

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	170019/S
Service	Multiple Sclerosis Management Service for Children
Commissioner Lead	<i>For local completion</i>
Provider Lead	<i>For local completion</i>

1. Scope

1.1 Prescribed Specialised Service

This service specification covers the provision of the Multiple Sclerosis Management Service for Children. This includes children with suspected Multiple Sclerosis (MS) or equally rare 'MS-like', recurrent acquired demyelinating syndromes (ADS) or who have had a first demyelination episode and have a high risk of relapse which require similar treatments, including:

- Neuromyelitis Optica Spectrum Disorder (NMO, NMOSD) and other AQP4 antibody associated demyelination;
- Myelin Oligodendrocyte Glycoprotein (MOG) antibody associated relapsing demyelination and
- Other forms of recurrent relapsing demyelination.

1.2 Description

Multiple Sclerosis (MS) is a condition of the central nervous system (CNS) characterised by chronic brain inflammation which damages the myelin coating around nerve fibres, a process known as demyelination. There is currently no cure for MS but treatments and specialist help can help to control disease activity, decrease disability from the condition and reduce ongoing symptoms. There is a particular need to focus on the early recognition of these serious neuro-inflammatory disorders to reduce long-term morbidity and neuro-disability and for early intervention, including for young or very young children where indicated.

1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

The service is accessible to all patients who are under the age of 18 with a demyelination syndrome where any of the listed conditions are established or being considered:-

- Multiple Sclerosis;
- Recurrent demyelination syndromes presenting with optic neuritis (ON), acute transverse myelitis (ATM), acute disseminated encephalomyelitis (ADEM), antibody mediated demyelination including aquaporin-4 (AQP4), antibody positive neuromyelitis optica (APNMO) and other NMO spectrum disorders (NMOSD). For the latter three conditions, the service will work alongside the existing nationally commissioned service and all affected children will be seen jointly with the NMO service;
- First demyelination with high risk of relapse.

All eligible patients will have access to care and treatment irrespective of their sexual orientation, gender, race, disability, psycho-social circumstances or geographical location. An important

feature of all services is that appropriate pathways are developed for socially disadvantaged patients who are often difficult to engage. The specification will cover the cost of activity undertaken by providers commissioned to provide this service, but not any activity undertaken locally by other providers as part of a shared care arrangement.

1.4 Exclusion Criteria

Patients managed in the Highly Specialised Service for Neuromyelitis Optica will continue to be managed in that service. The costs of medicinal products used for treatment interventions in Multiple Sclerosis are excluded from this service specification.

1.5 Transition

The service will manage transition by setting out clear communications and processes and establishing strong links with regional adult services. Transition planning will begin at 12 years of age, with identification of the respective adult service, depending on the specific problems identified for the child, until transfer at 17 years and 11 months. Transition to the local/most appropriate adult MS service will be co-managed and co-ordinated between the paediatric and adult services, with respective services providing specific input and where appropriate, review in established joint clinics.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

Patients with MS or 'MS-like' conditions must be assessed and treated in the three to four specialist paediatric neurology centres in age-appropriate outpatient and inpatient settings by professionals working in multi-disciplinary teams with expertise in multiple sclerosis. The use of new, highly efficacious medicinal products will significantly reduce disease activity and reduce the rate of acute admissions of patients in crisis presenting to their local centres as a result of relapses and secondary complications.

The service will provide multi-disciplinary team (MDT) decision-making by teams experienced in the treatment of MS in children. The MDT will undertake assessments, initiate treatment (defined as initiation of disease modifying therapy) and undertake ongoing surveillance of patients. Patients with these conditions frequently have co-morbidities, therefore the provision of holistic care will involve multiple health professionals in specialist and local hospital units. There will be three to four centres (Hub Lead Centres), geographically spaced, which will receive referrals from paediatric neurologists in that region/area or, in some circumstances, from a consultant paediatrician where a local arrangement is established for direct referrals to the Hub Lead Centre following discussions with the local paediatric neurologist and where the appropriate diagnostics have been undertaken.

Referring units will be invited to join local Hub Lead Centre MDT calls. Following diagnosis and the setting out of a care plan, there will be shared care of patients with paediatric neurologists in specialised centres and with paediatricians in district general hospitals.

Paediatric Neurologists will be able to make referrals to the service's MDT if they are uncertain about a patient's diagnosis and need additional support in care planning and delivery. The service will add value to the patient's pathway by providing specialist interpretation of existing test results; undertaking additional testing where appropriate; creating bespoke treatment packages, including the use of highly efficacious medicinal products and providing management advice following deterioration to local care providers.

The implementation and delivery of this specification by Hub Lead Centres will include the development of clear written guidance and shared care agreements and undertake clinical trials. Hub Lead Centres will initiate MS medicinal products including monoclonal antibodies. This will require prior approval via the Blueteq MS paediatric forms. In a small number of cases and on an individual patient basis, a Hub Lead Centre MDT may approve a local paediatric neurology unit to prescribe following endorsement by the regional commissioner.

Hub Lead Centres will set out with identified local units a Memorandum of Understanding which describes how decisions to treat will be made, and will include arrangements for ongoing provision of treatment and monitoring.

Referring clinicians will retain leadership for managing the patient's care. Once under the care of the service, patients will be able to contact the MS clinical team during normal working hours between Monday and Friday for any urgent advice.

