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Integrated Impact Assessment Report for Clinical Commissioning Policies			
Specification Reference Number	A12/S(HSS)c		
Specification Title	Severe Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (SJS-TEN), 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?		The incidence of SJS is estimated at 1 to 6 cases/million person-years, and 0.4 to 1.2 cases/million person-years for TEN, in all races and ages and both sexes. Preliminary analysis of national SUS data for 2014/15, using the single ICD10 code L512 (Toxic epidermal necrolysis [Lyell]) in any position, showed 109 spells seen at 64 providers of which 43 (67%) had a single patient. Outcome was coded as death in 22%

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<td>K1.3 What age group is the treatment indicated for?

K1.4 Describe the age distribution of the patient population taking up treatment?</td>
<td>of observations. This figure is an underestimate because other codes are sometimes used for cases of TEN. Clinical review of TEN cases at 3 centres (2 adult, one paediatric) showed that the number of TEN cases based on code L512 (total 16) was slightly inflated by a single miscoded case, but missed 11 true cases of TEN, 7 coded as L511 (Bullous erythema multiforme/Stevens-Johnson syndrome), and 4 with other codes. Therefore the number of TEN cases per year nationally has been estimated at 177 cases per year.

All ages. As at present, children will be managed in age appropriate units by paediatrically trained staff. The SJS-TEN guideline developed by the British Association of Dermatologists (BAD) and referenced in the service specification applies to adults, but the principles of management are the same in children, and the BAD is working with the British Society for Paediatric Dermatology to develop a Paediatric SJS-TEN guideline.

Variable but a retrospective survey of UK dermatologists in 12/13 showed the following age distribution:
<table>
<tr><td><10 yrs</td><td>10 – 18 yrs</td><td>18 – 30 yrs</td><td>30 – 50 yrs</td><td>50 – 70 yrs</td><td>>70 yrs</td></tr>
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	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	<table><tr><td>10</td><td>2</td><td>14</td><td>15</td><td>12</td><td>13</td></tr></table> Preliminary analysis of national SUS data for 2014/15, using the single ICD10 code L512 (Toxic epidermal necrolysis [Lyell]) in any position, showed 109 spells seen at 64 providers of which 43 (67%) had a single patient. Assessment of L512 code has given a total.
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	No growth expected in total numbers of patients apart from that due to improved coding. We anticipate that improved treatment will reduce average LOS, although more patients surviving may increase average LOS
	K1.8 How is the population currently distributed geographically?	Even distribution expected
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 restrict an existing treatment threshold / add an additional line / stage of treatment / other?	This specification will ensure the implementation of a national guideline for the management of this group of patients. The intention is to simplify the patient pathway, provide equity of care, reduce LoS and improve outcomes and substitute for a currently commissioned service.
	K2.3 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased	No expected growth in patient population.

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	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 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?	 No Expected stable patient numbers year on year.
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 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 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 accompanying excel worksheet shows a forecast in 15/16 of 177 spells for the service. In previous years the number of spells was smaller; 14/15 and 13/14 109 spells but it is thought that is due to improved coding in 15/16. Though given the size of the population there will be year on year variation. No expected change in activity. The aim of the service is to reduce morbidity and mortality. This is difficult to quantify at this stage but will be monitored and reported on. No expected change in activity.
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	SJS/TEN patient management should be carried out in a small number of centres each equipped with appropriate specialist

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	associated activity.	expertise. In this way, standardised care will be delivered to provide high quality care with improved clinical outcomes. Currently this model of care is not in place. 109 cases of SJS- TEN recorded in England last year were managed in 64 different hospitals, 43 of which saw only one case over the year. These would include adult general ICUs, paediatric ICUs, paediatric services, adult general medicine, not associated with dermatology or burns, isolated burns services and isolated dermatology services. Transfers for specialised care happens in an ad hoc manner with delayed access to definitive care.
	K4.2. What are the current treatment access criteria?	Patients with a clinical diagnosis of SJS-TEN are seen in a variety of clinical settings, with no specific access criteria other than a diagnosis of SJS-TEN made by the referring doctor"
	K4.3 What are the current treatment stopping points?	Recovery, repatriation or death. Most patients who survive are discharged home or back to their local hospital. Those with other serious comorbidities, where the SJS-TEN episode occurred in the context of another serious illness (e.g. cancer treatment or organ transplantation) will be repatriated to the relevant specialty, which may be in the same hospital.
K5 Comparator (next best alternative treatment) Patient	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient	Two different current pathways: 1. admit under medical/paediatric/dermatology team

