Integrated Impact Assessment Report for Service Specifications

Reference Number	A07/S(HSS)a		
Title	Atypical haemolytic uraemic syndrome (aHUS) (all ages)		
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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? K1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	Worldwide, the prevalence of aHUS ranges from 2.7–5.5 per million population, with an incidence of about 0.40 per million population based both on the patient's clinical need and on their capacity to benefit. Growth to 286 patients at year 10 expected.

	K1.3 What age group is the treatment indicated for?	All ages
	K1.4 Describe the age distribution of the patient population taking up treatment?	aHUS can occur at any age. Onset occurs in childhood slightly more frequently than in adulthood (around 60% and 40% of all cases respectively). Most children (70%) who develop aHUS will experience the disease for the first time before the age of 2 years.
	K1.5What is the current activity associated with currently routinely commissioned care for this group?	As at 31st December 2015 60 adults and 31 children were on eculizumab treatment for aHUS. An interim service is in place to manage this group of patients and in particular approve treatment with eculizumab.
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	Growth to 286 patients at year 10 expected.
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	Same
	K1.8 How is the population currently distributed geographically?	There is currently an uneven geographic distribution of cases. It is expected that this will smooth as the service develops and education and awareness spreads across England.
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or	An interim service was put in place by the HSCT to confirm that the patient has a diagnosis of aHUS and that they meet the

	restrict an existing treatment threshold / add an additional line / stage of treatment / other?	criteria for eculizumab. This service specification formally sets out the service to be provided by the HSS to provide a diagnosis and management advice service for aHUS patients.
	K2.3 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	Increased survival
	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	Activity growth already described, this is expected to even out across the country according to population as the service specification is implemented.
	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?	Year 2 + 20 Year 5 + 82 Year 10 +184
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	60 adults and 31 children were on eculizumab treatment for aHUS
	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	Yr 1 – 102 Yr 2 – 122 Yr 5 – 184 Yr 10 – 286
	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	The service specification has been written to develop a service to support the coordination of the use of eculizumab through an expert centre in accordance with NICE HTA1. Do nothing is therefore

		not an option.
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. K5. What are the current treatment access criteria? K6 What are the current treatment stopping points?	An interim service is in place which offers oversight of diagnosis and management advice. Other aspects of the service in accordance with the NICE TA are not currently part of this service. As described in the draft service specification As described in the draft service specification
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 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.	Before eculizumab became available, plasma therapy was traditionally the first-line treatment for aHUS. There was no national oversight or management of the patient group. Not applicable
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	Figures as described. The service will oversee the use of eculizumab for patients with a confirmed diagnosis of aHUS in England by initiating

	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.	prescriptions directly for local patients or by authorising the use of eculizumab in patients at remote centres under shared care arrangements.
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 Capacity requirements in the expert centre will be expanded
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)	Activity returns directly to the HSS team. The service will be required to keep a register of all patients in England with aHUS, including treatment history and relevant clinical data fields; to produce regular and ad hoc reports on the clinical effectiveness of eculizumab in the treatment of aHUS as used by the NHS in England. As described
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 K9.2 If this treatment is a drug, what pharmacy monitoring is required?	Would need to be included. Registry data as described

	K9.3 What analytical information /monitoring/ reporting is required?	A process for activity monitoring in line with all HSS would be put in place
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	Activity reports would be submitted to supplier managers as for all HSS
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	This service would not be included in a quality dashboard and outcome data would be reported separately
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	Yes as set out in NICE THA1
	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*	No
Section L - Service Impact		
Theme	**Questions**	***Comments*** *(Include source of information and details of assumptions made and any issues with the data)*
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision)	Tertiary centre with a network of renal centres managing the day to day care of patients
	L1.2 How will the proposed policy change the way the commissioned service is organised?	There will be some changes to meet the conditions of the NICE HTA, however the tertiary HSS nature of the service remains the same

L2 Geography & Access	L2.1 Where do current referrals come from?	Renal units
	L2.2 Will the new policy change / restrict / expand the sources of referral?	No
	L2.3 Is the new policy likely to improve equity of access?	Yes
	L2.4 Is the new policy likely to improve equality of access / outcomes?	Yes
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?	There is expected to be a 6 month lead in time until the full service is up and running including the development of a registry for data collection.
	L3.2 Is there a change in provider physical infrastructure required?	Not expected, there will an impact on diagnostic facilities but the service is mainly outpatient.
	L3.3 Is there a change in provider staffing required?	Yes
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	No additional.
	L3.5 Are there changes in the support services that need to be in place?	Yes
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	Networked arrangements with renal units will need to be agreed and possibly contractually defined
	L3.7 Is there likely to be either an increase or	No

	decrease in the number of commissioned providers? 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)	 A procurement exercise has been completed
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
Section M - Finance Impact		
Theme	**Questions**	***Comments*** *(Include source of information and details of assumptions made and any issues with the data)*
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which? M1.2 Is this treatment excluded from national prices? 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? M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that	No, treatment paid under arrangements outside of national tariff scope. Yes Yes To be agreed

	associated activity is not additionally / double charged through existing routes M1.5 is VAT payable (Y/N) and if so has it been included in the costings? M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	No 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)?	To be agreed. The average cost for an adult patient is £340k per year and for a child £124k per year. The expected cost to the NHS of eculizumab in 2015/16 is £27m rising to £46.7m in 2019/20. As above
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?	The changes to the service specification and the growth in activity will be a cost pressure. Not applicable
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	Cost neutral As above Not applicable

	reasons why this cannot be measured? M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	 No
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	Not identified
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	Assumed funded from specialised commissioning allocation envelope. Implementing this service specification will not impact the drug costs described as activity volumes unlikely to be affected. There will be an additional pressure over and above the service currently provided. Cost reductions could be achieved through service efficiency savings. Indicative cost estimates based on projected activity volumes. There would be variation over time if the projected volumes are different from planning figures.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective?	The major cost for this group of patients is for eculizumab. The long-term budget impact of eculizumab for treating atypical haemolytic uraemic syndrome is uncertain but considerable. Once the service is in place NHS England will work with the company to consider what opportunities might exist to reduce the cost of

	M7.2 What issues or risks are associated with this assessment?	eculizumab to the NHS. Economic evidence was considered as part of the NICE HTA and is available on the NICE website. Number of patients have been either over or understated. .
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? M8.2 If so, confirm the source of funds to meet these costs.	No