

Integrated Impact Assessment Report for Clinical Commissioning Service Specifications

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| Service Specification Reference Number | E09/S/(HSS)/tba | | |
| Service Specification Title | Multiple Sclerosis Management in Children | | |
| Lead Commissioner | Bernie Stocks | Clinical Lead | Edmund Jessop |
| Finance Lead | Jazz Nandra | Analytical Lead | Jazz Nandra |
| Section A - Activity Impact | | | |
| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) | |
| A1 Current Patient Population & Demography / Growth | A1.1 What is the prevalence of the disease/condition? | A1. 1 The incidence is understood to be 9.83 per million children per year. | |
| | A1.2 What is the number of | A1.2 There is understood to be a current national cohort | |

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| | <p>patients currently eligible for the treatment under the proposed service specification?</p> <p>A1.3 What age group is the treatment indicated for?</p> <p>A1.4 Describe the age distribution of the patient population taking up treatment?</p> | <p>of some 230 patients plus 78 new referrals per year. There are some 23 patients who will leave the service per year as they progress to adult services, those in Tier 3 and 4 will stay with the service until they progress to adult service and the balance of the new referrals will be discharged (after one year for Tier 1 and after two years at Tier 2).As well as the 'caseload' of more complex patients, at any point in time there will be other patients going through the service, most of whom will not remain on the caseload once assessment has been completed, any care planning needed has been completed for local delivery due to having a low level of need which is suitable for local care, or because MS or an 'MS-like' condition has been ruled out.</p> <p>A1.3 Paediatric patients 1- 18 years. The age cut off for the service is 18 after which patients transfer to adult services.</p> <p>A1.4 One to 18 years old, most though will be post 12 years of age as the POMS population is usually teenagers, with 80% aged 12-18, a further 20% will be</p> |

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| | <p>A1.5 What is the current activity associated with currently routinely commissioned care for this group?</p> <p>A1.6 What is the projected growth</p> | <p>under 12 and 10% will be under age 6. New referrals up to age 18 would be assessed subject to need and a treatment plan set out or an onward referral to the adult service made where appropriate.</p> <p>A1.5 As noted in A1.2, a cohort of 230* patients including those diagnosed with MS or 'MS-like' recurrent acquired demyelinating conditions which need the same treatment. In 2014 a survey was completed by 12 units in England who were seeing patients with MS at that time, children with MS were being seen in adult or general paediatric clinics or elsewhere, so it is known that there is a wide spread of care providers. The link to the survey is link to survey</p> <p>* 200 in the four centres which supported the development of this service specification, of which 120 have a diagnosis of MS and 80 are being investigated.</p> <p>A1.6 In line with the general paediatric population of 0.8%.</p> |

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| | <p>of the disease/condition prevalence (prior to applying the new service specification) in 2, 5, and 10 years?</p> <p>A1.7 What is the associated projected growth in activity (prior to applying the new service specification) in 2,5 and 10 years?</p> <p>A1.8 How is the population</p> | <p>A1.7 0.8% per year</p> <table border="1" data-bbox="1223 667 1771 1233"> <tbody> <tr><td></td><td>230</td></tr> <tr><td>1</td><td>231</td></tr> <tr><td>2</td><td>233</td></tr> <tr><td>3</td><td>236</td></tr> <tr><td>4</td><td>238</td></tr> <tr><td>5</td><td>242</td></tr> <tr><td>6</td><td>246</td></tr> <tr><td>7</td><td>249</td></tr> <tr><td>8</td><td>252</td></tr> <tr><td>9</td><td>253</td></tr> <tr><td>10</td><td>254</td></tr> </tbody> </table> <p>A1.8 There is no evidence of differences in geographical</p> | | 230 | 1 | 231 | 2 | 233 | 3 | 236 | 4 | 238 | 5 | 242 | 6 | 246 | 7 | 249 | 8 | 252 | 9 | 253 | 10 | 254 |
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| | currently distributed geographically? | distribution in England. |
| A2 Future Patient Population & Demography | A2.1 Does the new service specification: / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other? | <p>A2.1 Offers an additional line of assessment and treatment for patients managed by paediatric neurologists who are operating under NHS England specialised services contracts, although few have staff in these centres have expertise in this condition or the range of multidisciplinary staffing required to diagnose and manage care appropriately, resulting in variable access, quality of care and outcomes and delays in diagnosis.</p> <p>There will be three to four Hub Lead Centres which will be selected from the existing specialist providers following a procurement process. These will set out guidelines for use by referring units, involve referrers in MDT discussions, offer training, advice and information as appropriate and develop strong support relationships to ensure that patient care is improved across the pathway.</p> <p>Expert assessment, diagnosis and care planning will take place in the new national centres, with the majority of care for 90% of patients who have lower levels of need, being managed locally in the main thereafter.</p> <p>The new model of care will result in a new, formal national</p> |

