Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1625		
Policy Title	Rituximab for anti-NMDAR auto-immune encephalitis (all ages) Proposal **for routine commission** (ref A3.1)		
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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 policy 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.	The prevalence of the acute anti-NMDAR autoimmune encephalitis is not known. Current evidence suggests that the incidence of anti-NMDAR encephalitis, the commonest type of AE accounting for approximately 27% of all autoimmune encephalitis cases. The Evidence Review, based on current evidence suggests that in the UK, the incidence of paediatric anti-NMDAR encephalitis is estimated to be 0.85 per million children per year (95% confidence interval 0.64 to 1.06). The Evidence Review estimates that about 41 (range 30 – 48) cases of AE occur among children in the UK every year. As such, it is estimated that there are approximately 11 children (range 8-13) diagnosed with acute anti-NMDAR encephalitis every year among 12.2 million children living in the UK. Anti-NMDAR AE predominantly affects children – around 40% of all cases. Furthermore, some additional cases with anti-NMDAR AE emerge every year due to disease relapse occurring in 8% to 29% of patients. The Evidence Review notes that these figures may underestimate the true incidence. *Source: Policy Proposition section 6* *Clinical Evidence Review*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	It is estimated that 21 patients in 2017/18 are currently eligible for 2nd line treatment under the proposed policy commissioning. Upon implementation of the policy, it is estimated an additional 5 backlog patients would be immediately eligible in year 1. It is also estimated that there would be 3 relapsed patients per annum. *Source: Clinical Evidence Review, Policy Working Group* Anti-NMDAR autoimmune encephalitis predominantly affects children under 18 years (around 40% of all cases) and adults younger than 45

	years. Clinical advice from the Policy Working Group would expect a cohort of 8 – 20 children newly diagnosed each year and a cohort of 20 – 50 for adults for anti-NMDAR AE. Based on the Evidence Review, 44% of these fail to respond to first line treatment and would require 2nd line treatment. This provides a cohort for children who may be eligible for rituximab of 4 – 9 for children and 9 – 23 for adults. Total number for all ages who may be eligible for second line treatment under this policy is 13 - 32 In year 1 there is estimated to be 29 patients. This number is made up of a backlog of 5 patients who will all receive rituximab arising from the policy implementation and 3 patients that relapse. This number includes an assumption of 15% of children and adults who may relapse and require additional second line treatment, following advice from the Policy Working Group.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** Anti-NMDAR encephalitis predominantly affects children under 18 years and adults younger than 45 years.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	*Source: Clinical Evidence Review, Policy Proposition* Anti-NMDAR encephalitis predominantly affects children under 18 years (around 40% of all cases) and adults younger than 45 years. This age distribution has been accounted for in the modelling for demographic growth.
A1.5 How is the population currently distributed geographically?	**Evenly** If unevenly, estimate regional distribution by %: North | enter %

	<table><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: Policy Proposition section 6, Evidence Review* There is no known evidence of differences in geographical distribution in England.
A2 Future Patient Population & Demography	
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?	**<u>Constant</u>** No known factors other than demographic growth in patient population identified. *Source: Clinical Evidence Review, Policy Working Group*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	No *Source: Clinical Evidence Review, Policy 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? Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions	<table><tr><td>YR2 +/-</td><td>0</td></tr><tr><td>YR3 +/-</td><td>0</td></tr><tr><td>YR4 +/-</td><td>0</td></tr><tr><td>YR5 +/-</td><td>0</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table> *Source: Service specification proposition section 3.1*

made.	**Yes**
A3 Activity	
A3.1 What is the purpose of new policy?	**Confirm routine commissioning position of an additional new treatment** Anti-NMDAR encephalitis is an acute disease rapidly progressing into an encephalopathy syndrome. This policy proposition considers NHS England's commissioning position for rituximab as second-line therapy for a well-defined cohort of patients with acute anti-NMDAR AE who have not or have inadequately responded to the first-line therapy by four weeks of treatment initiation OR within six symptomatic weeks.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	Of the 24 that would be eligible for 2nd line treatment under the current pathway (includes relapses), 8 are estimated to already be receiving rituximab as a treatment option (via IFR requests). *Source: Clinical Evidence Review, Policy Working Group* This is the current number of patients who could go on to second line treatment.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	Of the 24 that would be eligible for 2nd line treatment under the policy proposition, 17 would be suitable for rituximab as a treatment option (see A6.2) with the additional 5 backlog patients receiving Rituximab in 2018/19 only. *Source: Clinical Evidence Review, Policy Working Group* Please specify Please see A6.2 for estimates of how many people will use rituximab as

	second line treatment in the proposed policy proposition pathway.
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.	Not Applicable *Source: Policy 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.	Currently patients who fail to respond to 1st line treatment will go onto a range of 2nd line treatment options. Policy Working Group estimates that for children: • Approximately 34% patients will already be using rituximab either as an IFR or by arrangement of the treating trust • Approximately 33% children will be on a cyclophosphamide infusion • Approximately 33% children will be on mycophenolate mofetil or azathioprine Policy Working Group estimates that for adults: • 34% using rituximab – either as an IFR or by arrangement of the treating trust • 50% will be on cyclophosphamide • 16% will be onycophenolate mofetil or azathioprine
A4.2. What are the current treatment access and stopping criteria?	Patients who have failed or not responded adequately to first line immunotherapy will go on to use second line treatment.

