

Integrated Impact Assessment Report for Service Specifications			
Service Specification Reference Number URN1685			
Service Specification Title	Hand and Upper Limb Transplant Service Proposal for routine commission (source A3.1)		
Lead Commissioner	Nicola Symes	Clinical Lead	Prof. Simon Kay
Finance Lead	Keith Moulds	Analytical Lead	Click here to enter text.

Integrated Impact Assessment – Index			
Section A – Activity	Section B - Service	Section C – Finance	
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff	
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient	
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this service specification to NHS England	
A4 Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this service specification to the NHS as a whole	
A5 Service Setting		C5 Funding	
A6 Coding		C6 Financial Risks Associated with Implementing this service specification	
A7 Monitoring		C7 Value for Money	
		C8 Cost Profile	

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 service specification 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.	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. Source: Service Specification Proposition section 3.1	
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	Estimated 3 patients per year Source: Previous Annual Activity data Please specify Click here to enter text.	
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	Adults Please specify Note: In exceptional cases, it may be appropriate to consider referral to the service for a child under the age of 18 years. Any such cases will require extensive clinical consultation and prior approval.	
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	Adults - not applicable due to low patient numbers Source: Working group Please specify Click here to enter text.	
A1.5 How is the population currently distributed geographically?	Evenly It is expected that there would be even geographical distribution, but	

	patient numbers are low. Those patients that have received a transplant to date have been geographically dispersed. If unevenly, estimate regional distribution by %: North Midlands & East London South Source: Click here to enter text.	
A2 Future Patient Population & Demography		
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?	Constant If other, Click here to enter text. Source: Service specification proposition section 3.1	
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	No Please specify Click here to enter text. Source: Service specification proposition section 6/other	
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed	YR2 +/- enter number. YR3 +/- enter number.	
service specification commissioning criteria, per year in years 2-5 and 10?	YR4 +/- enter number.	

	YR5 +/-	enter number.	
	YR10 +/-	enter number.	
	Source: Service	e specification propo	sition section 3.1
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	Yes Click here to e	nter text.	
A3 Activity			
A3.1 What is the purpose of new service specification?	commissione without a pub *PSSAG (Pres Please specify The associated	d by NHS England in the Ished specification with the Ished Specialised Section of the Ished Specialised Specialised Section of the Ished Specialised Specialise	eument for a service already n accordance with 'The Manual' but ervices Advisory Group) d in 2015 and service commissioned tion is currently in place.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	Estimated 3 pa Source: Previo	ous Annual Activity da	nta
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	•		ta

A4 Patient Pathway	
A4.1 Patient pathway Describe the current patient pathway and service.	Referrals for hand and upper limb transplantation would be made by one of the following specialised services: prosthetics, plastic surgery, orthopaedics or rehabilitation. 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
	Source: Service Specification
A4.2. What are the current service access and stopping criteria?	Inclusion criteria: Full or partial hand or upper limb loss (uni-lateral or bilateral) 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.
	(In exceptional cases, be appropriate to consider referral to the service for a child under the age of 18 years. Any such cases will require extensive clinical consultation and approval).
	Exclusion criteria: active or previous malignancy of current oncological concern, active infection, systemic infection, congenital limb anomalies,

	incapacitating proximal nerve injury
	Patients referred to the service will receive a full and comprehensive assessment to ensure their anatomical, immunological and psychological suitability for transplant, prior to inclusion on the waiting list for a donor limb. Source: Service Specification
A4.3 What percentage of the total eligible population are: a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria	If not known, please specify: Unknown a) enter % b) enter % c) enter % Source: required
 A4.4 What percentage of the total eligible population is expected to: a) Be referred to the proposed service b) Be eligible for care according to the proposed criteria for the service c) Take up care according to the proposed criteria for the service d) Continue care according to the proposed criteria for the service? 	If not known, please specify: Unknown a) enter % b) enter % c) enter % d) Source: required
A4.5 Specify the nature and duration of the proposed new service or intervention.	Time limited For time limited services, specify frequency and/or duration. Patients will receive an in-depth assessment, usually at least 1 year; if appropriate, patients will be listed for transplant; patients will receive a period of inpatient care and treatment at time of transplant; patients will be followed up for rehabilitation. Although patients will not require lifelong input from the service, they will require immunosuppression for the lifetime

	of the transplant. Source: Working Group			
	Godice: Working Group			
A5 Service Setting				
A5.1 How is this service delivered to the patient?	Select all that apply:		1	
	Emergency/Urgent care atte	endance		
	Acute Trust: inpatient		\boxtimes	
	Acute Trust: day patient			
	Acute Trust: outpatient		\boxtimes	
	Mental Health provider: inpa	atient		
	Mental Health provider: out	patient		
	Community setting		\boxtimes	
	Homecare			
	Other			
	Please specify: Click here to enter text.			
A5.2 What is the current number of contracted providers for the	NORTH	1		
eligible population by region?	MIDLANDS & EAST			
	LONDON			
	SOUTH	number		