Each Hub Lead Centre will:

i) Have an expert multi-disciplinary team led by a paediatric neurologist with expertise in MS, and including MS clinical nurse specialists, neuro-radiologists, clinical psychologists/neuropsychologists and will have an appropriate caseload to maintain expertise in the treatment of the condition.

ii) Provide a high quality expert service which will: i) review and treat patients; ii) provide urgent advice to referring clinicians for patients who present with a first episode of demyelination (usually complicated or severe), or who are in relapse, or who have complications resulting from treatment including trial of investigative medicinal products (clinical trials); iii) provide relapse assessment within seven days if uncertainty, iv) provide expert multi-disciplinary team (MDT) demyelination clinics where patients can be reviewed and treated, given the complexity of selecting the most appropriate agents and course length with the newer treatments available for paediatric MS and related conditions; v) carry out monthly (one full day or two half days per month) local MDT meetings to discuss all patients in the service with representation including a paediatric neurologist with an interest in MS, an MS Clinical Nurse Specialist and one neuro-radiologist with experience in the management of recurrent demyelination syndromes and a clinical psychologist. It will review diagnosis, determine the appropriateness of continued surveillance or initiation of treatment in affected patients and the optimal treatment regimen to be used; vi) ensure that patients initiating therapy have been discussed at an MDT meeting, with documentation of the recommendations provided to the patient, general practitioner and local paediatric services; and ensure that any delay in treatment initiation is discussed if this exceeds four weeks from target; ensure that patients receiving disease modifying therapy have a named care provider.

iii) Maintain high quality care and research nationally: i) provide leadership for evidence-based best practice in paediatric MS treatment, standardising investigation guidelines and disseminating information to professionals, patients and their families and/or carers; ii) facilitate clinically appropriate and cost effective prescribing of high cost drug treatments and have oversight of treatments with the potential for serious side effects in accordance with NHS England policy/NICE Technology Appraisals as they become available; iii) develop optimal partnership working with local experts to engage hard to reach groups in treatment programmes; iv) develop evidence collection to support future commissioning policy; v) agree a standardised minimum data set for treatment and outcomes which will feed into national databases, ensuring that patient confidentiality is maintained and consent secured, (these data will be made available to the national Multiple Sclerosis Registry); co-ordinate treatment trials and provide support to referring centres which have the appropriate patient population and resources to take part. Clinical trials are separately funded and outwith this service specification. The use in MS of new, highly efficacious medicinal products will significantly reduce disease activity and reduce the rate of emergency admissions of patients arising from relapses and secondary complications; have a role in providing education, patient information and professional awareness of MS and related conditions in children; ensure that there are plans for ongoing improvements in partnership working with referrers.

iv) Co-ordinate the delivery of care with referring units: Hub Lead Centres will i) undertake regular communication with referring units so that local teams are aware of appropriate investigations for the most important mimics of demyelination and the procedures to manage uncomplicated relapse; ii) the side effects of medications are clearly documented and local teams are well informed as to the expected range of results; iii) local teams are aware of the risks of delayed diagnosis to ensure that referrals are as timely and appropriate as possible; iv) host the quarterly regional MDT on a rolling basis, with all clinical disciplines represented (including at least

three paediatric neurologists with an interest in MS, one neurorehabilitation consultant, MS Clinical Nurse Specialists and one neuro-radiologist with experience in the management of recurrent demyelination syndromes). The MDT will support the co-ordination of care at referring units by providing a second opinion for the management of patients with severe MS-related disability and for complex patients in whom there has been a failure of response to initial treatments to reduce inflammation, (initial treatments are referred to as first line disease modifying treatment (DMT)). The MDT review will include undertaking a 'case note review' of the assessment undertaken in the referring unit, including the history, examination and specialist investigations, and offering advice on diagnosis, suggesting tailored management plans for each patient and identifying those elements of care that can be delivered locally. For those patients who require further investigation, the virtual MDT will recommend that the patient is referred to the national service. The service will reach agreement on the provision and support of outreach and in-reach within the constraints of the funded service. Partnership and outreach models will ensure the promotion of local access to treatment, the optimisation of partnership working and the use of local expertise in engaging hard to reach groups in treatment programmes.

Each of the Hub Lead Centres will meet the following criteria:

