Integrated Impact Assessment Report for Service Specifications

Reference Number	A07 S02		
Title	Service Specification: Renal Transplantation		
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Section K - Activity Impact			
Theme	**Questions**		**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?		All patients with CKD 5 and CKD 4 with progressive disease will be considered for transplantation and reasons for not being considered documented. Patients with progressive deterioration in renal function and medically suitable for transplantation will be offered the option of being placed on the national

		transplant list within six months of their anticipated dialysis start date to optimise their chance of a pre-emptive deceased donor transplant.
	K1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	On 31 March 2015, there were 5,394 adult patients on the UK active kidney transplant list which represents a 4% decrease in the number of patients a year earlier. There were 2,793 adult kidney only transplants performed in the UK in 2014/15 a decrease of 5% compared to 2013/14. On 31 December 2013 there were 24,773 patients with a functioning transplant having follow up – 16620 in the 19 transplant centres and 8153 in the 33 referring renal units
	K1.3 What age group is the treatment indicated for?	Adult patients => 18 years old.
	K1.4 Describe the age distribution of the patient population taking up treatment?	All age groups.
	K1.5What is the current activity associated with	See K1.2

	currently routinely commissioned care for this group?	
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	The number of transplants steadily increased each year from 1,915 in 2005/06 to 3,255 in 2013/14 before decreasing by 4% to 3,121 in 2014/15.
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	The rate limiting factor for growth is the availability of organs. Growth will therefore depend on an increase in the number of patients registering as potential donors both for living and deceased donation. The UK national strategy, Taking Organ Transplantation to 2020 is aiming towards increasing the number of deceased donor transplants to 74pmp, which for England would be around 4000 transplants per annum. The corresponding national living donor strategy is working towards 26pmp living donor transplants, which is around 1400 transplants per annum
	K1.8 How is the population currently distributed geographically?	National
K2 Future Patient Population &	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently	The service specification describes the service as currently commissioned. The

Demography	routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	specification has been amended and updated to reflect the latest national guidance on kidney transplant.
	K2.3 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	The rate limiting factor for growth is the availability of organs. Growth will therefore depend on an increase in the number of patients registering as potential donors both for living and deceased donation. See also K1.7
	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details	In 2013 the incidence rate of patients undergoing Renal Replacement Therapy (RRT) in the UK was stable at 109 per million population (pmp) reflecting RRT initiation for 7,006 new patients. From 2006 to 2013 the incidence rate pmp has remained stable for England. The median age of all incident patients was 64.5 years but this was highly dependent on ethnicity (66.0 for White incident patients; 57.0 for non-White patients) By 90 days, 66.1% of patients were on haemodialysis, 19.0% on peritoneal dialysis, 9.5% had a functioning

		transplant and 5.3% had died or stopped treatment.
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	Whilst prevalence rates for RRT have increased as described below incidence rates have remained stable therefore growth in activity will depend upon the availability of suitable organs for transplant. There were 56,940 adult patients receiving renal replacement therapy (RRT) in the UK on 31st December 2013, an absolute increase of 4.0 % from 2012. The actual number of patients increased 1.2% for haemodialysis (HD), 7.1% for those with a functioning transplant but decreased 3.3% for peritoneal dialysis (PD) The UK adult prevalence of RRT was 888 per million population (pmp). The reported prevalence in 2000 was 523 pmp See also K1.7 and national strategy predictions
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	There were 2,793 adult kidney only transplants performed in the UK in 2014/15 a decrease of 5% compared to

		2013/14. On 31 December 2013 there were 24,773 patients with a functioning transplant having follow up – 16620 in the 19 transplant centres and 8153 in the 33 referring renal units
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet	No change.
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet	NA
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	The specification describes the currently commissioned pathway.
	K5. What are the current treatment access criteria?	All patients with CKD 5 and CKD 4 with progressive disease will be considered for transplantation.
	K6 What are the current treatment stopping points?	NA
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline	RRT consists of either haemodialysis (HD), peritoneal dialysis (PD) or transplant.