	Source: Policy Proposition, Policy 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% Of the cohort of patients with anti-NMDAR AE 2-3% will fail to respond to any treatment. This has not been included in the modelling as the impact for the policy is less than 1 patient per year. *Source: Policy 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* • *Actual or estimated eligibility and uptake*	**No** If yes, Click here to enter text. *Source: Policy Working Group*
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	Not applicable a) enter % b) enter %

c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	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, please specify a) 100% b) 0% c) 100% d) 100% e) 100% *Source: Policy Working Group*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Time limited** Anti-NMDAR autoimmune encephalitis is an acute disease rapidly progressing into an encephalopathy syndrome. Cases are acutely managed and treated within a few weeks of disease onset, as this is predominantly an acute disease there is not an accrual of disease from previously undiagnosed cases. The policy sets out the starting criteria for patients for 2nd line treatment as those patients who have failed or not responded adequately to first line immunotherapy, defined as deterioration or less than 2-point improvement in mRS by four weeks of treatment initiation (usually within 6 weeks of symptom onset). The policy describes the dose for rituximab Paediatric patients: 375mg/m2 (capped at 500mg) x 4 doses at weekly intervals Adults: 1g x 2 doses two weeks apart.

	Response to the treatment must be monitored by modified Rankin Scale (mRS) score and improvement of neurological syndrome. Depletion of B cells can be monitored by CD19/20 levels in peripheral blood if clinically indicated (e.g. stopping criteria). A top up dose of rituximab during acute treatment in a patient who has not responded to one rituximab treatment course (from 4 weeks following completion of first treatment course) may be considered (Child: 375mg/m2 x2 doses at weekly intervals; Adult: 1g) if the patient has a higher clearance of rituximab which is confirmed by demonstrating failure to achieve B cell depletion. A subsequent treatment course of rituximab treatment, often termed “re-dosing” should only be considered in a patient that has relapsed who has previously responded (improved ≥ 2 mRS) to the first course of rituximab treatment; and have undergone adequate 1st line treatment at relapse. In patients with severe life threatening inflammation, rituximab may be used in combination with another second-line immunotherapy, usually cyclophosphamide, to provide urgent (faster speed of action) and broader (targeting more components of the immune system) treatment to reduce brain inflammation. Policy Working Group estimates that for children: • Approximately 70% children will use rituximab under this policy • Approximately 15% children will use cyclophosphamide infusion • Approximately 15% children will use mycophenolate mofetil or azathioprine Policy Working Group estimates that for adults: • Approximately 70% adults will use rituximab under this policy. • Approximately 15% adults will use cyclophosphamide • Approximately 15% adults will use ycophenolate mofetil or

azathioprine

Source: Policy proposition, Policy Working Group

A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

Select all that apply:

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☒
Acute Trust: day patient	☒
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☐
Other	☐

Please specify: For children this will be in an outpatient and day case setting. For adults this will be under an inpatient setting with some minimal outpatient follow up

A7.2 What is the current number of contracted providers for the eligible population by region?

	PAEDIATRIC	ADULT
NORTH	5	8

	MIDLANDS & EAST: 3, 5 LONDON: 4, 7 SOUTH: 3, 5
A7.3 Does the proposition requires a change of delivery setting or capacity requirements?	**No** *Source:* Policy Working Group
A8 Coding	
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** ☐

<table>
<tr><td></td><td>**If National Return, Clinical database or other selected, please specify:
Blueteq will be used to monitor usage</td></tr>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Select all that apply:<table>
<tr><td>OPCS v4.8</td><td>☒</td></tr>
<tr><td>ICD10</td><td>☒</td></tr>
<tr><td>Treatment function code</td><td>☒</td></tr>
<tr><td>Main Speciality code</td><td>☐</td></tr>
<tr><td>HRG</td><td>☒</td></tr>
<tr><td>SNOMED</td><td>☐</td></tr>
<tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr>
</table></td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Already specified in current NHS England Drugs List document</u>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:

The combination of Rituximab with this indication is not on the current MDS.

If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:
Upon approval of the policy, the above combination will be added to the current MDS.</td></tr>
<tr><td>A8.4 Identification Rules for Devices:</td><td><u>Not applicable</u></td></tr>
</table>

How are device costs captured?	If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance). Click here to enter text. If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. Click here to enter text.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**<u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u>** If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). The appropriate codes are : NCPBS23M – Paediatric Neurosciences NCPBS08O - Neurology If activity costs are already captured please specify whether this service needs a separate code. Choose an item. 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	

<table>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u>
Please specify
Click here to enter text.</td></tr>
<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>
If yes, please specify contract monitoring requirement:
Acute Contract Monitoring and Drugs Minimum Data Sets</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>
If yes, specify how routine performance monitoring data will be used for dashboard reporting.
Click here to enter text.
If no, will one be developed?</td></tr>
<tr><td>A9.6 NICE reporting</td><td><u>No</u></td></tr>
</table>

Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Access is through the existing tertiary paediatric neurology service or in adults following discussion with the regional adult neurologist with expertise in neuro-inflammation *Source:* Policy Proposition
B1.2 Will the proposition change the way the commissioned service is organised?	**No** *Source: Policy Working Group*
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care**
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☐ Secondary care ☒ Tertiary care ☒

	Other ☐ Please specify: The policy is for second line treatment
B2.2 What impact will the new policy have on the sources of referral?	**No impact**
B2.3 Is the new policy likely to improve equity of access?	**Increase** Please specify: Access is currently through Individual Funding Requests. Policy will increase equity of access *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** Please specify: Access is currently through Individual Funding Requests. The policy will improve equality of access *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify:
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text

B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** Access will be through the existing tertiary paediatric neurology service or in adults following discussion with the regional adult neurologist with expertise in neuro-inflammation.
B3.5 Is a change in provider staffing required?	**No** See above Click here to enter text.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**Yes** Please specify: Rituximab should only be administered in an area where full resuscitation facilities and close monitoring are available; either in a day-case setting or in acute admissions wards depending on clinical requirements. A doctor should be present on the ward/unit while the infusion is commenced
B3.7 Are there changes in the support services that need to be in place?	**No** Please specify: Click here to enter text.
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No** Please specify: Click here to enter text.
B3.9 Is there likely to be either an increase or decrease in the	**No change**

number of commissioned providers? If yes, specify the current and estimated number of providers required in each region

Please complete table: Not applicable

Region	Current no. of providers	Future State expected range	Provisional or confirmed
North			select
Midlands & East			select
London			select
South			select
Total			select

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 policy	☒
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:

	Click here to enter text.
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 commissioning arrangements, STPs)	**No** Please specify: 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	☒

	<table><tr><td></td><td>Partially paid by Local Tariffs</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr></table>
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.	The list price cost of MabThera (active substance: Rituximab) of 500mg/50ml is £1047.78 (including VAT). See A6.2 for dosing cycles for the Paediatric and Adult pathway.
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 %)	Click here to enter text. **Paediatric Pathway (Policy):** A patient would have: • Year 1: 4 x £1,475: Paediatric Day case infusions (HRG: PR01C: Paediatric Nervous System Disorders with CC Score 2-4) inclusive of a 57.1% top up. • Year 1: 1 x £339: Paediatric Neurology: Outpatient Attendance: First Attendance • Year 1: 1 x £189: Paediatric Neurology: Outpatient Attendance: Follow

<table>
<tr><td></td><td>Up
• The specialised commissioning service line for this pathway is NCBPS23M

Adult Pathway (Policy):
A patient would have:
• Year 1: 1 x £188: Neurology: Outpatient Attendance: First Attendance
• Year 1: 2 x £116: Neurology: Outpatient Attendance: Follow Up
• The specialised commissioning service line for this pathway is NCBPS08O</td></tr>
<tr><td>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.</td><td>Not applicable</td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Not applicable</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>Yes</u>
Please specify: Blueteq</td></tr>
<tr><td>C2 Average Cost per Patient</td><td></td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?</td><td><table><tr><td>YR1</td><td>£4,815</td></tr></table></td></tr>
</table>

<table>
<tr><td>Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR2</td><td>£4,968</td></tr><tr><td>YR3</td><td>£4,968</td></tr><tr><td>YR4</td><td>£4,968</td></tr><tr><td>YR5</td><td>£4,968</td></tr></table>
If yes, please specify:
No</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u>
Please specify:
Year 1: £50,155
Year 2: £29,276
Year 5: £29,276</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not Applicable</td></tr>
<tr><td>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?</td><td>Not applicable</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
</table>

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **No impact on providers** Please specify: Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost Pressure** Please specify: Year 1: £50,155 Year 2: £29,276 Year 5: £29,276
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
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.	CPAG Prioritisation reserve

C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	No material financial risk have been identified to implementing this policy
C6.2 How can these risks be mitigated?	Not applicable
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	The number of patients modelled is based on the mid-point (21) of the expected patient cohort of 13-32. If the number of patients were at the lower end of the range, the budget impact would reduce by c£21k per year. If the number of patients were at the higher end of the range, the budget impact would increase by c£7k per year.
C6.4 What scenario has been approved and why?	The mid-point of the expected cohort has been modelled as this is the most likely number of patients each year (excluding backlog).
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**<u>There is no published evidence of cost-effectiveness</u>** Please specify: The evidence review found no studies containing direct or indirect evidence on cost effectiveness of use of rituximab for children suffering with anti-NMDAR encephalitis were found. Studies where less than five patients received rituximab treatment and where a full text article was not available were excluded.
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐

	Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	☐
	Available clinical practice data suggests the new treatment has the potential to improve value for money	☐
	Other data has been identified	☐
	No data has been identified	☐
	The data supports a high level of certainty about the impact on value	☒
	The data does not support a high level of certainty about the impact on value	☐
	Please specify: Click here to enter text.	
C8 Cost Profile		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	Choose an item. If yes, specify type and range: Click here to enter text.	
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.	