Integrated Impact Assessment Report for Clinical Commissioning Policies			
Algorithm Reference Number	1781		
Service Specification Title	Treatment algorithm - Disease modifying therapies for multiple sclerosis Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Jacquie Kemp	**Clinical Leads**	Alasdair Coles
Finance Lead	Jazz Nandra	**Analytical Lead**	

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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant Service Specification documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	It is estimated that the number of people with MS in England is around 164 per 100,000. About 85% of people with MS have relapsing remitting MS (RRMS) at onset. Around two‑thirds of people who start with (RRMS) may develop secondary progressive MS (the disability gradually gets worse over time but this is not related to any relapses, which become less frequent or stop completely). About 10–15% of people with MS have primary progressive MS (PPMS).This algorithm is in line with NICE guidance and covers the population of patients with RRMS, with cladribine covering patients with PPMS. *Source: Algorithm supporting document, NICE*
A1.2 Number of patients currently eligible for the treatment according to the proposed Algorithm.	It is estimated that there are approximately 89,000 people with MS in England, and that each year 4,100 people are newly diagnosed with the condition. This means around one in every 600 people in the UK has MS. This means that there are a potential for 3,485 newly diagnosed patients eligible for DMTs per year

A1.3 Age group for which the treatment is proposed according to the algorithm commissioning criteria.

Over 18 years

Click here to enter text.

A1.4 Age distribution of the patient population eligible according to the proposed algorithm commissioning criteria

People with MS in UK				**People newly diagnosed with MS each year in UK**		
Age	**Women**	**Men**	**Total**	**Women**	**Men**	**Total**
Under 10	10	10	20	-	-	-
10-19	90	70	160	40	10	50
20-29	2,070	710	2,780	410	140	550
30-39	9,430	3,020	12,450	700	250	950
40-49	17,690	6,110	23,810	920	340	1,260
50-59	22,000	8,360	30,340	760	340	1,100
60-69	17,740	8,120	25,850	440	230	670
70-79	7,110	3,360	10,490	210	130	340
80-89	1,930	610	2,550	100	50	150
90 plus	250	50	300	20	-	20
Total	**77,790**	**29,960**	**107,800**	**3,620**	**1,490**	**5,110**

People with MS in England			**People newly diagnosed with MS each year**	
Nation	**Number of people with MS**	**Number of people per 100,000**	**Number of people**	**Number of people per 100,000**
England	89,030	164	4,040	7

Source: *MS Society statistics*

As per A1.3.

A1.5 How is the population currently distributed geographically?

Evenly

If unevenly, estimate regional distribution by %:

	<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table> *Source: Service Specification section 6, Evidence Review* Click here to enter text.
A2 Future Patient Population & Demography	
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new Service Specification) in 2, 5, and 10 years?	**Constant** As in A1.4 *Source: Clinical Evidence Review, Service Specification Working Group*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	Not known *Source: Algorithm Working Group*
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?	<table><tr><td>YR1 +/-</td><td>11,000 (treatments)</td></tr><tr><td>YR2 +/-</td><td>15,000 (treatments)</td></tr><tr><td>YR3 +/-</td><td>20,000 (treatment)</td></tr><tr><td>YR4 +/-</td><td>20,000</td></tr><tr><td>YR5 +/-</td><td>20,000</td></tr><tr><td>YR10 +/-</td><td>20,000</td></tr></table>

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	There will be an annual increase in treatments as new drugs are licensed and approved by NICE. For alemtuzumab as an example: NICE expected 24% of the eligible population to be accessing alemtuzumab by year 5 – current access is circa 7%. The 10 year position will be impacted by new drugs coming to the market. *Source: algorithm working grup, NICE,* **Yes**
A3 Activity	
A3.1 What is the purpose of the algorithm?	**Revise existing policy (expand or restrict an existing treatment threshold / Add an additional line of treatment / stage of treatment** Click here to enter text.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	As in A1.4 Various dependent on the chosen DMT *Source: NICE TA, Algorithm Working Group*
A3.3 What is the estimated annual activity associated with the proposed algorithm pathway for the eligible population?	For existing patients based on clinical evidence and NICE TA. Unknown how many currently diagnosed patients will take this treatment option, but assume it may be offered annually to circa 5,000 patients most of whom will be newly diagnosed when the DMTs are proven to be more

	effective. *Source: NICE, Algorithm working group* Please specify
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	None next best alternative is rehab and disability management Over the last 20 years DMTs have become available for the treatment of relapsing MS. This is not a cure but will slow progress of the disease and reduce the number of relapses experienced by the MS sufferer. *Source:* NICE, *Algorithm Working Group*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	As per A3.3 – patients move onto the next available appropriate MS drug. In some cases there may not be a suitable alternative and treatment with a DMT may stop. No other pathway beyond support and rehab
A4.2. What are the current treatment access and stopping criteria?	For a patient to be eligible for any DMT, they must fulfil the following: Sustained disability due to multiple sclerosis is less than EDSS 7.0, i.e. at least ambulant with two crutches. (Patients experiencing a relapse may transiently have disability greater than EDSS7.0; if they recover to a sustained EDSS less than 7.0, they are eligible for DMTs) The current DMT should be stopped if any of the following criteria are met: 1. No reduction in frequency or severity of relapses compared with pre-treatment phase following adequate exposure to the DMTs (which varies for each DMT, but should be a minimum of 6 months).