	There is one nationally designated provider for this Highly Specialised Service – Leeds Teaching Hospital NHS Trust. They will accept patients from across England.	
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	No Please specify: The service is already in place. Source: required	
A6 Coding		
A6.1 Specify the datasets used to record the new patient pathway	Select all that apply:	
activity.	Aggregate Contract Monitoring *	
*expected to be populated for all commissioned activity	Patient level contract monitoring	
	Patient level drugs dataset	
	Patient level devices dataset	
	Devices supply chain reconciliation dataset	
	Secondary Usage Service (SUS+)	
	Mental Health Services DataSet (MHSDS)	
	National Return**	
	Clinical Database**	
	Other**	

	**If National Return, Clinical database or other Highly Specialised commissioning Monthly data		
A6.2 Specify how the activity related to the new patient pathway will	Select all that apply:		
be identified.	OPCS v4.8		
	ICD10		
	Service function code		
	Main Speciality code		
	HRG		
	SNOMED		
	Clinical coding / terming methodology used by clinical profession		
A6.3 Identification Rules for Drugs:	Not applicable		
How are any drug costs captured? If already specified in the current NHS Englan specify drug name and indication for all that a			
	Click here to enter text.		
	If drug(s) NOT already been specified in the cu List please give details of action required and of discussed with the pharmacy lead:	•	
	Click here to enter text.		
A6.4 Identification Rules for Devices: How are device costs captured?	Not applicable If device(s) covered by an existing category of Device Category (as per the National Tariff Payfor all that apply: Click here to enter text.		

	If device(s) 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.
	Click here to enter text.
A6.5 Identification Rules for Activity:	Already correctly captured by an existing specialised service line
How are activity costs captured?	(NCBPS code within the PSS Tool
	If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).
	Click here to enter text.
	If activity costs are already captured please specify whether this service needs a separate code. Choose an item.
	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.
	Click here to enter text.
	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.
A7 Monitoring	
A7.1 Contracts	None
Specify any new or revised data flow or data collection	Please specify
requirements, needed for inclusion in the NHS Standard Contract	No new data requirements

Information Schedule.

specialised services commissioning.

Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England

A7.2 Business intelligence	<u>No</u>
Is there potential for duplicate reporting?	If yes, please specify mitigation:
	Click here to enter text.
A7.3 Contract monitoring	<u>Yes</u>
Is this part of routine contract monitoring?	If no, please specify contract monitoring requirement:
	Click here to enter text.
A7.4 Dashboard reporting	<u>No</u>
Specify whether a dashboard exists for the proposed service?	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?
	Yes, the new indicators within the revised specification will be used to produce a dashboard.
A7.5 NICE reporting	No No
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new	If yes, specify how performance monitoring data will be used for this purpose.
service specification?	Click here to enter text.
Section E	B - Service Impact
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	The service is currently delivered by one nationally commissioned
Centres, networked provision etc.)	provider.
	Source: required
<u>L</u>	

B1.2 Will the specification change the way the commissioned service is organised?	No Please specify: Click here to enter text. Source: required	
B1.3 Will the specification require a new approach to the organisation of care?	No change to delivery of car Please specify: Click here to enter text.	<u>re</u>
B2 Geography & Access		
B2.1 Where do current referrals come from?	Select all that apply:	
	GP	
	Secondary care	\boxtimes
	Tertiary care	
	Other	
	Please specify:	
	Click here to enter text.	
B2.2 What impact will the new service specification have on the	No impact	
sources of referral?	Please specify:	
	Click here to enter text.	
B2.3 Is the new service specification likely to improve equity of access?	No impact Please specify:	
	i lodgo opodny.	

