SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	1685
Service	**Hand and Upper Limb Transplant Service (Adults)**
Commissioner Lead	*Highly Specialised Services, NHS England*
Provider Lead	*Leeds Teaching Hospitals NHS Foundation Trust*

1. Scope

1.1 **Prescribed Specialised Service**
This service specification covers the provision of Hand and Upper Limb Transplantation Services (Adults). [56A]

1.2 **Description**
Hand transplantation services include services provided by designated Highly Specialist Hand and Upper Limb Transplant Centre(s). This applies to provision in adults. This service specification should be considered alongside the associated clinical commissioning policy https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/07/d00pa-hand-transplnt-forearm-loss.pdf

1.3 **How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners**
NHS England commissions the Hand and Upper Limb Transplant Service (Adults) from a Highly Specialised Hand and Upper Limb Transplant Centre. CCGs do not commission any elements of this service.

This service is 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 and the number of staff trained to provide this service is extremely small.

Activity is identified via local data flows, which will apply to Highly Specialised Hand Transplant Centre(s) only.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

The hand and upper limb transplantation service (Adults) is a highly specialised national service which works closely with local specialist rehabilitation and prosthetic services to support people with upper limb loss.

The service will use donor limbs to reconstruct an absent (or partially absent) hand or upper limb, lost as result of trauma, infection or a defective upper hand or limb.

Hand and upper limb transplantation would, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable.

Referral

As a highly specialised tertiary service, it is anticipated that referrals for hand and upper limb transplantation would be made by one of the following specialised services: prosthetics, plastic surgery, orthopaedics or rehabilitation.

It is expected that the referral will include a recent report from the patient's local specialist prosthetic service. If this is not available, it will be sought as part of the assessment process, and the patient may require formal re-assessment by their local service.

In line with the published clinical commissioning policy:

> **Inclusion criteria**: Full or partial hand or upper limb loss (uni-lateral or bi-lateral) with viable bone and suitable motor and sensory structures; complete loss of function in one or both hands; over 18 years of age, unsuitable for current prostheses, highly motivated.
>
> **Exclusion criteria:** active or previous malignancy of current oncological concern, active infection, systemic infection, congenital limb anomalies, incapacitating proximal nerve injury

Care Pathway

Following referral, the service will ensure a timely assessment of suitability for hand and upper limb transplantation.

Each episode of care will include:

- Assessment by individual members of the multidisciplinary team.
- Full team multidisciplinary assessment.
- Follow up of patients with repeat assessments, as required.
- Follow up of patients whilst on the waiting list for transplant.

- Transplantation.
- Post-operative care.
- Rehabilitation.
- Routine medical review to monitor episodes of rejection and immunosuppression.
- Long term review of transplant (at least annually).
- Readmission for complications/secondary surgery as required.

Assessment
Specialised assessment will be completed by a multidisciplinary team including: consultant hand surgeon, transplant physician, immunologist, specialist in amputee rehabilitation, clinical psychologist, physiotherapist, occupational therapist, specialist nurse, radiologist and medical illustrator.

The assessment will include evaluation of patients use and benefits of prosthetic limbs; immunological and medical screening; discussion with the patient concerning transplant and the effects of immunosuppression; detailed psychological assessment and occupational therapy assessment.

The highly protocolled evaluation pathway will be used to assess patient suitability for treatment.

Those patients that are accepted following psychological, surgical, immunological and medical screening and after detailed occupational therapy and prosthetic assessment should proceed to an offer of being placed on the waiting list for hand and upper limb transplantation based on the Multi-Disciplinary Team (MDT) decision.

Each potential transplant patient and the referrer will be sent a letter detailing the results of assessments and discussions undertaken in the MDT clinics before signing and consenting to transplant.

Patients should be offered information provided in a format that is accessible to them to help them to make informed decisions about their healthcare. Information will be provided at appropriate points within the assessment process, and patients will be given appropriate time and space to consider all the information and the implications of transplantation.

Any patient not considered suitable for transplantation will be referred back to their referrer with any needs identified by the service highlighted.

Surveillance
During the waiting period, patients will have continued immunological and psychological surveillance and review. Patients will be monitored for immunologic status and sensitisation which contributes to a virtual cross match at the time of donation. Specialist Nurses in Organ Donation (SNODs) employed by NHS Blood & Transplant (NHSBT) maintain vigilance for a suitable donor using visual and biometric data. NHS Blood and Transplant will remain responsible for all aspects of organ donation.

It is the patient's responsibility to make themselves available to be contacted by the transplant centre at any time and to notify them of any change in medical state.