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| | <p>A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p> <p>A 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.</p> <p>A2.4 What is the resulting</p> | <p>pathway where local paediatric neurologists can refer to MS experts those patients who are suspected of having MS or a 'MS-like' condition or who are at high risk of demyelination or can then ask for management advice in the event of any worsening of symptoms.</p> <p>A2.2 None, the population with suspected MS and demyelinating disease is relatively static.</p> <p>A2.3 Not other than the population growth indicated above.</p> <p>A2.4 There is not expected to be any change in the</p> |

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| | expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10? | number of patients accessing the service. |
| A3 Activity | <p>A3.1 What is the current annual activity for the target population covered under the new service specification? Please provide details in accompanying excel sheet.</p> <p>A3.2 What will be the new activity should the new / revised service specification be implemented in the target population? Please provide details in accompanying excel sheet.</p> <p>A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing'</p> | <p>A3.1 National estimate of 230 patients who are seen in paediatric neurology clinics in specialist units or in local units.</p> <p>A3.2 As now there will be some 78 new patients per annum with a similar number either being discharged or progressing to the adult service</p> <p>A3.3 As now</p> |

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| | comparator if service specification is not adopted? Please details in accompanying excel sheet. | |
| A4 Existing Patient Pathway | <p>A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p> | <p>A4.1 There is no existing formalised pathway, patients are currently managed in line with the generic NHS England Specialised Services Paediatric Neurology Specification, depending on need and if the patient has been correctly diagnosed.</p> <p>A4.2 The Association of British Neurologist guidelines are followed regardless of age.</p> <p>A4.3</p> <ul style="list-style-type: none"> i) Some patients do not wish to continue drug treatments due to side effects, but then may relapse, go home and be monitored but may subsequently decide to go back on treatment. Up to 10% of patients may have side effects from drugs or not want to continue with treatment for other reasons. ii) when a patient is transitioned to adult services (the |

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| | | <p>patient will then have continuity of care from the adult service).</p> <p>iii) clinical decision not to treat (case by case one or two cases per year).</p> |
| A5 Comparator (next best alternative treatment) Patient Pathway | <p>A5.1 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.</p> <p>A5.2 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</p> | <p>A5.1 Local general paediatric outpatient clinics refer to paediatric neurology centres, this activity is funded via specialised services contracts.. Care at each of these points is variable due to lack of expertise and some patients are having avoidable relapses due to lack of effective assessment, care planning and management.</p> <p>A5.2 Stopping points would be:</p> <p>i) 10% of patients on drug therapy per annum may discontinue drugs due to side effects or do not want to continue with treatment for other reasons.</p> <p>ii) when a patient is transitioned to adult services – 23 per year in total</p> <p>iii) clinical decision not to treat (case by case – one or two per year).</p> |

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| | success). If possible please indicate likely outcome for patient at each stopping point. | |
| A6 New Patient Pathway | <p>A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new service specification.</p> <p>A6.2 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</p> | <p>A6.1 From a starting cohort of 230 patients, a final steady state cohort of around 254 patients is expected, of which half will have a diagnosis of MS and the remainder with a MS-like' disease or are at a high risk of demyelination/relapse. There will be 78 new referrals each year, with some 23 per year transitioning to adult services and c 55 being discharged back to local services</p> <p>A6.2 see A5.2</p> |

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| | at each stopping point. | |
| A7 Treatment Setting | <p>A7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery <p>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p> | <p>A7.1 Acute: Outpatient, daycase, inpatient</p> <p>A7.2 Patients will go to the Hub Lead Centre for initial review and periodic assessment prior to discharge (Tiers 1 and 2) and in some cases for annual review. Those who relapse will be discussed at the Hub Lead Centre MDT.</p> |
| A8 Coding | A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? | A8.1 SUS |