	associated activity. K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	Criteria for the initiation of RRT are described in the following guidance: "Renal Association Guidelines on the Planning, Initiating and Withdrawal of Renal Replacement Therapy" In 2013 by 90 days, 66.1% of patients were on haemodialysis, 19.0% on peritoneal dialysis, 9.5% had a functioning transplant and 5.3% had died or stopped treatment The risk adjusted 1, 5 and 10 year graft survival following a first deceased donation transplant are 94%, 86% and 74% respectively, and 97%,91% and 80% for first living donor transplant
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or	See K3.1 See K5.2

	number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
K7 Treatment Setting	K7.1How is this treatment delivered to the patient? K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	Acute Trust: Inpatient No
K8 Coding	89.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	Inpatient and outpatient activity is recorded via SUS/HES. Outcome data is also recorded in the UK Transplant Registry... HRGs Preparation for transplantation Recipient work-up (LA12A) and live donor screening (LA10Z) and assessment (LA11Z) Transplant inpatient episodes LA01A Kidney Transplant from Cadaver non-heart beating donor 19 years and over LA02A Kidney Transplant from Cadaver heart beating donor 19 years and over

		LA03A Kidney Transplant from Live donor 19 years and over LB46Z Live Donation of Kidney Post-transplant outpatient follow up Recipient (LA13A) and live donor (LA14Z) follow-up
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? If so, these must be communicated to CTownley@nhs.net, ideally by end of October to inform following year's contract	Already included.
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	NA
	K9.3 What analytical information /monitoring/ reporting is required?	Monitoring already in place.
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	No change required.
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	Information for quality monitoring collected and reported by NHSBT.
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	None.

	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	NA
Theme	**Questions**	
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision) L1.2 How will the proposed policy change the way the commissioned service is organised?	Tertiary Centres No change
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new policy change / restrict / expand the sources of referral? L2.3 Is the new policy likely to improve equity of access? L2.4 Is the new policy likely to improve equality of access / outcomes?	Specialist renal centres based in transplant centres and referring renal units No change No change No change
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed? L3.2 Is there a change in provider physical	The specification describes updated standards for currently commissioned service. Removal of the threshold for

	infrastructure required?	undertaking ABOi transplants may result in an increase in centres undertaking these procedures. The specification and BTS Guidelines set out the laboratory requirements related to ABOi. Trusts will need to demonstrate compliance with these standards if they wish to undertake ABOi transplants.
	L3.3 Is there a change in provider staffing required?	No See L3.2
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	See L3.2
	L3.5 Are there changes in the support services that need to be in place?	No
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	Provision will remain as at present.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new policy,	

	competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (E.g. future CCG lead, devolved commissioning arrangements)?	No
Theme	**Questions**	
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	Local prices. Work is ongoing to develop a national tariff for transplant.
	M1.2 Is this treatment excluded from national prices?	NA
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	There is significant variation in current reported costs. National project underway to identify source of variation. Reference costing guidance to be amended to achieve greater consistency.
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes	Proposal for shadow monitoring of proposed tariff in 16/17.
	M1.5 is VAT payable (Y/N) and if so has it been	NA

	included in the costings? M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	 No
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1? M2.2 What is the revenue cost per patient in future years (including follow up)?	See M1
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England? M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	Cost neutral. The adoption of the new service specification is not the direct cause of activity growth.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs) M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole? M4.3 Where this has not been identified, set out the reasons why this cannot be measured? M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	Cost neutral

M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	NA
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy? M6.2 Can these be mitigated, if so how? M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	None
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? M7.2 What issues or risks are associated with this assessment?	The first year of care after a kidney transplant costs around £17,000 and £5,000 for every subsequent year; whereas the average cost of dialysis is £45,000 per annum (this includes the cost of dialysis and the management of complications including hospital admission). In addition, many patients can return to work and therefore have a lower dependency on state support. None
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy?	None

	M8.2 If so, confirm the source of funds to meet these costs.	NA