Transplantation
On identification of a potential donor by the SNODs and after discussion with the lead surgeon, the recipient should be alerted and admitted. The patient (recipient) is likely to be alerted of a potential donor 12 hours' in advance of potential surgery.

At time of offer, cross match and Human Leukocyte Antigen (HLA) screen performed will be performed and donation offered if appropriate.

If donation is accepted, the patient should follow a standard surgical protocol, through the analogous procedure of microsurgical replantation of amputated limbs.

The service will require suitable operating theatre(s) capacity, including an operating microscope, microsurgical instruments and specialised microsurgical operating department staff to be available at short notice. Theatre staff are likely to receive up to 12 hours' notice of potential surgery for planning purposes.

Post-Operative Care
Standard post-operative care for replantation is undertaken as an inpatient with initial monitoring on a High Dependency Unit (HDU).

The service will need to ensure suitable High Dependency Unit (HDU) capacity as well as specialist nursing staff can be made available at short notice. The ward staff are likely to receive up to 12 hours' notice of potential surgery for planning purposes.

Monitoring for acute rejection, which, unlike solid organ transplants, manifests itself visibly and standard immunological protocols are followed in its management.

Therapeutic drug monitoring at regular intervals to ensure appropriate levels of immunosuppression and to monitor for any side effects.

Physiotherapy and occupational therapy protocols are in place for the early management and start of early mobilisation as an inpatient.

Rehabilitation
Patients will receive rehabilitation in line with standard protocols for rehabilitation of patients with replanted limbs. Rehabilitation will be provided by the service and shared care arrangements will be established with the patient's local specialised hand therapy / rehabilitation services.

Review and Follow-up

Each patient will be reviewed regularly by the specialist medical team, clinical psychologist, physiotherapist and occupational therapist.

Regular blood tests will be performed to ensure effective immunosuppression management as well as regular monitoring of blood pressure and blood sugar levels.

Patients will be reviewed at least annually at the multi-disciplinary hand and upper limb transplant clinic. More frequent local follow-up may be arranged as part of a shared care agreement with the patient's local rehabilitation service.

Revision or secondary surgery will be undertaken as required.

2.2 **Interdependence with other Services**

The service will be required to maintain effective relationships and communication with local specialist rehabilitation and prosthetic services, including consultants with experience in upper limb amputee rehabilitation and experienced prosthetists with upper limb experience. The service will also develop effective relationships with local specialised hand therapy services regarding the appropriate referral and assessment of potential patients, as well as developing shared care arrangements for the rehabilitation and long term support for transplanted patients.

The service is required to maintain a close and effective working relationship with NHS Blood and Transplant (NHSBT) as the responsible service for organ donation. The service will match limbs offered by NHSBT to candidates on the waiting list, in accordance with current NHSBT policy. The service must be able to respond to donor offers without delay, and it is expected that prosthetic restoration will be offered to the donor.

Core components of the hand and upper limb transplant team include:

- A minimum of 4 surgeons with microsurgical experience and experience of limb replantation
- Transplant physicians
- Transplant immunologists
- Clinical psychologists
- Hand therapists (including physiotherapists and occupational therapists)
- Specialist plastic surgery trained nursing staff

Other services required:

- Radiology
- Operating Department
- High Dependency Unit
- Anaesthetics
- Pharmacy

- Microbiology
- Histopathology
- Medical Illustration
- Diabetic management

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This service specification relates to the population defined as the commissioning responsibility of NHS England as set out in *"Who Pays? Determining responsibility for payments to providers*" (2013) guidance https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf (or subsequent published updates).

Commissioning arrangements for the devolved nations in relation to this service are as set out in "*UK-wide Commissioning Arrangements of Highly Specialised Services*".

3.2 Population Needs

No data currently exists to quantify the fraction of upper limb amputees that may be suitable for hand and upper limb transplant. It is, however, anticipated that this subgroup will be small. The number of patients that will seek the procedure and meet the stringent inclusion criteria may be as low as 3 patients per year.

3.3 Expected Significant Future Demographic Changes

It is not expected that there will be an increase in the hand and upper limb amputee population, which would result in an increased demand for this service.

3.4 Evidence Base

International data is collected and collated by the International Registry for Hand and Composite Tissue Transplantation (IRHCTT) who publish updated case series biennially, www.handregistry.com. The data collated to date reveal that Hand and Upper Limb (HAUL) transplant recipients express satisfaction with cosmetic, sensory, functional, and social outcomes after transplantation.

