treatments would restore sight.</p> <p>1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners</p> <p>NHS England commissions Osteo-odonto-keratoprosthesis services for adults from Highly Specialised Osteo-odonto-keratoprosthesis Centres. CCGs do not commission any elements of this service.</p> <p>This service is being commissioned by NHS England because the number of individuals requiring the service is very small; the cost of providing the service is high because of the specialist interventions involved; and the number of doctors and other expert staff trained to deliver the service is very small.</p>
2. Care Pathway and Clinical Dependencies
<p>2.1 Care Pathway</p> <p>The cornea is the clear outer layer at the front of the eyeball. The cornea helps to focus light rays on to the retina (the light-sensitive film at the back of the eye). This "picture" is then transmitted to the brain. When the cornea becomes severely diseased it appears cloudy (opaque) resulting in very poor sight. The main treatment for corneal blindness is a corneal transplantation; replacing the cloudy cornea with a clear cornea from either a human organ donor or a prosthesis from acrylic material. However, corneal transplantation is not appropriate for everyone.</p>

Osteo-odonto-keratoprosthesis (OOKP) uses the patient's own tooth root and alveolar bone to support an optical cylinder and is only considered in end stage corneal disease when there is no other available treatment to restore sight.

OOKP is indicated in patients with severe dry eyes and/or damaged ocular surfaces. Conditions most often associated with these include:

- Stevens Johnson syndrome
- ocular cicatricial pemphigoid
- severe chemical injury
- other cicatrising conjunctival diseases

Referral to the service

Patients would usually be referred to this highly specialised service by a specialist corneal surgeon, where, following initial assessment, they are considered unlikely to gain adequate benefit from conventional corneal transplantation.

Assessment

Patients will undergo comprehensive assessment by a specialist multi-disciplinary team including ophthalmic and maxillofacial consultants, involving examination of the eyes, teeth and mouth to assess suitability for OOKP. This will include assessment of current visual function, imaging, electrodiagnostic and a psychological assessment.

The OOKP service is led by a consultant ophthalmic corneal surgeon and includes the following multidisciplinary team members:

- a second consultant ophthalmic corneal surgeon
- consultant ophthalmic retinal surgeon
- consultant ophthalmic oculoplastic surgeon
- consultant ophthalmic glaucoma surgeon
- consultant maxillo-facial surgeon
- consultant clinical psychologist
- consultant radiologist
- theatre nurses
- ward and outpatient nurses
- visual field technicians and clinical photographers

Following assessment, those patients considered clinically suitable and who choose to undergo this procedure will then be listed for surgery.

Surgery

OOKP is a two-stage surgical procedure that firstly involves the extraction of the patient's own tooth and bone, which are then fashioned into a 'bolt' and placed within the eye for supporting a synthetic optical cylinder. The second stage of the procedure is performed about four months after the first stage. Each surgical procedure will require a short inpatient stay.

Follow-up

Initial frequent follow up is required for ongoing assessment of the success of the prosthesis (vision testing, visual fields, imaging and clinical examination) and to monitor for post-surgical complications (i.e. laminar resorption, retinal detachment, glaucoma).

Following the procedure, all patients will require lifelong follow up at time intervals as deemed appropriate by the clinical team (at least annually and more frequently if required).

The service is required to ensure suitable arrangements are in place to enable provision of urgent/emergency clinical advice and support in the event patients experience complications out of hours.

2.2 Interdependence with other Services

Specialised Ophthalmology Services (including Corneal, Oculoplastic, Retinal)
Maxillofacial Surgery
Ward and Theatre facilities
Radiography
Clinical photography

3. Population Covered and Population Needs

3.1 Population Covered by This Specification

NHS England commissions the service for the population of England. Commissioning on behalf of other devolved administrations is reviewed annually and a current list is available from NHS England commissioners.

The NHS England Standard Contract includes provision for the service to treat eligible patients from overseas under S2 and aligned referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of this contract. Trusts performing procedures on patients outside of S2 arrangements and aligned referral arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with NHS England.

3.2 Population Needs

Up to 5 patients are expected to undergo OOKP surgery annually, with a caseload of approximately 60 patients who are being followed up by the service.

Inclusion criteria

- Aged 18 years and over.
- Corneal blindness resulting in visual acuity in both eyes (or the remaining eye for patients with one eye) of 6/60 or lower.
- Ascertainment of visual potential through determination of an intact retina and optic nerve.
- Successful completion of pre-surgical assessment including psychological testing.
- Patient highly motivated to regain sight.
- Commitment by the patient to regular life-long follow up.

3.3 Expected Significant Future Demographic Changes

No significant changes expected.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

Aim: To provide a national OOKP service which improves the visual acuity (short, medium and long term) of patients who proceed with surgery.

Objectives:

- To perform a robust assessment of suitability of all patients referred to the OOKP service for surgery.
- To provide advice on most appropriate alternative management to all those referred to the service who are not deemed suitable for the procedure.
- To perform OOKP surgery in those deemed suitable with a view to increasing visual acuity.
- To provide lifelong follow up of patients who have surgery to maximise clinical outcomes and identify and manage post-surgical complications.