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| | A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes) | A8.2 ICD 10 for day case infusions G35.X & OPCS is X89 ICD 10 for inpatient relapse is G35.X Outpatients are coded to TFC 421 Paediatric Neurology or TFC 216 Paediatric Ophthalmology |
| A9 Monitoring | <p>A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>A9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>A9.3 What analytical information /monitoring/ reporting is required?</p> <p>A9.4 What contract monitoring is required by supplier managers?</p> | <p>A9.1 No</p> <p>A9.2 No – MS drugs are excluded</p> <p>A9.3 SUS inpatient and outpatient activity</p> <p>A9.4 No</p> |

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| | <p>What changes need to be in place?</p> <p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new service specification?</p> <p>A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i></p> | <p>A9.5 No</p> <p>A9.6 No</p> <p>A9.7 No</p> |
| Section B - Service Impact | | |

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| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) |
| B1 Service Organisation | <p>B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)</p> <p>B1.2 How will the proposed service specification change the way the commissioned service is organised?</p> | <p>B1.1 Paediatricians in local District General Hospital units refer to paediatric neurology clinics in specialist hospitals if they suspect MS or 'MS-like' demyelination, where activity is funded under specialised services contracts, treatment function code 421.</p> <p>B1.2 The new service will</p> <ul style="list-style-type: none"> • Provide three Hub Lead Centres to which local referring units in each geographic area will send patients for multi-disciplinary team (MDT) review, diagnosis, care planning and offering of advice as part of a shared care model. In cases of first line treatment failure, the MDT will suggest escalating treatment as appropriate. |
| B2 Geography & Access | <p>B2.1 Where do current referrals come from?</p> <p>B2.2 Will the new service</p> | <p>B2.1 Local units with general paediatric outpatient clinics refer into specialised services funded paediatric neurology services if they suspect MS or demyelination.</p> <p>B2.2 Referrals will come from the same sources.</p> |

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| | <p>specification change / restrict / expand the sources of referral?</p> <p>B2.3 Is the new service specification likely to improve equity of access?</p> <p>B2.4 Is the new service specification likely to improve equality of access / outcomes?</p> | <p>B2.3 Equity of access to specialist care will improve.</p> <p>B2.4 Equality of access will improve as patients will have improved access to experts in this field which will improve quality of outcomes through patients being seen by experts in this condition, reducing the rate avoidable admissions. It will do this by reducing the current variation in time to diagnosis, setting out appropriate care planning and treatment regimens, providing access to appropriate therapeutic medications to manage the condition.. Currently, there are patients who relapse resulting in emergency admissions to local hospitals due to not receiving appropriate assessment, management and access to appropriate medications. Guidelines will be produced for referrers to indicate the type and quality of testing to be completed prior to referral (e.g resolution of MRI) so that diagnostic testing does not have to be repeated at the national centre</p> |

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| B3 Implementation | <p>B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the service specification is agreed?</p> <p>B3.2 Is there a change in provider physical infrastructure required?</p> <p>B3.3 Is there a change in provider staffing required?</p> <p>B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> <p>B3.5 Are there changes in the support services that need to be</p> | <p>B3.1 There is a short lead in time required prior to implementation including the procurement process. If approved in May 2017, it should be in place from Quarter 4 2017/18.</p> <p>B3.2 No</p> <p>B3.3 Yes, some new posts may be required to be made or additional hours recruited to the contracts of existing post holders in order to form the Hub Lead Centre MDT's.</p> <p>B3.4 Outpatient clinic facilities, daycase facilities including couches or beds for patient infusions and as now, access to beds for the very rare cases high risk inpatient relapse cases who would be transferred and admitted.</p> <p>B3.5 Yes, minor changes will be required but units that will be in scope to provide would already have the majority</p> |

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| | <p>in place?</p> <p>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new service specification, competitive</p> | <p>of the infrastructure and MDT staffing that would be needed.</p> <p>B3.6 If approved, there will be a provider selection process</p> <p>B3.7 No change as although the service does not exist as set out in the service specification, to qualify to act as a Hub Lead Centre, providers will have to be a paediatric neurology specialist centre with an existing cohort of paediatric patients with MS and expertise in the management of these patients.</p> <p>B3.8 Procurement process including competitive provider selection, including the need to meet essential criteria.</p> |