	2. Intolerable adverse effects of the drug 3. Development of inability to walk (EDSS 7.0), persistent for more than 6 months, due to multiple sclerosis. 4. Confirmed secondary progressive disease with an observable increase in disability for more than a 12 month period, in the absence of relapse activity, and an EDSS of 6.0 or greater (except for the rare phenotype of "relapsing-progressive multiple sclerosis" detailed below). Criteria 1 and 2 might lead to switching to alternative DMTs. Criteria 3 and 4 will lead to stopping all DMTs. *Source: Service Specification , Service Specification Working Group*
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify a) 100% b) 0% c) 100% d) 100% e) 100% *Source: Service Specification Working Group*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway*	**No** If yes, Click here to enter text. *Source: Service Specification Working Group*

• *Actual or estimated eligibility and uptake*	
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable a) enter % b) enter % c) enter % d) enter % e) enter % *Source: required*
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, Unknown due to uncertainty about ptients choosing this treatment who have been diagnosed and continue to follow a RRMS pathway. a) 0% b) 0% c) 0% d) 0% e) 0% *Source: Algorithm Working Group, NICE*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	*For a patient to be eligible for any DMT, they must fulfil the following:* • *Sustained disability due to multiple sclerosis is less than EDSS 7.0, i.e. at least ambulant with two crutches. (Patients experiencing a relapse may transiently have disability greater than EDSS7.0; if they recover to a sustained EDSS less than 7.0, they are eligible for DMTs)*

<table>
<tr><td></td><td>• No evidence of non-relapsing progressive multiple sclerosis</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Oral or intravenous drugs in an outpatient or acute hospital setting</td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td><table><tr><td></td><td>Neuroscience Centres</td></tr><tr><td>NORTH</td><td>8</td></tr><tr><td>MIDLANDS & EAST</td><td>5</td></tr><tr><td>LONDON</td><td>6</td></tr><tr><td>SOUTH</td><td>5</td></tr></table>
Plus MS clinics within a DGH where there are direct links with the tertiary centre and there is an active MDT</td></tr>
<tr><td>A7.3 Does the requires a change of delivery setting or capacity requirements?</td><td><u>No</u>

Source: Service Specification Working Group</td></tr>
<tr><td colspan="2">A8 Coding</td></tr>
</table>

A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	☐
Patient level contract monitoring	☒
Patient level drugs dataset	☒
Patient level devices dataset	☐
Devices supply chain reconciliation dataset	☐
Secondary Usage Service (SUS+)	☒
Mental Health Services DataSet (MHSDS)	☐
National Return**	☐
Clinical Database**	☐
Other**	☒

**If National Return, Clinical database or other selected, please specify:
BluTeq reporting

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

OPCS v4.8	☒
ICD10	☒
Treatment function code	☒
Main Speciality code	☒
HRG	☒
SNOMED	☐
Clinical coding / terming methodology used by clinical profession	☐

A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**Already specified in current NHS England Drugs List document** AA30D-AA30F
A8.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable** Click here to enter text.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Already correctly captured by an existing specialised service line (NCBPS code) outside of the PSS tool** If activity costs are already captured please specify whether this service needs a separate code. **No** If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. Click here to enter text. If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**Yes - other** Please specify: Schedule 6 to be amended Bluteq reporting is used as a form of monitoring use and prior approval if the patient hs undergone the relevant criteria checks.

<table>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:<table><tr><td>Drugs or Device MDS</td><td>☒</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table>Please specify: Click here to enter text.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u>
If yes, please specify mitigation:
Click here to enter text.</td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
.</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>
Click here to enter text.
If no, will one be developed?</td></tr>
<tr><td>A9.6 NICE reporting
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new Service Specification?</td><td><u>Yes</u>
If yes, specify how performance monitoring data will be used for this purpose.
There are currently 13 NICE approved Disease Modifying Therapies for multiple sclerosis. These are administered in various different routes depending on the DMT and are detailed in the algorithm. Only NICE approved therapies are included in this algorithm and this pathway is already embedded in current practice, BluTeq reporting (as a method of prior approval) and national funding.</td></tr>
</table>

<table>
<tr><th colspan="2">Section B - Service Impact</th></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>MS care is organised within provider networks, this intervention will require referral to a MS specialist who is part of an MDT
Source: Algorithm</td></tr>
<tr><td>B1.2 Will the specification change the way the commissioned service is organised?</td><td><u>No</u>

Source: Service Specification Working Group</td></tr>
<tr><td>B1.3 Will the specification require a new approach to the organisation of care?</td><td>No</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table>Please specify:
Neurologist with speciality interest in MS</td></tr>
<tr><td>B2.2 What impact will the new Service Specification have on the</td><td><u>No impact</u></td></tr>
</table>

sources of referral?	patients are already on treatment
B2.3 Is the new Service Specification likely to improve equity of access?	**Increase** Please specify: Yes, with a clear pathway patients will be able to access the appropriate DMT more consistently *Source: Equalities Impact Assessment*
B2.4 Is the new Service Specification likely to improve equality of access and/or outcomes?	**Increase** Please specify: It may improve patient outcomes *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the specification can occur?	**No action required** Please specify: These are treatments that are already available
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4** If yes, outline the plan: Click here to enter text.