A composite functional score developed by IRHCTT shows 40% of all HAUL recipients achieve an 'excellent' outcome, whereas 53% achieve 'good' and 7% achieve 'fair' outcomes. No transplants have resulted in a 'poor' outcome.

Data extrapolated from analogous surgical techniques suggest that hand transplant is likely to have excellent clinical outcomes. Replantation of a traumatically detached limb (auto transplantation) is technically similar to HAUL-VCA. In one study, limb replantation resulted in a good or excellent function in 50% of cases, whereas prosthetics failed to produce a good or excellent outcome in any case (Graham B, J Hand Surg 1998;23A:783). Indeed, one may expect better outcomes from HAUL-VCA when compared to replantation, through the beneficial secondary effects of the

immunomodulatory drug Tacrolimus which, whilst required for immunosuppression, also enhances speed and quality of nerve regeneration (Gold BG. J Neurosci 1995;15:7509).

Reconstruction of the absent hand using allotransplantation has additional, less readily quantifiable benefits such as improved self-image, improved psychological wellbeing, enhanced activities of daily living and social function, with the majority of patients returning to employment.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

The aim of the service is to provide hand and upper limb transplantation to reconstruct an absent (or partially absent) upper limb or hand, lost as result of trauma, infection or a defective upper hand or limb. Hand and upper limb transplantation would, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable or unsatisfactory. With the overall aim being to improve functional capacity and quality of life.

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	**x**
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	Number of referrals	NEL CSU	2,3,5	effective
102	Number of patients declined for transplant	NEL CSU	2,3,5	effective
103	Number of patients listed	NEL CSU	2,3,5	effective
104	Number of patients transplanted	NEL CSU	2,3,5	effective
105	Median length of time on waiting list from referral to MDT clinic assessment	Provider	2,3,5	effective
106	Median length of time from initial MDT clinic to active waiting list	Provider	2,3,5	effective
107	Average length of stay including critical care	NELCSU	2,3,5	effective
108	Number patients with post transplant infection	NELCSU	2,3,5	effective
109	Number of hand transplants declined by patients	NELCSU	2,3,5	effective
110	Number of patients with post operative complications	Provider	2,3,5	effective
111	Number of patients treated or exonerated for signs of rejection within 24 hours of detection	Provider	2,3,5	effective
112	Number of patients with improvement of DASH score >14	Provider	2,3,5	effective
113	Number of patients with improvement in Canadian Occupational Performance Measure (COPM) score of >1	Provider	2,3,5	effective
114	Number of patients with psychological rejection of transplant	NELCSU	2,3,5	effective
115	Number of patients showing psychological improvement			
Patient Experience				

201	Patient feedback	Self declaration	4	responsive, caring
202	Patients receive psychological well being assessment	Self declaration	4	responsive, caring
203	There is information for patients and carers	Self declaration	4	responsive, caring
Structure and Process				
301	There is a specialist team	self declaration	2,3,5	well led, safe ,
302	There is a pre-transplant MDT assessment clinic	Self declaration	2,3,5	safe, effective, caring
303	There are 2 operating theatres equipped for plastic surgery	Self declaration	2,3,5	safe effective
304	There is a specialist plastic surgery ward	Self declaration	2,3,5	safe effective
306	There is a training strategy in place	self declaration	1,2,3,5	safe, effective
307	There are agreed patient pathways	Self declaration	3,4	effective
308	There are agreed clinical protocols	self declaration	1,2,3,5	safe, effective
309	The service submits data to the International Registry	Self declaration	1,2,3,4,5	responsive
310	There are audit and education meetings	Self declaration	4,5	effective, responsive
311	There is debrief and feedback following each transplant	Self declaration	4,6	effective, responsive

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

Not applicable

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

- The provider must routinely submit data to the International Registry for Hand and Composite Tissue Transplantation (IRHCTT).
- The provider must comply with the agreed policies and protocols as set out by NHS Blood and Transplant.

- The providers must comply with NICE interventional Procedure Guidance for Hand Allotransplantation (IPG 383).

5.2 Other Applicable National Standards to be met by Commissioned Providers

Not applicable.

5.3 Other Applicable Local Standards

Not applicable.

6. Designated Providers (if applicable)

Designated provider: Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary
Great George St
Leeds LS1 3EX

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:
ADL - Activities of Daily Living
HAUL - Hand and Upper Limb
HLA - Human Leukocyte Antigen
IRHCTT - International Registry for Hand and Composite Tissue Transplantation
MDT - Multidisciplinary Team
NHSBT - NHS Blood and Transplant
SNOD - Specialist Nurse in Organ Donation