- 1) Appropriate expertise and caseload:** demonstration of a caseload of complex and non-complex patients to develop and maintain expertise in the treatment of paediatric MS and related conditions; a substantive body of consultant paediatric neurologists to manage acute childhood demyelination and its complications; access to neuro-imaging and a designated radiologist to discuss and report neuro-imaging.
- 2) Dedicated specialist nursing support:** paediatric MS clinical nurse specialist to undertake and communication role with referring units, manage the patient caseload and carry out clinical commitments. A minimum of one dedicated clinical nurse specialist should be designated in each Hub Lead Centre plus cross-cover.
- 3) Access to an MDT for the acute and follow-up evaluation of patients:** access to both clinical psychology and neuropsychology for assessment, rehabilitation of individual patients; access to physiotherapy and occupational therapy for assessment, rehabilitation of individual patients and advice for fatigue management. These staff will maintain expertise in MS and ADS conditions, identify appropriate and consistent neurocognitive, emotional and behavioural assessment protocols, and provide advice to local services about the assessment and follow-up of patients, also research, knowledge about outcomes and provide family support.
- 4) Appropriate paediatric and relevant clinical support:** access to paediatric specialities required to support the management of children with complex and recurrent demyelination; access to appropriate laboratory support for the diagnosis and management of MS and related conditions; access to clinical neurophysiology support which may be provided by a clinical neurophysiology or ophthalmology department, a designated pharmacist(s) (full or part time) to manage pharmaceutical needs of patients including adherence support, medication review, provision of specialist medications and advice about drug interactions; a dedicated adult neurologist with an expertise in MS who will provide support for transition; links to primary care and community services and secondary care paediatricians.
- 5) Appropriate infrastructure: dedicated ring-fenced clinic facility;** an administrator with appropriate supporting staff to provide administrative support to enable communication with referring units (mandatory for lead centre); facilities, including teleconferencing for multi-disciplinary meetings: administrative support to ensure accurate recording of information, and timely communication of decisions to patients and other care providers.
- 6) Robust patient support processes:** provision of adherence support; access to welfare advice and support.

Hub Lead Centres will work with their referring units to establish and develop expertise and MDT support. The service will ensure that all MDT staff maintain and further develop skills and specialist expertise in the management of paediatric MS patients and will develop and make available for referrers and other local clinicians and families as appropriate, age-related education materials on MS and 'MS-like' diseases.

Stratified model of care based on clinical need

There will be four levels of care to cater for different complexities of clinical need, enabling the care of children to be provided as close to home as possible as follows:

Level 1 Description: Initial suspected demyelinating event; unexplained white matter lesions on scans (Radiologically Isolated Syndrome (RIS), complex migraine with imaging chances, erythematosis, Systemic Lupus Erthematosus, (SLE) vasculitis etc).

Applies to the 75% of patient referrals which meet clinical criteria for relapsing remitting MS, and whose diagnosis and management follows the expected trajectory. These patients will be managed in shared care, with diagnosis and bi-annual review by a Hub Lead Centre, with most care delivered by specialists at the referring centres under existing local payment mechanisms. Most patients are likely to be assessed, reviewed and discharged back to local care within one year. Support will include:

- a) Shared care model with local centre to review at a minimum of six monthly intervals;
- b) Monitor bloods for complications of treatment;
- c) Prescribe treatment other than those specialist MS medications;
- d) Review at relapse and arrange urgent Magnetic Resonance Imaging (MRI) and bloods as required;
- e) Liaise with specialist as required;
- f) Provide management advice on relapse as appropriate;
- g) Where appropriate, recommend that the referring unit arranges for provision of psychology/neuropsychology, and input from liaison psychiatry, paediatric psychology and CAMHS services as appropriate;
- h) Where appropriate, recommend that the referring unit refers to school for educational support;
- i) Hub Lead Centre to provide annual review with Magnetic Resonance Imaging (MRI) annually if required and stable.

Level 2: Relapsing ADS (RRMS, NMO and MOG). Applies to the 20% of referrals where the presentation is unusual, where the patient was less than two years of age at onset or who have aggressive disease with frequent relapses. These patients will be managed mainly by the Hub Lead Centres, with shared care with specialists in referring units as appropriate. Most patients will be assessed, reviewed and discharged back to local care within two years. Support will include:

- a) Shared care model with Hub Lead Centre undertaking the initial assessment, arranging bloods and other tests to exclude mimics, review and repeat MRI at presentation until diagnosis secure;
- b) Hub Lead Centre to see at a minimum frequency of six monthly visits and local centre to review in between as required; arrange MRI scans six to 12 monthly as required;
- c) Referring unit to monitor bloods for complications of treatment in between Hub blood monitoring and reviews;
- d) Referring unit to prescribe treatment other than specialist MS medications;
- e) Hub Lead Centre to prescribe MS medications and monitor for specialist complications;
- f) Referring unit to review at relapse and arrange urgent MRI and bloods as required;
- g) Referring unit to liaise with specialist at Hub Lead Centre as required for advice;
- h) Referring units to treat patients in relapse as appropriate with telephone advice from Hub Lead Centre which will review patient within the same week depending on need. In very rare cases, complex and urgent relapse patients would receive inpatient relapse management at the Hub Lead Centre;
- i) Where appropriate, recommend that referring unit arranges for provision of local neuropsychology, and input from liaison psychiatry, paediatric psychology and CAMHS services as appropriate. Referring unit to refer to school for educational support and, where appropriate, input from Hub Lead Centre Paediatric Neuropsychology team;
- j) Referring unit to provide physiotherapy;
- k) Local unit to liaise with Local Education Authority to ensure education needs are being met.

* Where the Hub Lead Centre serves a local population; it will take on the role of the Referring unit.

