

D12/S(HSS)/c

**2013/14 NHS STANDARD CONTRACT
FOR OSTEO-ODONTO-KERATOPROSTHESIS SERVICE FOR CORNEAL
BLINDNESS (ADULTS)**

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATION

Service Specification No.	D12/S(HSS)/c
Service	Osteo-odonto-keratoprosthesis service for corneal blindness (Adults)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1.1 National/local context and evidence base

Osteo-odonto-keratoprosthesis (OOKP) is a technique used to replace damaged corneae in blind patients for whom cadaveric corneal transplantation is not an option. It was developed some 40 years ago in Italy and uses the patient's own tooth root and alveolar bone to support an optical cylinder. OOKP surgery is only considered in end stage corneal disease when there is no other available treatment to restore sight.

Patients with the following primary diagnoses are treated:

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

Long-term cost effectiveness of OOKP has been formally studied. Long-term results from major centres including Brighton and Sussex University Hospitals NHS Trust are also in the published ophthalmic scientific literature.

2. Scope

2.1 Aims and objectives of service

Strategic objectives of the service:

- to serve eligible corneal blind patients
- sight restoration
- sight maintenance
- prevention and treatment of complications

The purposes and goals of the service

As above, ensuring world class standards.

Sussex Eye Hospital, part of Brighton and Sussex University Hospitals NHS Trust (BSUH) has been designated to provide this service, which covers the assessment of suitability for all patients referred for OOKP operations (in two phases), lifetime follow-up and management of any complications of the procedure.

The service provides visual rehabilitation of patients with end-stage corneal blindness not amenable to stem cell and/or cadaveric corneal grafting, or any other form of artificial cornea.

2.2 Service description/care pathway

The OOKP service is led by a consultant ophthalmic surgeon. The team consists of:

- consultant maxillo-facial surgeon
- consultant clinical psychologist
- consultant radiologist
- theatre nurses
- ward nurses and outpatient nurses
- supported by visual field technicians and clinical photographers

Referral criteria, sources and routes

The service receives referrals from the British Isles, the European Union, and beyond. New patients are seen by the consultant ophthalmic surgeon, consultant maxillo-facial surgeon, consultant clinical psychologist and assessed for suitability. Surgery is scheduled for suitable cases. Surgery is usually in two stages, spaced two to four months apart. Each stage takes four to six hours of surgical time and a one week stay in hospital. Patients are followed up for life, usually at three monthly intervals, unless shared care is entered into with the referring consultant corneal

surgeon.

At each follow up, the OOKP eye is examined in detail. Complications are looked

out for and dealt with either medically or surgically. The consultant ophthalmic surgeon is available 24/7 for any OOKP emergencies. Possible complications include laminar resorption, extrusion and infective endophthalmitis; glaucoma; retinal detachment; oculoplastic and oral complications.

There is an OOKP user self-help group which is patient-led but supported by the clinical team.

See 'Seminars in Ophthalmology' 2005 article which details the scope of the service.

Pathway

Potential patient makes contact with NHS England commissioned OOKP service, OOKP lead corresponds by mail or email, if potentially suitable, then patient to obtain formal referral from their current consultant to NHS England commissioned OOKP service;

consultant corneal surgeon emails or writes with a potential referral

- OOKP lead corresponds by mail or email, and if potentially suitable, formal referral is sent in by post;

formal referral letter from referring corneal consultant

- letter is coded for "Initial Assessment" at joint OOKP clinic;
- Transport and interpreter arranged as necessary

Patient attends joint OOKP clinic:

- assessment by eye team, oral surgical team, and clinical psychologists
- tests include dental imaging, ultrasound scan, photography and if necessary electrodiagnostics
- electrodiagnostics are usually done at referring hospital
- patient is offered OOKP surgery at the end of this visit, if suitable
- patients sometimes require a second visit to decide
- patient's name goes on waiting list
- patient attends local dentist for oral hygiene

Patient called for stage 1 OOKP surgery (see Seminars article as above):

- admitted one to two days beforehand for pre-operative preparations (repeat blood tests, electrocardiogram (ECG), chest X-ray, mouth wash, etc. – all detailed in OOKP protocol)
- Stage 1 OOKP surgery done under general anaesthesia on dedicated all day operating list
- recovery then returns to ward

- dressing removed after 48 hours.
- sutures removed after 5 days
- Patients return home after one week in hospital

Outpatient follow-up:

- Interim outpatient check-ups every week or two for the first month
- Further check-up two weeks before stage 2 surgery to ensure it can go ahead

The interval between stages 1 and 2 is usually two to four months. This will be delayed if there are complications, such as buccal mucous membrane imperfection which may require surgical repair.