<table>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u></td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u>
See above
.</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u>
Please specify:</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>
Please specify:
.</td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u>
Please specify:</td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>No change</u>
Please complete table: Not applicable
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future
State expected range</td><td>Provisional or confirmed</td></tr>
<tr><td>North</td><td></td><td></td><td><u>C</u></td></tr>
<tr><td>Midlands & East</td><td></td><td></td><td><u>P</u></td></tr>
</table></td></tr>
</table>

London			P
South			C
Total			P

Please specify:
Not applicable

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

Publication and notification of new algorithm	☒
Market intervention required	☐
Competitive selection process to secure increase or decrease provider configuration	☐
Price-based selection process to maximise cost effectiveness	☐
Any qualified provider	☐
National Commercial Agreements e.g. drugs, devices	☐
Procurement	☐
Other	☐

Please specify:
Publication with supporting Circular and provider letter.

B4 Place-based Commissioning

B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved

Yes
Please specify: Adult specialist neurosciences services are one of the 20

commissioning arrangements, STPs)	services identified for consideration to transfer to STP commissioning Click here to enter text.

Section C - Finance Impact

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☒
	Paid entirely by Local Tariffs	☐
	Partially paid by National Tariffs	☐
	Partially paid by Local Tariffs	☐
	Part/fully paid under a Block arrangement	☐
	Part/fully paid under Pass-Through arrangements	☐
	Part/fully paid under Other arrangements	☐

C1.2 **Drug Costs** Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Activity costs will be covered within tariff (HRG code AA30D-AA30F) *Neurology top up will be applied within a specialised neurology centre*
C1.5 **Activity Costs covered by Local Tariff** List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Not applicable
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	Not applicable

C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**Yes** Please specify: Blueteq is already in operation for these drugs
C2 Average Cost per Patient	
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required? Are there any changes expected in year 6-10 which would impact the model?	Varies depending on the DMT: Example for allemtuzimab: £23,127 (£21,135 drug only) including activity costs for each subsequent cycle up to a maximum of two additional cycles A national spend of £249,.4million in 2016/17 During 2016/17 there were 10,600 approved treatments started with DMTs with 194 patients stopping treatment. If yes, please specify: No financial plan as this is current practice and following NICE TAs
C3 Overall Cost Impact of this Service Specification to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost neutral** Please specify: Costs are already being covered within regional budgets As far as it is possible to determine this is likely to be cost neutral or cost saving as per the improving value scheme which est a saving at year 4 of £4million
C3.2 If the budget impact on NHS England cannot be identified set	It is currently unknown how many patients will choose this treatment but

out the reasons why this cannot be measured.	most DMTs have been available for aa few years now since NICE have endorsed and approved their use as part of a TA
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Not applicable
C4 Overall cost impact of this Service Specification to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost neutral** *or cost saving* Budget impact for providers: **No impact on providers** Please specify:
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral** Please specify:. There are likely to be savings overall due to the cost efficiency of the DMTs and following a prescribing protocol in line with NICE. As far as it is possible to determine from the improving value scheme which estimated a saving at year 4 of £4million
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	

C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**Yes** Please specify: Potentially public sector as may reduce need for carers
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	N/A
C6 Financial Risks Associated with Implementing this Service Specification	
C6.1 What are the material financial risks to implementing this algorithm?	Patients with a diagnosis may access these therapies and it is difficult to estimate how many of the currently diagnosed and eligible MS population will want to start a DMT.
C6.2 How can these risks be mitigated?	Use of the algorithm and Blueteq as outlined
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	N/A
C6.4 What scenario has been approved and why?	This is current practice and DMTs are already available to patients the algorithm describes the treatment pathway for each drug and provides a start and stop criteria to ensure consistency of approach across the country.

<table>
<tr><th colspan="2">C7 Value for Money</th></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>Published evidence indicates the treatment has the potential to be cost-effective</u>
Please specify:
NICE-</td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table><tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr><tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☒</td></tr><tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☒</td></tr><tr><td>Other data has been identified</td><td>☐</td></tr><tr><td>No data has been identified</td><td>☐</td></tr><tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr><tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr></table>Please specify:</td></tr>
<tr><th colspan="2">C8 Cost Profile</th></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated</td><td><u>No</u></td></tr>
</table>

with this Service Specification?	If yes, specify type and range:
C8.2 If yes, confirm the source of funds to meet these costs.	