Level 3: Relapsing ADS failed first line (highly active RRMS, NMO and MOG). Applies to the 2.5% of patients where treatment of the underlying condition is challenging or where highly specialist input is required, therefore care will be managed by the Hub Lead Centre and include regular joint discussion with the referring units. Support will include:

- a) Shared care model, with Hub Lead Centre undertaking initial assessment, arranging bloods and other specialist tests to exclude mimics;
- b) Hub Lead Centre to review regularly and repeat MRI and testing until diagnosis secure and following diagnosis, to see at a minimum frequency of six monthly intervals, although three monthly more likely;
- c) to k) - as Level 2;
- l) As Level 2 except that frequency may need to be adjusted to requirement. Here, the Hub Lead Centre may also be involved in delivering the treatment (such as monoclonal infusions or when treatment only available as part of clinical trial);
- m) Referring unit to review in between as required;
- n) Referring unit to monitor bloods for complications of treatment in between Hub Lead Centre blood monitoring and review;
- o) Referring unit to prescribe first line disease modifying treatments (other than specialist MS medications);
- p) Hub Lead Centre to prescribe MS medications for highly active second line MS and infusions, monitor for specialist complications and ensure that specialist management is undertaken of impacts of this treatment and its side effects;
- q) Referring unit to undertake outpatient review at relapse and arrange urgent MRI and bloods as required;
- r) Referring unit to liaise with specialist as required for advice;
- s) Referring unit to treat relapse as appropriate following advice;
- t) Where appropriate, recommend that referring unit arranges for provision of psychology/neuropsychology, and input from liaison psychiatry, paediatric psychology and CAMHS services as appropriate;
- u) Hub Lead Centre clinical psychologists/neuropsychologists will provide expertise in management of patients with MS and ADS conditions, identify appropriate and consistent neurocognitive, emotional and behavioural assessment protocols, and provide advice to local services about the assessment and follow-up of patients. They will also take a role in research and contribute to knowledge about outcomes. Family and systemic support will also be provided;
- v) Referring unit to refer to school for educational support and, where appropriate, input from Hub Lead Centre paediatric clinical psychology and neuropsychology team;
- w) Referring unit to provide physiotherapy with support from Hub Lead Centre physiotherapy if needed.

Level 4: Neuroinflammatory disorders Not Otherwise Specified, (NOS), CLIPPERS, Primary

Angiitis of the Central Nervous System (PACNS), neurosarcoid etc. Applies to the 2.5% of patients who present with a relapsing neuroinflammatory condition of uncertain underlying aetiology and who need highly specialised investigation and treatment.

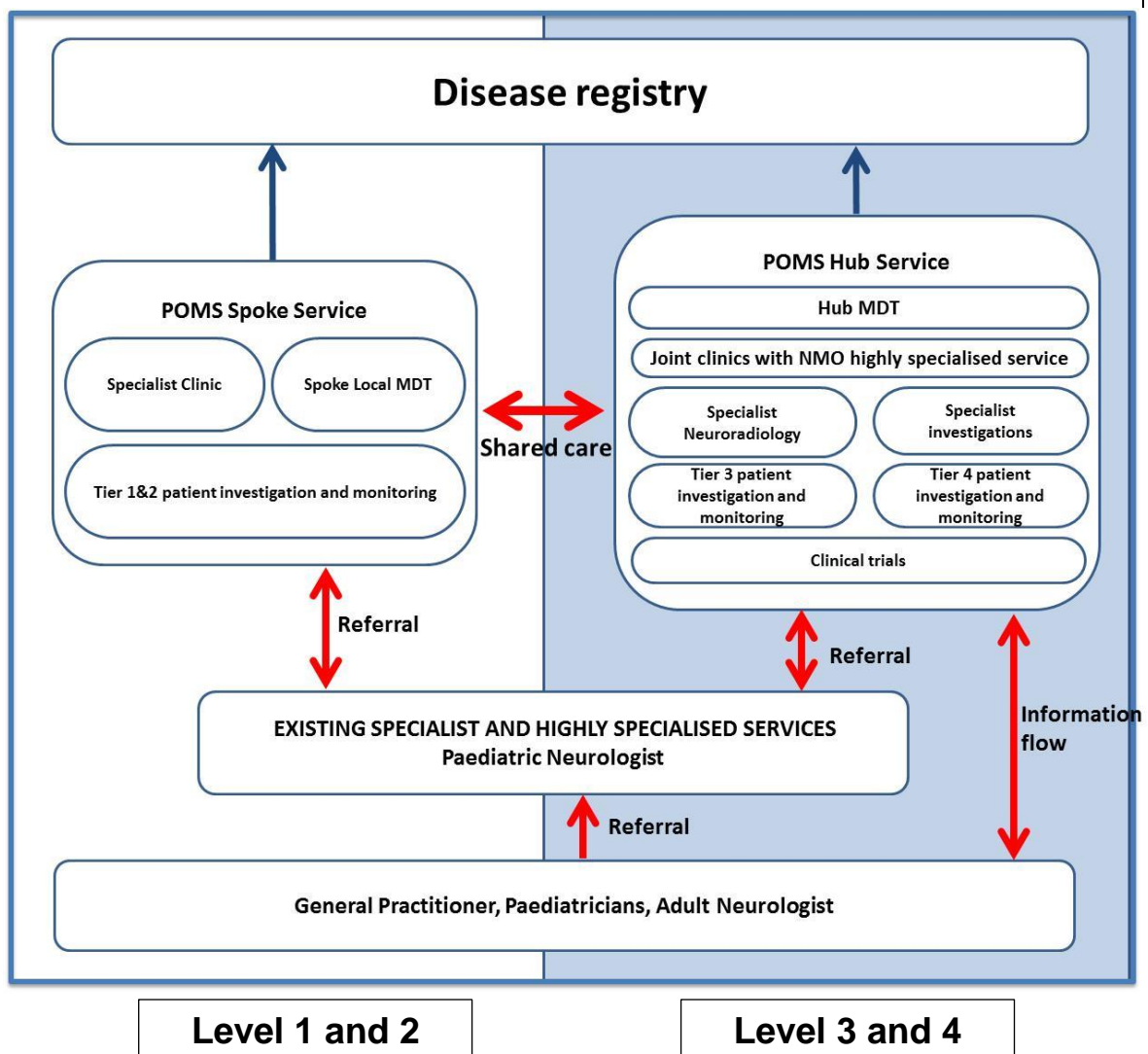
Support will include:

- a) Shared care model, with Hub Lead Centre to assess initially, to arrange bloods, genetics, specialist tests to exclude mimics;
- b) Hub Lead Centre to review regularly and repeat MRI and testing until diagnosis secure and at a minimum frequency of three monthly intervals until condition more stable;
- c) ...to k) as Level 2;
- l) As Level 3 and with additional intensity and frequency required as determined by condition
- m) Referring unit to review in between as required;
- n) Referring unit to monitor bloods for complications of treatment in between Hub Lead Centre blood monitoring and review;
- o) Referring units to prescribe treatment other than those specialist medications;
- p) Hub Lead Centre to prescribe medications for highly active inflammation and infusions and monitor for specialist complications;
- q) Referring unit to review at relapse and arrange urgent MRI and bloods as required;

- r) Referring unit to liaise with specialist as required for advice;
- s) Referring unit to treat relapse as appropriate following advice;
- t) Hub Lead Centre clinical psychologists/neuropsychologists will provide expertise in management of patients with MS and ADS conditions, identify appropriate and consistent neurocognitive, emotional and behavioural assessment protocols, and provide advice to local services about the assessment and follow-up of patients. They will also take a role in research and contribute to knowledge about outcomes. Family and systemic support will also be provided;
- u) Referring unit to refer to school for educational support with, where appropriate, input from Hub Paediatric clinical psychology and neuropsychology team;
- v) Referring units to provide physiotherapy with support from Hub Lead Centre physiotherapy if needed.

The agreed pathway is summarised below:

Overview of Stratified Model for Multiple Sclerosis Management Service for Children



2.2 Interdependence with other Services

Within each Hub Lead Centre, the service will demonstrate that it has well-established links to:-

- neurorehabilitation services, ranging from specialist spinal units to neurocognitive services;
- formal links to other specialist centres to facilitate transfer of care as required;

- formal pathways to support transition of paediatric patients to adult services as required;
- formal pathways to transition paediatric MS patients on trials to adult research facilities;
- child and adolescent mental health services for patients with significant mental health needs, ranging from Third Sector support services to clinical psychology, neuropsychology, liaison psychiatry and liaison with community mental health services in the patient's place of residence.

The Hub Lead Centres will jointly develop and provide age appropriate information resources to improve knowledge and understanding, and build confidence in these staff groups to aid shared decision making. The Third Sector and patient advocacy organisations will be invited to support the development and sharing of these as part of their role in supporting adherence, peer support and self-management programmes.

The service will also ensure that it describes the links and interfaces of its services and care with other relevant pathways and organisations (e.g. Local Authorities, stakeholder groups, the Third Sector) as required.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This specification covers children under the age of 18 with a demyelination syndrome. This service specification covers the population defined as the commissioning responsibility of NHS England. Commissioning arrangements for the devolved nations in relation to this service are as set out in "UK-wide Commissioning Arrangements of Highly Specialised Services" [web link is <https://www.england.nhs.uk/publication/nhs-providers-of-highly-specialised-services/>].

3.2 Population Needs

Each year in UK, there are likely to be 78 new patients who present with recurrent demyelination and immediately fulfil the criteria for MS or are at risk of being diagnosed with paediatric MS within the first 12 months after presentation (56% of CIS as identified in study) or those who have relapsing demyelination/other ADS who need detailed assessment and treatment in the highly specialist service. The mean age of presentation will be 12 years of age, although transition to highly specialist adult units will often only occur at 18 years, depending on the complexity of the person's case, which means that the average patient will spend up to six years in the service. Those patients who, following assessment, are not found to have MS or an 'MS-like' condition will be discharged back to local care. Approximately half of patients in the service will be expected to have a diagnosis of MS, the remainder will be expected to have relapsing demyelination such as MOG positive or NMO associated demyelination.

Given that treatment is complex, costly and can have significant side-effects, the service will support evidenced-based practice to meet the need for pharmacological and symptomatic treatment of symptoms. Cognitive difficulties, fatigue, and neuropsychiatric disorders are increasingly recognised as significant co-morbidities in the paediatric population (Goretti et al 2012 *Mult Scler.* **18**:329-334) as in the adult population. Cognitive deficits include difficulties with learning, memory, attention and executive functioning. Patients with MS that starts in childhood generally maintain good recovery from relapses with minimal-to-no progression in disability within the first 10 years of disease onset; however, irreversible disability and secondary progression ultimately occur at a much earlier age than in adult-onset MS (Chinitis et al 2013). A 2006 research paper on the costs and quality of life of people with MS in Europe found that costs increase more than threefold to fourfold in patients with severe disease (EDSS >7.0) compared with patients with an earlier disease state (EDSS <4.0), and that the effect of advancing disease is detrimental to quality of life (Kobelt G et al, 2006). Early intervention to effectively treat paediatric MS is therefore beneficial to the individual child and their family, and is likely to reduce longer term costs within the health and social care services.