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Pathway	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.	with medical treatment, wound care and ad hoc MDT care on ward, HDU or ICU. 2. Admit to burns unit with standardised burns MDT care, not always including dermatological/medical support. Patients managed with varying care pathways under different specialty leads. No equity of access. May be late diagnosis Recovery/repatriation or death. Current mortality rate of 22%
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 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.	177 spells, 861 critical care bed days and 708 excess beddays. The patient pathway is clearly set out with stopping criteria. It is expected that mortality will reduce: we expect that, with the new improved service, of 177 patients per year, 90% (159) will survive and 10% (18) will die.
K7 Treatment Setting	K7.1How is this treatment delivered to the patient?	Acute Trust: Inpatient

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	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	There is expected to be a significant reduction in the number of centres doing this work, with an anticipated 3 centres for children and 4 centres for adults.
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)	Data will be reported directly through agreed HSS routes. Also via SUS. Reporting via usual HSS reporting mechanism. A difficulty exists that while L512 is specific for TEN, L511 covers both SJS-TEN and milder conditions. All patients accessing the service will be logged and activity reported.
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? K9.3 What analytical information /monitoring/ reporting is required? K9.4 What contract monitoring is required by supplier managers? What changes need to be in	Specification to be included in standard contract. Patients with TEN are usually treated with Ivlg, which is routinely recorded on the national database at http://www.ivig.nhs.uk/IgD.html HSS reporting of activity and agreed outcome monitoring. Activity reports would be submitted to supplier managers as for all HSS

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	place? K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? 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*	 No No 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) L1.2 How will the proposed policy change the way the commissioned service is organised?	Secondary care and tertiary centres with different management pathways and access points over 64 services in England and Wales. No network. Patient care will be rationalised in fewer centres, anticipated 3 for children and 4 for adults. Currently care for this group of patients is provided in 64 hospitals in England.
L2 Geography & Access	L2.1 Where do current referrals come from?	GP, Dermatologist, ED, Medical/Paediatric Ward, Intensive Care Unit

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		(ICU/PICU) High Dependency Unit (HDU), Burns Facility, Burns Unit
	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 would need to be a procurement process to run for the service. There would need to be ongoing work around data collection.
	L3.2 Is there a change in provider physical infrastructure required?	Bed capacity in the HSS centres will need to increase
	L3.3 Is there a change in provider staffing required?	There will be some compliance requirements to be met. Although centres will manage few patients at once care of SJS-TEN is very resource intensive. Additional psychology resource, and consultant on-call cover will be required
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	There will be standardised dependencies required across centres. This will of course depend on the outcome of any procurement exercise.

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	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)	No
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	Yes there will be a decrease in 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)	Competitive selection process
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?	32% of spells are coded to JD03A - Intermediate Skin Disorders Category 2, with Major CC. The remaining activity is distributed across 31 other HRGs.
	M1.2 Is this treatment excluded from national	The core spell is included within national tariff

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	prices?	but the associated critical care days are locally priced despite having a national currency.
	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?	Local investigation shows that there is scope for some of the activity to be incorporated into block arrangements for Burns services. The activity used for the costing is sourced from the T.N.R.
	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	N/A
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	Costing based on existing pricing to providers.
	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?	The revenue cost per patient is £19,805.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	Would expect revenue cost per patient to adjust in line with annual tariff inflator/deflator
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?	Cost neutral
	M3.2 Where this has not been identified, set out the	

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	reasons why this cannot be measured?	
M4 Overall cost impact of this policy to theNHS 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)	Cost neutral overall. Some of this work is being coded and therefore funding by CCGs currently so a transfer of resources would be needed to be made to NHS England to ensure the proposal is cost neutral to NHS England.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	Cost neutral
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	N/A
	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	N/A
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	Currently capture of data is poor; there is a risk that in future years this activity will be more accurately identified thus increasing costs. There has been activity identified that suggests that some activity sits within block arrangements for Burns services.
	M6.2 Can these be mitigated, if so how?	Total number of cases is small so overall risk would be limited. This work is happening in the system at the moment, the risk is that is hasn't been identified not that it will increase.

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	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	Data collected for activity in 13/14, 14/15 and 15/16. In addition there have been local meetings with providers to assess charging mechanisms and to assess assumptions regarding average critical care days, length of stay etc.
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?	*e.g. NICE appraisal, clinical trials or peer reviewed literature* Risk associated with the financial impact include current poor data quality and coding, activity currently being charged within a block and the wide variation in critical care days which ultimately drive the final revenue cost of the patient.
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 The cost of treating these patients is already in the system.

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