Integrated Impact Assessment Report for Clinical Service Specifications

Reference	E09/S/(HSS)/tba		
Title	Paediatric Onset Multiple Sclerosis		
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Finance Lead Lead	Shekh Motin	**Analytical Lead**	Charlotte Ellis, Peter Street
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		K1.1 Incidence of 9.83 per million children per year K1.2 86 new referrals per year resulting in an ongoing cohort of 516 including 200 patients who will have a definite diagnosis of POMS and a further 300 who will either be diagnosed with a a 'POMS-like' condition which will need managing in the same way or are at a high risk of demyelination/relapse.

	arrangements?	
	K1.3 What age group is the treatment indicated for?	K1.3 Paediatric patients 10-16 years, but treatment may go beyond 16 years as they transition to adult services. The age cut off for the service is 18 after which children are transferred to adult services, Transition planning starts at 17.
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 10 – 16 years old Mean is around age 13. Most will be post 12 years of age as the POMS population is usually teenagers, although 20% are under 12.
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5.1 500+ patients K1.5.2 currency Outpatient appointments A) news B) f/ups 1.5.2 simple/MRI 1.5.3 complex MRI (GA) n.b the ICD10 code is G35X 1.5.4 DC Infusions/ (inpatient beds) 1.5.5 Inpatient/LoS/Relapses 1.5.6 regular blood tests 1.5.7 genetic testing Inpatients Admissions for day case infusions and relapsing patients who are admitted
	K1.6 What is the projected	K1.6 in line with demographic growth targets in K1.1 in line with general

	growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	paediatric population.
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	K1.7 5% growth based on increased auto immune cases and the growth seen by experts over the last five years.
	K1.8 How is the population currently distributed geographically?	K1.8 No known hot spots
K2 Future Patient Population & Demography	K2.1 Does the new service specification: 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?	K2.1 There will be a transfer of care from tertiary specialist care to the new national highly specialised service, once it is established, although some patients who have a lower level of need will be able to be appropriately managed locally once national review has been undertaken, including assessment and care planning. The new model of care will result in a new, formal pathway which secondary care specialists can refer on to the national experts those patients who are suspected of having POMS, have a 'POMS-like' condition or are at high risk of demyelination, as opposed to the current situation where although some children are able to access expert opinion in centres local to them where national experts work from (although these are not properly established and the range of staffing and care on offer is less than that included in the specification), whilst others do not and are likely to be receiving sub-optimal diagnosis, care and outcomes as a result.

	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2.1 Given that the population with suspected POMS is relatively static, the overall activity levels will be similar to that predicted for year 1, although the way the treatment is proposed to be delivered will be quite different as it will include more flexible options for new POMS patients as compared to those with advanced symptoms of the disease K2.2.2 There is likely to be a significant expansion in the awareness of clinicians on the important role which neuro-inflammatory conditions have in Paediatric Neurological disorders and an increase in the number of available targeted pharmaceutical treatments, many of which are suitable only for highly specialist use. The combination of these two factors has resulted in the development of a previously unrecognised clinical service.
	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	K2.3 Not known at this time.
	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?	K2.4 At present this is difficult to quantify as early diagnosis reduces the need for long term treatment and improved outcomes and the prevalence is estimated to be static, although early diagnosis and increased awareness of the conditions will identify cases earlier, which may increase numbers slowly and marginally over time.
K3 Activity	K3.1 What is the current	K3.1 Nationally there are estimated to be 60-80 new patients per year

	annual activity for the target population covered under the new service specification Please provide details in accompanying excel sheet	who are referred to specialist tertiary units, although these services are not staffed appropriately to manage these patients.
	K3.2 What will be the new activity should the new service specification be implemented in the target population? Please provide details in accompanying excel sheet	K3.2 86+ new patients per year comprising 38 who are suspected of having POMs, or a 'POMS-like' condition or who are likely to present with recurrent demyelination and 48 who have a high risk of relapse.
	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	K3.3 As now as some activity is already being seen by the specialist units
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.	K4.1 No existing formalised pathway – patients are currently managed by specialised paediatric neurology **Specifications.**
	K4.2 What are the current treatment access criteria?	**K4.2** As there is not a dedicated POMS service now, children are seen in District general hospital general outpatients, then referred into specialist/tertiary paediatric neurology outpatients if the condition is identified.