3.3 Expected Significant Future Demographic Changes

No significant changes in demography or presentation are expected in this population.

3.4 Evidence Base

It is estimated that 180 people in England aged 19 or under are living with MS and that a further 50 are diagnosed every year, (MS Society 2016). Early diagnosis of MS resulting in access to appropriate personalised treatments provides the best opportunity to significantly improve cognitive outcomes, lessen motor disability and in the long term reduces healthcare costs. (Ghezzi A 2016). The onset of MS and related disorders in childhood is rare and lack of awareness frequently results in diagnostic delay. There is evidence from both a UK and Canadian study that at least 5% of adult MS cases appear in childhood, but often go unrecognised. (Banwell et al 2007 Lancet Neurol. 6(10): 887-902); Harding et al. J Neurol Neurosurg Psychiatry. 2013 Feb;84(2):141-7).

As in adults, MS in children can be diagnosed when a patient presents with evidence of demyelination in different areas of the brain over time. International consensus criteria have been developed not only to ensure early diagnosis, but also to highlight mimics and conditions that are not MS and not likely to relapse (Krupp et al 2013 Mult Scler. 19(10): 1261-7). In a recent paediatric surveillance study in the UK, 125 first episodes of such cases of demyelination were identified. Of these, 40 involved inflammation in many regions and were termed acute disseminated encephalomyelitis (ADEM). In 85, specific regions of the brain were selectively involved, including the eyes (optic neuritis; 30 cases), spine (transverse myelitis; 25 cases) and other areas in the brain (30 cases); collectively these conditions are termed clinically isolated syndrome (CIS). Together these 125 give an incidence of 9.83 per million children per year (95%CI 8.18-11.71; Absoud et al 2013 Mult Scler. 19(1): 76-86). Following a first demyelinating episode, 30% of children go on to have a recurrent demyelinating syndrome (reviewed in Banwell et al 2007 Lancet Neurol 6(10): 887-902).

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

This highly specialist service for patients with MS or 'MS-like' conditions will promote early diagnosis and enable access to therapy for all paediatric patients with Multiple Sclerosis and related disorders. It will provide the following activities: i) prompt referral and transfer of eligible patients whilst minimising inappropriate referrals and investigations; ii) accurate diagnosis with the appropriate multispecialty input including support from paediatric neurologists, neuroradiologist, clinical nurse specialist, neuropsychologist, plus other staff members as required (e.g. psychiatry, occupational and physiotherapy); iii) prompt and expert management of all patients according to level of health need, iv) development of care plans and provision of ongoing care as appropriate.

As a consequence, the service will contribute to a marked improvement in the pace and accuracy of diagnosis, improve long term outcomes for patients and enhance the patient's and their family or carers' experience of the care journey.

NHS Outcomes Framework Domains

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

4.2 Indicators:

Please see table at Appendix A

See also Schedule 6 of the contract for detailed definitions of indicators

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

There is a requirement to hold national audit meetings involving all designated centres on an annual basis. Hub Lead Centres and their Referrers will contribute to national data collection of treatment and outcomes and support development of a national database. Each Hub Lead Centre must ensure that: all practitioners participate in continuous professional development and networking; patient outcome data is recorded and audited across the service; it participates in the national audit commissioned by NHS England, including the collection of experience and outcome data from their Hub and Referrers.

Audit meetings should address:

- Clinical performance and outcomes;
- Process-related indicators e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow-up etcetera;
- Stakeholder satisfaction, including feedback from patients, their families, referring clinician and GPs.

4.4 Applicable CQUIN goals are set out in Schedule 4D

To be agreed with the commissioner.

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

The providers (Hub Lead Centres) will adhere to clinically and cost effective use of high cost drug treatments in accordance with NHS England policy / NICE Technical Appraisal Guidance.

5.2 Other Applicable National Standards to be met by Commissioned Providers

To be established.

5.3 Other Applicable Local Standards

The providers of the service must ensure they are fully integrated into their Trust's corporate and clinical governance arrangements and comply fully with the Clinical Negligence Scheme for Trusts (CNST) and Care Quality Commission (CQC) requirements in terms of quality and governance.

6. Designated Providers (if applicable)

The MS Management Service for Children will comprise three to four centres (Hub Lead Centres) located in the North of England, the Midlands and the South of England/London which will connect with referring centres and will have strong links with existing adult MS units. Hub Lead Centres will be defined through the compliance process on the basis of pre-existing expertise.

