



# **Clinical Commissioning Policy: Hand Transplant**

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# Clinical Commissioning Policy: [Clinical Commissioning Policy for hand transplant]

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Complex disability**

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## **Policy Statement**

NHS England will routinely hand transplant commission in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

## **Equality Statement**

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

## **Plain Language Summary**

Hand transplantation is used to replace an amputated hand or arm using parts from a deceased donor. The transplanted arm is able to sense its surroundings, move naturally with strength and dexterity, looks, feels and heals like a natural hand. Immunosuppressive drug therapy is taken to stop the body rejecting the transplant.

Hand transplant is an established procedure worldwide but is not currently routinely commissioned by the NHS in England. For a small minority of suitable patients, transplant offers an alternative to a prosthesis (artificial hand).

The estimated cost of the transplant episode is £64,765 (unilateral transplant) £85,368 (bilateral transplant) per patient. The ongoing annual costs for immunosuppressants and blood tests are £2,373 per patient.

The estimated need is for three transplants per annum.

## 1. Introduction

Hand transplant is more technically known as hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA).

Worldwide, approximately 80 hand transplants have been performed. Success rates are high provided patients are selected carefully and fully prepared psychologically.

## 2. Definitions

Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to the touch and heal itself when injured.

## 3. Aim and objectives

1. This policy aims to :
  - a. Outline the policy for provision of hand transplant to patients of the NHS in England
2. The objectives are to:
  - b. Outline the scientific evidence
  - c. Outline the costs of hand transplant
  - d. Set out a commissioning policy

## 4. Epidemiology and needs assessment

1. Hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA) is appropriate to reconstruct an absent upper limb or hand, lost as result of trauma or infection. HAUL-VCA would, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable or unsatisfactory.
2. Up to 20% of the adult population with upper limb amputations choose not to use prosthesis. Of those that do accept a prosthesis, as many as 26% of adults and 45% of children and adolescents are dissatisfied with their device and choose not to use them. Reasons cited include poorly developed fine motor control, absence of sensory function, weight and a lack of warmth and humanness (Biddiss EA. Prosthet Orthot Int 2007 31: 236).
3. HAUL-VCA is an alternative to a prosthesis in very small subset of upper limb amputees who are both physically and psychologically suited and in whom the benefits outweigh the risks of immunosuppression.
4. Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to

the touch and heal itself when injured.

5. Reconstruction of the absent hand using allotransplantation has additional, less readily quantifiable benefits such as improved self-image, and improved psychological and social function (Petruzzo P, Transplantation 2010;90:1590). Hand transplant recipients have enhanced activities of daily living and the majority return to employment.
6. Data from 1996 estimates there are 1,285,000 upper and lower limb amputees in the US, representing 0.4% of the population (CDC. National Health Interview Survey. Atlanta: Centers for Disease Control, 1996), with an incidence of 50,000 new cases per year (Esquenazi, A. Disability & Rehabilitation, 2004; 26:831). The total number of upper limb amputees in England is not known, but the prevalence is likely to be similar to that of the United States, representing 250,000 individuals and 10,000 amputations per year. Data suggests that 1 in 4 amputations performed occur in the upper limb.
7. No data currently exist to quantify the fraction of upper limb amputees that may be suitable for HAUL-VCA. It is, however, anticipated that this subgroup will be small. Of 20 patients previously screened as part of a pilot HAUL-VCA programme in England, only 2 patients have been both suitable and, after discussion of the inherent risks of the procedure, willing to proceed. The number of patients that will seek the procedure and meet the stringent inclusion criteria may be as low as 3 patients per year.
8. In one US programme, with similar inclusion and exclusion criteria to the England programme, of 600 patients screened, only 6 have been considered suitable and received a transplant (Kaufman CL. World experience after more than a decade of clinical hand transplantation: update from the Louisville hand transplant program. Hand Clin. 2011;27:417–21).
9. Patients suitable for HAUL-VCA must be highly motivated; generally fit and well; must have failed a trial of, or be unsuitable for, a prosthesis; be able to balance complex issues of risk and benefit; and be psychologically suitable (show understanding, appropriate expectations, have adequate coping mechanisms, be able to accept a donor limb etc). HAUL-VCA is not currently considered suitable for congenital limb absence or for those who have required amputation secondary to the presence of tumour.
10. Although an increase in referrals may be anticipated to follow successful transplantation, the likely growth of the procedure will remain small due to the stringent inclusion criteria.