		The Association of British Neurologist guidelines are followed regardless of age.
	K4.3 What are the current treatment stopping points?	K4.3 See specification (Section 3.4) A diagnosis of POMs is not cureable, just treatable. Stopping points would be when a patient is transitioned to adult services or clinical decision not to treat (case by case).
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.	K5.1 Currently GPs send referrals to secondary care generic paediatric outpatient clinic which may decide to refer on to a tertiary care paediatric neurology centre.
	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.	K5.2 Not applicable, as a diagnosis e of POMs is not cureable, but are treatable. Stopping points would be: i)if patients do not wish to have treatment, then they may relapse, go home and be monitored but may subsequently decide to go back on treatment. 10% may discontinue due to side effects or do not want to continue with treatment for other reasons. ii) when a patient is transitioned to adult services iii) clinical decision not to treat (case by case).
K6 New Patient	K6.1 Describe or include a	K6.1 A final steady state cohort of 516 patients is expected, of which

Pathway	figure to outline associated activity with the patient pathway for the proposed new service specification 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.	200 will have a diagnosis of MS and the remainder a further 300 with 'POMS-like' disease or are at a high risk of demyelination/relapse, including 86 new referrals each year. See specification (Section 1.1). K6.2 Same as 5.2
K7 Treatment Setting	K7.1How is this treatment delivered to the patient?	K7.1 Acute Trust: Inpatient **Yes for day cases and admission of relapsing patients where local services cannot adequately manage these.** Outpatient **Yes** Mental Health Provider: Inpatient **No** Outpatient **No**

	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	Community setting: **Yes** Homecare delivery: **No** K7.2 No expected change in delivery setting
K8 Coding	k8.1 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)	K8.1 SUS Q for Andreas which Peter will ask K8.2 • ICD 10 – MRI is G35X • ICD 10 for day case infusions G35 • ICD 10 for inpatient relapse is G35
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	K9.1 Yes

	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 Standard monitoring via senior pharmacist – all are exempt from tariff, are pass through drugs and are outside of this costing/specification due to the very high cost and high variability. (see GOSH website) Notes for the following table (working purposes only – 'Yes' = NHS commissioned, Yes/No = needs IFR) NATALIZUMAB (15ml) 20 mg in 1mL Injection Concentrate YES INTERFERON BETA-1A(REBIF in RebiSmart) (HOME CARE) (18 MIU) 66 micrograms in 1.5 mL Pre-filled Cartridge YES INTERFERON BETA-1A(AVONEX)(6 MILLION UNIT)(HOMECARE) 30 micrograms in 0.5mL Pre-filled Syringe YES RITUXIMAB (50mL) 10 mg in 1mL Injection YES/NO – but depends on indication, if not approved indication then Individual Funding Request (IFR) required GLATIRAMER ACETATE(COPAXONE)(HOMECARE) 20 mg in 1mL Pre-filled Syringe YES INTERFERON BETA-1A(REBIF in Rebismat)(36 MIU)(HOMECARE) 132 micrograms in 1.5 mL Pre-filled Cartridge YES IMMUNOGLOBULIN (FLEBOGAMMADIF) (5%) 20 g Intravenous Infusion YES/NO – but depends on indication (RED & Blue commissioned by NHS England, if Grey indication - IFR required INTERFERON BETA-1A(REBIF) (18 MILLION UNIT)(HOMECARE) 22 micrograms in 0.5mL Pre-filled Cartridge YES
	K9.3 What analytical	K9.3 SUS inpatient and outpatient activity

	information /monitoring/ reporting is required?	
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 Activity monitoring of outpatient and inpatients as other like contracts.
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 To be consider as part of procurement process
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new service specification?	K9.6 None relate to POMS
	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*	K9.7 Yes where applicable
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 service specification change the way the commissioned service is organised?	L1.1 Networked specialised paediatric neurology centres in tertiary centres but very few have the specialist expertise required. L1.2 The new service will • Provide a Hub and Spoke service with three Hubs, each with a named Hub Lead Centre which will establish a network with the participating specialist acute spoke units for the management of children with POMS in their geographic area. • Hub Lead Centres will jointly provide a multicentre assessment that will be undertaken as a virtual clinic; this will offer advice regarding diagnosis (following review of history examination and specialist investigations) and further management. In cases of first line treatment failure, the MDT will suggest escalating treatment in an appropriate manner. • Hub Lead Centres will provide a multi-disciplinary demyelination clinic where patients will be reviewed and managed jointly in shared care with the referring local hospital team. For more information, see the draft specification Section 3.
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new service specification policy change / restrict / expand the sources of referral?	L2.1 Trusts without specialist neurology services, but there is also a gap in service which even specialist units cannot meet – the new model of care will provide consistent, appropriate care and care planning, will act as a resource of expert advice and involve network hubs acting as lead centres of expertise to raise the level of understanding and practice including research. L2.2 Referrals should still come from the same source, but geographically there may be some changes within the POMS Hubs, depending on how quickly the services are developed.