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

Glossary of Terms

ADS	acquired demyelinating syndromes	
ADEM	acute disseminated encephalomyelitis	
ATM	acute Transverse Myelitis	
AQP4	Aquaporin-4	Antibody mediated demyelination
CAMHS		Child and Adolescent Mental Health Services
CIS		Clinically Isolated Syndrome
CLIPPERS		Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids.
CNS	Central Nervous System	<p>The nervous system is made up of two main components: the central nervous system (CNS) and the peripheral nervous system (PNS): The CNS consists of the brain and the spinal cord, and contains billions of specialised cells known as neurons. Neurons have specialised projections called dendrites and axons that contribute to their unique function of transmitting signals throughout the body. Dendrites carry electrical signals to the neuron, while axons carry them away from the neuron.</p> <p>The PNS consists of the nerves and nerve cells that are outside the brain and spinal cord.</p>
CTCAE	Common Terminology	The NCI Common Terminology Criteria for Adverse Events v3.0 is a descriptive terminology which can be utilised for Adverse Event

	Classification of Adverse Events	(AE) reporting. A grading (severity) scale is provided for each AE term http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf
	Demyelination, demyelinating episode	An immune dysregulation (impairment) involving the nervous system in which the myelin sheath of central nervous system neurons is damaged. This damage reduces the conduction of signals in the affected nerves and results in long term scarring.
DMT	Disease modifying treatment	
IMP	Investigative Medicinal Product	The active treatment that is tested in a clinical trial
MDT	Multi-Disciplinary Team	Team of specialists composed of members from different healthcare professions with specialised skills and expertise. The members collaborate together to make treatment recommendations that facilitate quality patient care.
MRI		Magnetic Resonance Imaging
MS	Multiple Sclerosis	Multiple sclerosis (MS) is a neurological condition which affects around 100,000 people in the UK. Most people are diagnosed between the ages of 20-40, but it can affect younger and older people too
MOG		Myelin Oligodendrocyte Glycoprotein
NEDA	No evidence of disease activity	A newly evolving concept of using a wider range of clinical and investigative measures to make sure the condition is dormant whilst on treatment
NICE TA	National Institute for Health and Care Excellence – Technology Appraisal	https://www.nice.org.uk/about The National Institute for Health and Care Excellence (<i>NICE</i>) provides national guidance and advice to improve health and social care. Technology appraisals are mandatory recommendations on the use of new and existing medicines and treatments within the NHS. These can include the use of medicines, medical devices, such as hearing aids or inhalers or diagnostic techniques - tests used to identify diseases.
NMO/ NMOSD	Neuromyelitis Optica Spectrum Disorder	Condition where there is immune mediated inflammation in the spine and eyes
NOS		Not otherwise specified
ON	optic neuritis	
PACNS		Primary angiitis of the Central nervous system
RIS		Radiological Isolated Syndrome

RRMS	Relapsing Remitting Multiple Sclerosis	
SLE		Systemic Lupus Erythematosus

References

- Absoud et al., 2013; Banwell et al., 2007; Goretti et al., 2012; Harding et al., 2013; Hinton and Kirk, 2015; Krupp et al., 2013.
- Absoud, M., et al., 2013. Paediatric acquired demyelinating syndromes: incidence, clinical and magnetic resonance imaging features. *Mult Scler.* 19, 76-86.
- Banwell, B., et al., 2007. Multiple sclerosis in children: clinical diagnosis, therapeutic strategies, and future directions. *Lancet Neurol.* 6, 887-902.
- Chitnis, T., Tardieu, M., Amato, M. P., Banwell, B., Bar-Or, A., Ghezzi, A., ... Wassmer, E. (2013). International Pediatric MS Study Group Clinical Trials Summit: Meeting report. *Neurology*, 80(12), 1161–1168. <http://doi.org/10.1212/WNL.0b013e318288694e>.
- Ghezzi A, Amato MP, Makhani N, Shreiner T, Gärtner J, Tenenbaum S. Pediatric multiple sclerosis: Conventional first-line treatment and general management. *Neurology*. 2016 Aug 30;87(9 Suppl 2):S97-S102.
- Goretti, B., et al., 2012. Fatigue and its relationships with cognitive functioning and depression in paediatric multiple sclerosis. *Mult Scler.* 18, 329-34.
- Harding, K.E., et al., 2013. Long-term outcome of paediatric-onset multiple sclerosis: a population-based study. *J Neurol Neurosurg Psychiatry.* 84, 141-7.
- Hinton, D., Kirk, S., 2015. Paediatric multiple sclerosis: a qualitative study of families' diagnosis experiences. *Arch Dis Child.* 100, 623-9.
- Kobelt G et al. Costs and quality of life of patients with multiple sclerosis in Europe. *J Neurol Neurosurg Psychiatry* 2006;77:918–926.
- Krupp, L.B., et al., 2013. International Pediatric Multiple Sclerosis Study Group criteria for pediatric multiple sclerosis and immune-mediated central nervous system demyelinating disorders: revisions to the 2007 definitions. *Mult Scler.* 19, 1261-7.
- MS in the UK. MS Society. 2016
https://www.mssociety.org.uk/sites/default/files/MS%20in%20the%20UK%20January%202016_0.pdf.