Patient called for stage 2 OOKP surgery (see Seminars article as above):

- admitted one day beforehand for pre-operative preparations (detailed in OOKP protocol)
- stage 2 OOKP surgery done under general anaesthesia on dedicated all day operating list
- recovery then return to ward, postured face up
- dressing removed after 24 hours
- sutures removed after 5 days
- patients return home after one week in hospital

Outpatient follow-up:

- initial frequent follow-up in outpatients, eventually settling to quarterly follow up.
- This is varied according to need, and whether a shared care arrangement is in place with referring corneal surgeon. This is only possible if the referring surgeon has had special training from the national service.
- regular assessment for glaucoma, retinal detachment, lamellar resorption, loosening of optical cylinder, through vision testing, visual fields, photography, ultrasound, radiological imaging, in addition to clinical examination
- clinical psychological support is activated if there is a risk of renewed sight loss

Surgical procedures are necessary for glaucoma, oculoplastic, retinal detachment and lamellar resorption complications. If a lamella becomes unduly small, then a new one is created (repeat stage 1 OOKP surgery), and exchanged with the eroded lamella (repeat stage 2 OOKP surgery) after two to three months.

24-hour cover is provided for emergencies.

Discharge criteria & planning including any transition arrangements

- patients are not discharged unless they have irreversibly lost all sight and visual potential in both eyes

- where the referring consultant ophthalmic surgeon is conversant with OOKP surgery, then it is possible to enter into share care so the patient would attend Brighton only twice a year

Patient information is provided in various forms:

- **a patient information leaflet**
this is provided for all patients accessing the service and reviewed every two years to ensure it is up to date
- **interview**
The information in the leaflet is also discussed with the patient by all members of the clinical team. During the assessment with the psychologist special attention is given to going through the main aspects of the procedure to ensure that these have been understood, and also to ensure that the patient is committed to self-care post surgery and life-long follow up. Attention to self-care post surgery and in preparation for surgery is discussed at this stage as well as at discharge. The risk of complications such as glaucoma which could endanger sight necessitates this emphasis on ensuring patients understand the need for life-long follow up. Likely gains and possible risks associated with OOKP surgery are discussed as are issues patients may not always have considered such as living with a changed appearance
- **on-going communication with the clinical team**
It is best practice to provide written material as is the availability of staff to deal with questions which may arise for patients post consultation. Members of the assessment team will take phone calls and can deal with email enquiries to support patients in decision-making pre-surgery and in dealing with other issues which arise after surgery has taken place. In addition, the service in conjunction with the patient support group will have a list of patients who have undergone OOKP surgery who are willing to be approached to provide a patient perspective both on OOKP surgery and on living with an OOKP.
- **family members and carers**
Family members and carers, with the patient's permission, are usually part of the initial consultation. They are encouraged to ask questions and read the information literature as, especially in the early days post-surgery; their practical and emotional support can be invaluable.
- **assessment letters**
These are written directly to patients and provide the patient with a summary of what was discussed and further advice where appropriate. With the patient's permission this may be copied to other staff involved with the patient's care.

2.3 Population covered

This service covers patients registered with an English General Practitioner, resident in Scotland, resident in the European Union (EU) and eligible for treatment in the NHS under reciprocal arrangements.

Patients from Wales and Northern Ireland are not part of this commissioned service

and the trust must have separate arrangements in place for patients from these and other non EU referrers.

2.4 Any acceptance and exclusion criteria

The service is commissioned by NHS England for all eligible patients from England and Scotland.

The provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

See also BSUH trust policy on Equality and Diversity (2008).

Referring corneal surgeons are asked to ascertain that both eyes (or the remaining eye for one-eyed patients) have poor vision of 6/60 or below. They are asked to ascertain visual potential in the eye to be rehabilitated. In other words, the patient should have corneal blindness alone, with a working retina and optic nerve. Tests to include a healthy B-scan ultrasound and sometimes electrodiagnostics. The referring surgeon should also ascertain the patient's desire to regain vision, and that they are willing to commit to regular life-long follow up in Brighton and Hove.

See Seminars article for contraindications, but briefly:

- those under 18 years of age;
- those with little or no visual potential;
- those unable to attend life-long follow up in Brighton;
- those unwilling to accept the appearance following OOKP surgery;
- those who are adapted to blindness;
- those who are psychologically frail, and who may therefore not be robust enough to withstand the possibility of renewed sight loss (especially after sight has been restored).

The service has strict exclusion criteria including:

- age
- visual potential of the eye
- family support
- psychological robustness

Patients are on an 18-week pathway, despite nationwide relaxation of this rule. Most of our patients are booked within 13 weeks, but OOKP referrals are usually seen much earlier in the pathway due to the existence of dedicated joint OOKP clinics.

2.5 Interdependencies with other services

All stakeholders and providers are part of the formal OOKP team, described in the OOKP Standards of Care document. In addition, there is a patient-led OOKP patient

self-help group.

There is an informal network of corneal specialists in the UK, EU and further afield who refer patients into the OOKP service.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

There is an expectation that practitioners will participate in continuous professional development and networking. Provide assurance that this will be built into roles within the service.

See also service standards for osteo-odonto-keratoprosthesis

4. Key Service Outcomes

Visual outcome:

- acuity
- visual field
- quality of vision including level of glare

Psychological well-being, including:

- preparedness for further surgery
- possibility of device failure in the future
- quality of life patients enjoy

Length of Wait:

- maximum 13 weeks from referral to first outpatient department appointment
- maximum 18 weeks from first outpatient department appointment to start treatment

Outcome reporting on an annual basis is the visual acuity for each patient at 12 months

5. Location of Provider Premises

Brighton and Sussex University Hospitals NHS Trust, Brighton.

Adopted