	L2.3 Is the new service specification likely to improve equity of access?	L2.3 Yes
	L2.4 Is the new service specification likely to improve equality of access / outcomes?	L2.4 Yes it will reduce the variation in diagnosis, care and outcomes that patients currently experience.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the service specification is agreed?	L3.1 Yes, will need to recruit more specialist nurses with time commitment for POMS and psychology time to support the new structure of clinics and the virtual MDT.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 The providers will be chosen as part of a procurement process if the service specification is funded, so this is unknown at this time.
	L3.3 Is there a change in provider staffing required?	L3.3 Yes. (see L3.1)– although this is subject to the outcome of the procurement process as to which providers are selected and the staffing needs they identify at the time. It is likely though, that any units will need to make appointments to upskill to the level of expertise needed.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 Access to beds for patient infusions and access to beds for inpatient relapse cases.
	L3.5 Are there changes in the	L3.5 Yes, education and setting up of outreach models and services

	support services that need to be in place?	
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 If approved, there will be a provider selection process
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 As the service does not exist as such, currently no providers have a contract for this service. It is proposed that there are three national hubs for this service, North, Midlands and London, with the London Hub across two sites.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new service specification , competitive selection process to secure revised provider configuration)	L3.8 Procurement process including competitive provider selection.
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)?	L4.1 No

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?	M1.1Combination of national & local tariff.
	M1.2 Is this treatment excluded from national prices?	M1.2 Will move to a local tariff
	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?	M1.3 Yes, comes under new neurology tariff
	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	M1.4 It is not thought that a price has as yet been proposed for this as this process is setting out bottom-up costs.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 No

<table>
<tr><td></td><td>M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new service specification?</td><td>M1.6 No</td></tr>
<tr><td>M2 Average Cost per Patient</td><td>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)?</td><td>£4 - £8,000

£4- £8,000</td></tr>
<tr><td>M3 Overall Cost Impact of this Service Specificationto NHS England</td><td></td><td>Note - Additional activity will be based on the clinical pathway being clearly identified and once the service is up and running, patient referral numbers are expected to increase patients currently seen in District General Hospitals or specialist tertiary units who may not currently being identified as possible POMS or ADS cases are picked up through better understanding of the symptoms. The cost of those seen in DGHs now will be at tariff general paediatric outpatient rate, whereas the new tariff for these patients would be a local tariff.
Service enhancements in the proposed national service versus the current available service would be:
<table>
<tr><td colspan="3">The service enhancements in the proposed national service versus the current available service - dedicated time</td></tr>
<tr><td></td><td>Available in existing tertiary paediatric neurology centres</td><td>Available in proposed national service</td></tr>
<tr><td>Additional MRI</td><td></td><td>✓</td></tr>
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		Additional diagnostic and psychological testing		✓	
		Specialist drugs	✓	✓	
		Access to clinical trials		✓	
		Dedicated POMS resources – which will be dedicated to POMS clinics/service : • Paediatric Neurology time • Clinical Nurse Specialists • Psychologists • Physio/Occupational therapy • pharmacists	Some of these will be available	✓ ✓ ✓ ✓	
		Developing our outreach strategy to support local services identifying, through their general neurology services, these patients earlier.		✓	
		Development of virtual clinics and opportunities to offer flexible transfusion clinics.		✓	
		Ensure that there are regular relapse clinics set up with the right combination of MDT.		✓	

		<table><tr><td>Work with networks like the UK CID to meet regularly throughout the year.</td><td></td><td>✓</td></tr></table>
	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	M3.1 the service proposal is a cost pressure related to the higher level of MDT clinical expertise, assessment and testing. Costings have been developed using proxy bottom up costs from providers who have supported the development of the proposal, including the delivery of the additional responsibilities for MDTs and Lead hubs, which do not exist currently. There are also likely to be increased clinical staff members required including nursing and psychology which will increase costs.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	M4.3 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)	M4.1 Cost neutral
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2 Cost neutral given that there will be a reduction in the activity in the specialised units for the complex cases, with the work instead taking place in the highly specialised units under the new contract for this POMS service .
	M4.3 Where this has not been identified, set out the	M4.3 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?	 M4.4 No
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	*M5 There will be less activity in the local specialist units and the activity will instead take place in the national patient.* *Additional funding to be requested via the 16/17 Prioritisation monies.*
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this service specification 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	*M6.1 If there is a growth in prevalence but none is known* *M6.2 No* *M6.3 Not applicable*
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective?	M7.1 The evidence provided shows that early intervention helps short term and long term complications. This would allow the child to attend and finish education, helping to obtain employment rather than unable to be in a

		position to complete education and unable to work resulting on being on dependent of social care.
	M7.2 What issues or risks are associated with this assessment?	*M7.2 It is the best available view based on current activity and anticipated future demand.*
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this service specification? M8.2 If so, confirm the source of funds to meet these costs.	M8.1 Low level, non-recurrent costs for equipment eg, infusion chairs, for Trusts that do not have these. M8.2 NHS, although some may be sourced via charity funding