Date published: <insert publication date>

Appendix A: Full description of quality metrics

No.	Indicator	Detail			Data Source	O.F Domain , 1,2,3,4,5	CQC Key question
		Descriptor	Notes	Evidence documents			
Clinical Outcomes - quantitative data where possible using national data need to minimise the burden							
101	Timely review of all newly referred cases	All cases need to be discussed by core members of the MDT including MS Lead Clinician within seven days from receipt of referral.		Annual Report	Provider / National Database	2, 4, 5	Safe, effective, caring, responsive
102	Assessment and management of emergency relapse cases	% Patients physically assessed and admitted to a local unit/spoke unit within 48 hours of notification of symptoms including direct liaison between the local/spoke unit and the Hub Lead Centre about an appropriate management plan for the patient.		Annual Report	Provider / National Database	2, 4, 5	Safe, effective, caring, responsive
103	% Patients discussed at the MDT meeting	Patients initiating therapy should have been discussed at a multi-disciplinary meeting with documentation of the recommendations provided to the patient and the general practitioner.		Annual Report	Provider / National Database	5	Safe, effective, caring, responsive
104	% Patients waiting longer than 4 weeks for start of first dose of disease modifying treatment	% Patients waiting longer than 4 weeks for start of first dose of disease modifying as defined in the service specification.		Annual Report	Provider / National Database	1, 2, 3	Safe, effective, caring, responsive
105	% Patients achieving a slowing in progression of disease	Patients initiating therapy should achieve disease remission as currently defined (NEDA).		Annual Report	Provider / National Database	1, 2, 3, 4, 5	Effective, Caring

106	% of patients with a Paediatric Investigation Plan	Patients initiating treatment with medication should have a Paediatric Investigation Plan (PIP) as mandated by the European Medical Agency (EMA) to support rigorous evaluation of new medications in the paediatric population.		Annual Report	Provider / National Database	2, 3, 4, 5	Safe, effective
107	Clinical trials	% of patient caseload recruited to a clinical trial.		Annual Report	Provider / National Database	1, 2, 3, 4, 5	Safe, effective, caring, responsive
108	Number of medication errors resulting in significant harm.	Medication errors resulting in significant harm to patients as defined by the Clinical trials classification of adverse events (CTCAE).		Annual Report	Provider / National Database	1, 2, 4, 5	Safe, effective
Patient Experience - PROMS PREMS can be difficult to gather if no national survey can put in process indicator if required							
201	Patient Quality of Life measurement	Patients being diagnosed early and have appropriate management should have enhanced QOL as outlined in the service specification including decreased waits, clear care pathways, improved access to local services including physiotherapy, CAMHS.		Operational Policy	Self-declaration	2, 5	Effective, caring, responsive
202	Patient information	Patients and their families are provided with information including details of their disease and link to local support group.		Operational Policy	Self-declaration	5	Effective, caring, responsive
203	Patient experience	A patient experience survey has been undertaken to review service provision.	(New patients to be surveyed one year and follow ups the next).	Annual Report	Self-declaration	2, 4, 5	Safe, effective, caring, responsive
Structure and Process - infrastructure requirements, staffing, facilities etc							
301	Team leadership	Team leadership of Hub Lead Centres will be a Consultant paediatric neurologist with expertise in paediatric MS.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Well led

302	Hub Lead Centre MDT membership	At least three Consultant Paediatric neurologists with an interest in MS; one neurorehabilitation consultant; a consultant neuroradiologist; at least 1 WTE dedicated Clinical Nurse Specialist; Administrative support. Cross-cover arrangements should be in place for the above disciplines.	Virtual national Hub Lead Centre	Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
303	Hub Lead Centre MDT meetings	The Hub Lead Centre MDT meeting should be held at least monthly unless the meeting falls on a public holiday. The attendance at each individual scheduled treatment planning meeting should constitute a quorum, for 95% or more, of the meetings. The quorum will be made up of the following core members, or their cover: paediatric neurologist with expertise in paediatric MS; MS Clinical Nurse Specialists; neuro-radiologist; and clinical psychologist.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
304	Hub Lead Centre and referring team MDT meetings	MDT meetings with referring teams will take place at least monthly. All referring teams should be represented, with specialties in attendance as per this service specification.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
305	National meetings	National meetings will take place at least twice per annum. Representation will include Lead Clinicians from Hub Lead Centres and other specialties as detailed in this service specification.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
306	All patients should have a minimum dataset completed.	All patients should have a minimum dataset completed at MDT meetings.		Operational Policy	Self-declaration	1, 2, 3, 4, 5	Safe, effective, responsive caring
307	Permanent record of consultation	GPs and patients are provided with a permanent record of each MDT discussion/consultation on their patient.		Operational Policy	Self-declaration	1, 2, 3, 4, 5	Safe, effective, responsive caring

308	Access to specialist advice	There will be a 24 hour rota for the provision of expert on-call advice to referring units.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
309	Access to support services.	Access to support service as per the service specification including access to dedicated pharmacist and adult neurologist for transition.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective, caring, responsive
310	Service infrastructure for hub Lead Centres and Hubs (Referring teams)	There are designated conference room facilities with electronic image viewing facilities (PACs and Image exchange portal IEP) and video-conferencing facilities to enable communication with diagnostic MDTs.		Operational Policy	Self declaration	1, 2, 3, 4, 5	Safe, effective
311	Clinical guidelines	There are clinical guidelines in place which, where available, reflect national guidelines.		Operational Policy	Self-declaration	1, 2, 3, 4, 5	Safe
312	Patient pathways	There are agreed patient pathways in place.		Operational Policy	Self-declaration	1,2,3,4	Safe, effective, caring, responsive
313	Clinical audit	The team annually reviews and audits their clinical activity on an annual basis.		Operational Policy	Self-declaration	1, 2, 3, 4, 5	Safe
314	Data collection	All patients should be recorded on the OPTIMISE database		Operational Policy	Self-declaration	1, 2, 3, 4, 5	Safe, effective, responsive caring