NHS Outcomes Framework Domains

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	x
Domain 3	Helping people to recover from episodes of ill-health or following injury	x
Domain 4	Ensuring people have a positive experience of care	x
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	x

4.2 Indicators Include:

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Proportion of patients with visual acuity 6/12 or better at 12 months post operation	Provider / SSQD	2, 3, 4, 5	Effective, caring, safe
102	Proportion of patients who develop complications 12 months post surgery	Provider / SSQD	2, 3, 4, 5	Effective, caring, safe
103	Proportion of patients who have a qualitative assessment of functional impact and quality of life benefits pre surgery	Provider / SSQD	2, 3, 4, 5	Effective, caring, safe
104	Proportion of patients receiving annual follow-up	Provider / SSQD	2, 3, 4, 5	Effective, caring, safe
Patient Experience				
201	A patient experience exercise is undertaken at least annually.	Self declaration	2,4	Well led, responsive
202	There is information for patients and carers.	Self declaration	2,3,4	Well led, caring

Structure and Process				
301	The Osteo-Odonto-Keratoprosthesis Service for Corneal Blindness (Adults) has team members as detailed in the service specification.	Self declaration	1,2,3,4	Well led, effective, caring, safe
302	A multi-disciplinary team meeting is held on a monthly basis.	Self declaration	1,2,3,4	Well led, effective, caring, safe
303	Out of hours rota	Self declaration	1,2,3,5	Well led, effective, caring, safe
304	Specific training	Self declaration	1,2,3,4	Well led, effective, caring, safe
305	Unique infrastructure	Self declaration	1,2,3,4	Well led, effective, caring, safe
306	The hospital has a policy whereby patients are managed in line with the Seven Day Services Clinical Standards policy.	Self declaration	1,2,3,4	Well led, effective, caring, safe
307	There are agreed patient pathways as per the service specification.	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring.
308	There are agreed clinical guidelines as per the service specification.	Self declaration	1, 2, 3, 5	Safe, effective, caring.
309	The provider participates in local and national audits as required.	Self declaration	2, 4	Safe, effective
310	The provider reviews annually its' contribution to research, trials and other well-designed studies	Self declaration	2, 4	Safe, effective

Detailed definitions of indicators, setting out how they will be measured, is included in schedule 6.

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

5.2 Other Applicable National Standards to be met by Commissioned Providers

The provider will be fully integrated into the trust's corporate and clinical governance arrangements and will comply fully with the clinical negligence scheme for trusts and Care Quality Commission (CQC) requirements in terms of quality and governance. The provider should ensure that:

- regular meetings take place with patient representatives
- all practitioners participate in continuous professional development and networking
- patient outcome data is recorded and audited across the service.

The commissioners and provider will conduct a formal annual clinical meeting. All providers must participate in the national audit commissioned by NHS England. Audit meetings should address:

- clinical performance and outcome
- process-related indicators, e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow up etc.
- stakeholder satisfaction, including feedback from patients, their families, referring surgeon and GPs

The provider should demonstrate equitable geographical access across the country and take actions to address gaps in access.

6. Designated Providers (if applicable)

Highly Specialised Service – designated provider(s) only

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

OOKP Osteo-odonto-keratoprosthesis

Date published: <insert publication date>

Appendix 1

Change form for published Specifications and Products developed by Clinical Reference Group (CRGs)

Product name: Service Specification D12/S(HSS)/c: Osteo-odonto-keratoprosthesis service for corneal blindness (Adults)

Publication number:

CRG Lead: Nicola Symes, Lead Commissioner, Specialised Ear and Ophthalmology CRG

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Overview of OOKP and the indication for the surgery	Rewording of this section	Section 1.1 in original document. Moved to section 2.1 in new version	Rewording into easier to understand language. Moved to different section complies with new service spec template.	Working Group	22/3/2021
Reference to provider of the service	Reference to provider removed	Multiple sections. Section 1.1, 2.1, 2.2, 5	Service being re-procured and so there may be a new provider/s.	Working Group	22/3/2021
Aims and objectives present but lack of clarity and detail	Greater clarity around the aims and objectives	Section 2.1 in original document. Moved to section 4.1 in new version	Rewording to outline more explicitly the aims and objectives of the service. The objectives of the service have not	Working Group	22/3/2021

			changed. Moved to different section complies with new service spec template.		
Very detailed outline of the care pathway from the perspective of the provider	Removed granular detail of care pathway. Outlined a broad overview of the pathway of patients	Section 2	Previous care pathway outlined the specifics around how the provider delivers the service. There would not be an expectation that future potential providers would be expected to deliver the service in an identical fashion. A rewording of the care pathway outlines how NHSE would expect the service to be delivered.	Working Group	22/3/2021
Lack of requirement for provider to engage with patient groups	Inclusion of need to engage with patient groups	Section 2.1	A requirement of the service.	Working Group	22/3/2021
Patient inclusion criteria and contra-indications	Rewording of section to merge contra-indications into the inclusion criteria.	Section 2.4 in original document. Moved to section 3.2 in new version.	Reworded to make the section easier to understand and create more clarity. Moved to different section complies with new service spec template.	Working Group	22/3/2021

Absence of key applicable national standards	Applicable national standards included.	Section 5 new version	A requirement of the service	Working Group	22/3/2021
Outcome measures of service	Rewording of outcomes measures to provide greater clarity.	Section 4 in original document. Moved to section 4.2 in new version.	Some outcomes were required as part of the service delivery but were absent from the spec. These have been included. Further rewording of existing outcomes measures to provide better clarity (making them more measurable). Moved to different section complies with new service spec template.	Working Group	22/3/2021
Section around how service meets NHS Outcomes Framework Domains	Section included	Section 4.1	A requirement as per the new service spec template.	Working Group	22/3/2021
Lack of detail of interdependencies with other services	Greater clarity on interdependencies	Section 2.2	Provides more clarity on interdependencies which provides greater transparency for potential future providers.	Working Group	22/3/2021