It is likely that there are a significant number of upper limb amputees in the UK who may wish to explore the possibility of HAUL-VCA. Many of these will be excluded on receipt of their referral because of inherent characteristics (congenital, too young, previous history of malignancy, co-morbidities). Complex assessment, performed within a specialist setting by a multidisciplinary team is required to carefully select the small proportion of amputees that may benefit from transplantation.

## 5. Evidence base

1. HAUL-VCA is an alternative to prosthetics and is indicated especially in those cases of distal loss where prostheses fail, or offer an inferior solution.
2. Due to the level of amputation, prosthetics are not suitable for all. In such situations, no alternative therapies exist.
3. Due to the low number of procedures performed and the unique nature of each case, no randomised controlled trials comparing the outcomes of HAUL-VCA to alternative treatments (prostheses no reconstruction) exist.
4. It is expected from international results that hand transplantation will be superior in all patient reported outcome measures to prostheses.
5. International data is collected and collated by the International Registry for Hand and Composite Tissue Transplantation (IRHCTT, [www.handregistry.com](http://www.handregistry.com)), who publish updated case series biennially.
6. The IRHCTT data reveal that HAUL-VCA recipients express satisfaction with cosmetic, sensory, functional, and social outcomes after transplantation.
7. A composite functional score developed by IRHCTT shows 40% of all HAUL-VCA recipients achieve an 'excellent' outcome, whereas 53% achieve 'good' and 7% achieve 'fair' outcomes. No transplants have resulted in a 'poor' outcome.
8. Protective sensation has been achieved in all patients within 12 months and, as time progressed, 90% showed tactile and 72% of them discriminative sensibility.
9. The majority (70%) return to work and 75% report an increased quality of life (Petruzzo P, Transplantation 2010;90:1590).
10. 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).
11. A study evaluating functional outcomes following HAUL-VCA showed marked improvement in a standardised test of upper limb function, the DASH (disabilities of arm, shoulder and hand) score. In their series, DASH score improved by a mean of  $27.6 \pm 19.04$  points (Landin L. Transpl Int. 2012;25:424). To put this in context, a carpal tunnel release improves the DASH score by a mean of 12 points.
12. Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to

the touch and heal itself when injured. Reconstruction of the absent hand using allotransplantation has additional, less readily quantifiable benefits such as improved self-image, and improved psychological and social function. Hand transplant recipients have enhanced activities of daily living and the majority return to employment.

## 6. Rationale behind the policy statement

Hand transplant is an established procedure worldwide but is not currently routinely commissioned by the NHS in England. For a small minority of suitable patients, transplant offers an alternative to a prosthesis (artificial hand).

## 7. Criteria for commissioning

Hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA) is appropriate to reconstruct an absent upper limb or hand, lost as result of trauma or infection. HAUL-VCA would, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable or unsatisfactory.

A highly protocolled evaluation pathway leads to the majority of potential candidates not being accepted for treatment on current standards. Those that are accepted following psychological, surgical, immunological and medical screening and after detailed occupational therapy assessment would proceed to an offer of waiting list for hand transplantation.

## 8. Patient pathway

1. The national caseload of new patients requiring evaluation each year is anticipated to be approximately 10 or 12. Between 2 and 4 operations are expected to be performed each year. Patients would be referred to the service from primary care, from secondary care practitioners working in areas such as hand, plastic and orthopaedic surgery and from rehabilitation centres. As many upper limb amputees do not require on-going medical care, the opportunity to self-refer to the programme is important. Self-referral can be performed by telephone, email, letter or through a website. Self-referring patients would be urged to request a formal written referral to be made from their primary care physician to the hand transplant service.
2. Patients who, on the basis of their referral letter, may be suitable for hand transplantation would be invited to a multidisciplinary outpatient appointment at which clinical and laboratory assessment is performed and verbal and written information provided to the patient. All core components of the team (surgeons, transplant physicians, immunologists, prosthetists and psychologists) would be in attendance.
3. A highly protocolled evaluation pathway leads to the majority of potential candidates not being accepted for treatment on current standards. Those that



are accepted following psychological, surgical, immunological and medical screening and after detailed occupational therapy assessment would proceed to an offer of waiting list for hand transplantation.