	Olials have to automite of
	Click here to enter text.
	Source: Equalities Impact Assessment
B2.4 Is the new service specification likely to improve equality of	No impact
access and/or outcomes?	Please specify:
	Click here to enter text.
	Source: Equalities Impact Assessment
B3 Implementation	
B3.1 Will commissioning or provider action be required before	No action required
implementation of the proposition can occur?	Please specify:
	Click here to enter text.
B3.2 Time to implementation:	No - go to B3.4
Is a lead-in time required prior to implementation?	If yes, specify the likely time to implementation: Enter text
B3.3 Time to implementation:	Choose an item.
If lead-in time is required prior to implementation, will an interim plan	If yes, outline the plan:
for implementation be required?	Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	No No
	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?	No Please specif Click here to	•		
B3.7 Are there changes in the support services that need to be in place?	No Please specif Click here to	•		
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No Please specif Click here to	•		
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and	No change Please complete the table:			
estimated number of providers required in each region	Region	Current no. of providers	Future State expected range	Provisional or confirmed
	North	1	1	select
	Midlands & East	0	0	select
	London	0	0	select
	South	0	0	select
	Total	1	1	select
	Please specifical Click here to	•		

B3.10 Specify how revised provision will be secured by NHS	Select all that apply:		
England as the responsible commissioner.	Publication and notification of new service specification	\boxtimes	
	Market intervention required		
	Competitive selection process to secure increase or decrease provider configuration		
	Price-based selection process to maximise cost effectiveness		
	Any qualified provider		
	National Commercial Agreements e.g. drugs, devices		
	Procurement		
	Other		
	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	No Please specify:		
commissioning arrangements, STPs)	Click here to enter text.		
Section C	- Finance Impact		
C1 Tariff/Pricing			

C1.1 How is the service contracted and/or charged?	Select all that apply:		
Only specify for the relevant section of the patient pathway	Drugs	Not separately charged – part of local or national tariffs	\boxtimes
		Excluded from tariff – pass through	
		Excluded from tariff - other	
		Not separately charged – part of local or national tariffs	\boxtimes
		Excluded from tariff (excluding ZCM) – pass through	
	Devices	Excluded from tariff (excluding ZCM) – other	
		Via Zero Cost Model	
		Paid entirely by National Tariffs	
		Paid entirely by Local Tariffs	\boxtimes
		Partially paid by National Tariffs	
	Activity	Partially paid by Local Tariffs	
		Part/fully paid under a Block arrangement	
		Part/fully paid under Pass-Through arrangements	
		Part/fully paid under Other arrangements	
04.0 D = 0.040	Nint amplica		
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.			
C1.3 Device Costs	Not applica	able	

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.	
C1.4 Activity Costs covered by National Tariff List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Not applicable
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.	No change to existing practice
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	No Please specify: Click here to enter text.
C2 Average Cost per Patient	

C2.1 What is the estimated cost per patient to NHS England, in	No change to	existing practice	
years 1-5, including follow-up where required?	YR1	enter number.	
	YR2	enter number.	
	YR3	enter number.	
	YR4	enter number.	
Are there any changes expected in year 6-10 which would impact the model?	YR5	enter number.	
	If yes, please	e specify:	
	Click here to	antar taxt	
C3 Overall Cost Impact of this Service specification to NHS En	gland		
C3 Overall Cost Impact of this Service specification to NHS En C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	Cost neutra Please spec	<u>I</u> fy:	
C3.1 Specify the budget impact of the proposal on NHS England in	gland Cost neutra	<u>I</u> fy:	
C3.1 Specify the budget impact of the proposal on NHS England in	Cost neutra Please spec	<u>I</u> fy: enter text.	

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: No impact on CCGs Budget impact for providers: Cost neutral Please specify: Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	Cost neutral Please specify: Click here to enter text.
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?	No Please specify: Click here to enter text.
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.	Not applicable

C6.1 What are the material financial risks to implementing this service specification?	None – no changes to the current service provision	
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?	Not applicable – no change to existing service	
C6.4 What scenario has been approved and why?	Not applicable	
C7 Value for Money		
C7.1 What published evidence is available that the service is cost	There is no published evidence of cost-effectiveness	
effective as evidenced in the evidence review?	Please specify:	
	Click here to enter text.	
C7.2 Has other data been identified through the service	Select all that apply:	_
specification development relevant to the assessment of value for money?	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	
	Available pricing data suggests the service is lower cost compared to current/comparator treatment	
	Available clinical practice data suggests the new service specification has the potential to improve value for money	
	Other data has been identified	
	No data has been identified	\boxtimes

	The data supports a high level of certainty about the impact on value
	The data does not support a high level of certainty about the impact on value
	Please specify: Click here to enter text.
C8 Non-Recurrent Costs	
C8.1 Are there non-recurrent revenue costs associated with this service specification?	No If yes, please specify and indicate whether these would be incurred or passed through to NHS England: Not applicable If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact. Choose an item.
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	No If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs). Not applicable