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| | selection process to secure revised provider configuration) | |
| B4 Collaborative Commissioning | B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements) | B4.1 No |
| Section C - Finance Impact | | |
| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) |
| C1 Tariff | C1.1 Is this treatment paid under a national prices*, and if so which? | C1.1 Overall there is a cost neutral effect as the service is currently commissioned/ funded by NHS England specialised services through a combination of national and local tariffs. Drug costs are outside this proposal as separate payment systems are already in place for these via the high cost drugs system and as the drug need and related costs per patient vary widely, it would not be appropriate to include these here. |

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| | <p>C1.2 Is this treatment excluded from national prices?</p> <p>C1.3 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?</p> <p>C1.4 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?</p> <p>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> | <p>C1.2 No</p> <p>C1.3 Yes, some items are covered under local prices but not attributable to other services.</p> <p>C1.4 N/A</p> <p>C1.5 N/A</p> |

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| | C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new service specification? | C1.6 N/A |
| C2 Average Cost per Patient | <p>C2.1 What is the revenue cost per patient in year 1?</p> <p>C2.2 What is the revenue cost per patient in future years (including follow up)?</p> | <p>C2.1 Year 1 is £3,434 per patient</p> <p>C2.2 As per Year 1</p> |
| C3 Overall Cost Impact of this service specification to NHS England | C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. | <p>C3.1 Cost neutral.</p> <p>The will be an offset of costs from a reduction in the burden of care to local specialist neurology providers from a) planned clinic appointments b) diagnostic testing in the search for a diagnosis and c) a reduction in the number of unplanned emergency admissions related to avoidable deterioration and relapses d) bespoke care plans will</p> |

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| | <p>C3.2 Where this has not been identified set out the reasons why this cannot be measured.</p> | <p>reduce the current burden of care to local providers to a series of planned interventions and follow ups. As a consequence,, any net additional costs to the NHS by Hub Lead Centres activity will be negligible. The evidence base for this is recently evaluation of the gaps in provision for children in UK using patient and multi professional interviews identifying that the time to diagnosis the mean to diagnosis of children with MS was 24 months. The findings suggest that delayed presentation to healthcare services, generalists' assumptions about the nature of reported symptoms, lack of awareness of paediatric MS and delayed referral to specialists in paediatric MS to early investigation and accurate diagnosis (Hinton D, et al. Arch Dis Child 2015;100:623–629). Furthermore, in patients investigated there is often underwent numerous investigations with often inaccurate and sometimes wrong diagnosis prior to the eventual diagnosis of MS.</p> <p>C3.2 N/A</p> |
| C4 Overall cost impact of this service specification to the NHS | C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. | C4.1 Cost Neutral |

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| as a whole | <p>providers, CCGs).</p> <p>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p> <p>C4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p> | <p>C4.2 Cost neutral. 85% of the activity is already happening at the four centres which supported the development of the costings. Plus there is estimated to be a further 15% activity taking place above this in England in the units which took part in the 2014 survey. The increase in planned OP attendances is offset by other savings (see financial model).</p> <p>C4.3 N/A</p> <p>C4.4 No</p> |
| C5 Funding | C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning</i> | C5.1 N/A |

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| | <i>less clinically or cost-effective services</i> | |
| C6 Financial Risks Associated with Implementing this service specification | <p>C6.1 What are the material financial risks to implementing this service specification?</p> <p>C6.2 Can these be mitigated, if so how?</p> <p>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p> | <p>C6.1 None known</p> <p>C6.2 N/A</p> <p>C6.3 N/A</p> |
| C7 Value for Money | C7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i> | C7.1 The evidence provided by the MS Society/MS Trust shows that early intervention in childhood/adolescence helps reduce short term and long term complications and results in better outcomes for patients into adulthood. |

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| | C7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence.</i> | C7.2 Low risk of actual activity being different to estimates. |
| C8 Cost Profile | <p>C8.1 Are there non-recurrent capital or revenue costs associated with this service specification? <i>e.g. Transitional costs, periodical costs</i></p> <p>C8.2 If so, confirm the source of funds to meet these costs.</p> | <p>C8.1 Low level, non-recurrent costs for equipment e.g, infusion chairs, for Trusts that do not have these circa £15K per provider.</p> <p>C8.2 NHS England as part of the procurement.</p> |