4. During the waiting list period, patients would continue to 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.
5. On identification of a potential donor, the patient would be admitted, a time of offer cross match and Human Leukocyte Antigen (HLA) screen performed and donation offered if appropriate.
6. If donation is accepted, the patient would follow a standard surgical protocol, through the analogous procedure of microsurgical replantation of amputated limbs. Following transplantation, a protocol exists for monitoring for acute rejection, which, unlike solid organ transplants, manifests itself visibly and standard immunological protocols are followed in its management.
7. Physiotherapy and occupational therapy protocols would be in place for the early and intermediate management and for early mobilisation as an outpatient.
8. The hand transplant service requires the following components

#### Diagnosis and Assessment:

Assessment for suitability and provision of prosthetic limbs

Laboratory based biochemical, immunological, haematological and virological and bacteriological assessment

Transplant physician assessment

Surgical assessment

Psychological assessment

Radiological assessment (Plain radiographs and occasionally MRI assessment)

#### Operative Components:

A single operating theatre and specialised microsurgical operating department staff are required.

An operating microscope and microsurgical instruments are required in addition.

#### Post-Operative Components:

Routine postoperative care provided, initially in the high dependency unit followed, 2-3 days later by standard ward care.

Postoperative physiotherapy and occupational therapy provided three times per week for the first 3 months.

Therapeutic drug monitoring at regular intervals.

Standard surgical follow up along with outpatient monitoring of the side effects of medication.

### **9. Governance arrangements**

Hand transplantation is a highly specialised procedure. It is expected that only three transplants will be required per annum; hence only one centre in England will be commissioned to provide the procedure

Auditing and monitoring. Functional and psychological outcomes will be closely monitored. Normal arrangements will apply for reporting to NHS Blood and Transplant in line with legal and other requirements for solid organ transplantation.

### **10. Mechanism for funding**

Currently covered by IFR processes, only three transplantations estimated per year.

**See cost breakdown at appendix 1.**

### **11. Audit requirements**

HAUL-VCA remains a developing technology. Continued, careful data collection is required.

The domains assessed will include:

Surgical outcomes: Complications, range of motion, sensibility, power etc

Functional outcomes: DASH, Chen's functional score, hand transplantation score system

Psychological outcomes: Satisfaction, acceptance, coping, and quality of life, patient reported outcomes.

Side effects of immunosuppression.

### **12. Documents which have informed this policy**

Commissioning for Patients: Guidelines for National Commissioning of Specialized Services for Patients of All ages with limb loss. (Department of Health 2011).

National Service Specification for Amputee Rehabilitation.

National Service Framework for long-term conditions (2005)

British Society of Rehabilitation Medicine (2003), Amputee and Prosthetic Rehabilitation –standards and guidelines (2nd edition) section 4.19, British Society of Rehabilitation Medicine, London

National Prosthetic Centre Managers Group (2010), National Service Specification for Prosthetic and Amputee Rehabilitation Services, National Prosthetic Centre

Managers Group, Preston

Royal College of Physicians & British Society of Rehabilitation Medicine (2010), Medical rehabilitation in 2011 and beyond. A report of a working party (6.21), London

British Association of Prosthetists and Orthotists (2005), Guidelines for best practice No 1: The Role of the Prosthetist/Orthotist (Issued 2000 and then re-issued in February 2005, British Association of Prosthetists and Orthotists, Paisley

Upper limb Prosthetic Rehabilitation – Guidance document. College of Occupational Therapists (2006) College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB

### **13. Links to other policies**

National Service Specification: Complex Disability Equipment-Prosthetic Specialised Services for People of All Ages with Limb Loss

National Service Framework for long-term conditions (2005)

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

### **14. Date of review**

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

## References

1. Biddis, EA & Chau, TT. Upper limb prosthesis use and abandonment: A survey of the last 25 years. *Prosthetics and Orthotics International* September 2007; 31(3): 236-257.
2. Brent, Graham. Adkins, Paula et al. Major Replantation Versus Revision Amputation and Prosthetic Fitting in the Upper Extremity: A Late Functional Outcomes Study. *The Journal of Hand Surgery*; 1998; 23A:783-791.
3. Esquenazi, A. Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration. *Disability and Rehabilitation*, 2004; 26, no. 14/15, 831-836
4. Gold, Bruce G. Kiyoshi, K. & Storm-Dickerson, T. The Immunosuppressant FK506 Increases the Rate of Axonal Regeneration in Rat Sciatic Nerve. *The Journal of Neuroscience*, November 1995; 15(11): 7509-7516.
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6. Kaufman, Christina L. Breidenback, Warren. World experience after more than a decade of clinical hand transplantation: update from the Louisville Hand Transplant Program. *Hand Clinic*, 2011; 27, 417-421.
7. Petruzzo, Palmina. Lansetta, Marco et al. The International Registry on Hand and Composite Tissue Transplantation. *Transplantation* 2010; 90: 1590-1599. College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB

## Appendix 1.

### Summary of cost analysis

1. The tariff is based on the following:
  - a. Length of stay, approximately four days.
  - b. Theatre time, approximately four hours.
  - c. Drug prescribing as for renal transplantation.
  - d. Radiology and pathology testing are anticipated to be minimal.
  - e. Physiotherapy, in-patient for four days, outpatient twice per week for four weeks then continued in the community.
  - f. Outpatient attendances weekly for four weeks then monthly for 6 months, then ad hoc.
2. No maintenance contracts are required.

<b><u>Cost per episode</u></b>	<b>Unilateral: £64,765</b>
	<b>Bilateral: £85,368</b>

Additional costs per patient      Maintenance drugs:      £1782 / year (lifelong)  
Blood tests:      £591 / year (lifelong)

<b><u>Possible cost savings:</u></b>	Over a 5 year programme treating 10 patients (15 limbs) £100,000 - £750,000 lifetime saving (estimate) on prostheses for the whole cohort.  30% likely to have abandoned prostheses prior to considering transplant, therefore 10 limbs for costing.
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3. Estimating the lifetime cost of prostheses for patients with upper limb amputations is challenging. Patients vary in age, sex, activity levels and expectations regarding prostheses. Furthermore, the provision of a range of prostheses and adequate maintenance services may vary geographically. While analysis of data from a Scottish study of World War 1 and II patients (Stewart & Jain, 1999) estimates the costs at approximately £10500/ lifetime/patient, this is likely to be an underestimate for the current patient population. Firstly this study reflects older styles of prostheses in an older generation of patients, and secondly the cost of stump socks and other consumables were not included.

4. A study of US servicemen amputees (Blough et al., 2010) calculated a median lifetime prosthetic cost of \$370,000 for a group of 6 bilateral upper limb amputees from the Vietnam cohort, which was dramatically increased in a group of 7 younger bilateral upper limb amputees from the Iraq and Afghan wars to \$2,160,000. While a high-demand young military cohort is not representative of our UK transplant cohort

at this stage, this may change over time. These two studies illustrate the broad range of potential prosthetic costs to be considered.

5. For this programme's expected cohort of 10 to 12 predominantly civilian transplanted patients (1 bilateral:1 unilateral ratio), the cost of each individual prostheses could range from under £1000 to £30 000 to reflect the most basic cosmetic limb or hook prosthesis up to the more expensive myoelectric prostheses. All would require some repair and replacement over a lifetime. Patients undergo a trial of prosthesis (if they have not before) as part of the transplant assessment, but these savings still apply to ongoing repair and future replacement costs.

6. Further cost savings are anticipated to the social care budget and wider society, rather than directly to the NHS, with respect to reduced dependence upon carers and an increased likelihood of return to work with reduced dependence upon state benefits.

### **5 year projected development of service**

*Provision by one national centre*

<b>Projected maximum cost of over 5 years: £815,690 plus drugs £23,730 per annum</b>
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