Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1853
Policy Title	Rituximab for Refractory Systemic Lupus Erythematosus (SLE) in adults and post pubertal children
Proposal	**for routine commission**(ref A3.1)

Integrated Impact Assessment – Index		
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A3 Comparator (next best alternative treatment) Patient Pathway	B3 Collaborative Commissioning	C3 Overall Cost Impact of this Policy to NHS England
A4 New Patient Pathway		C4 Overall cost impact of this policy to the NHS as a whole
A5 Treatment Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this Policy
		C7 Cost Profile

About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes with each theme setting out a number of questions. • All figures should be provided up to 5 years only. • The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year. • 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.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact	
A1 Activity	
A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment. Include OPCS codes where applicable.	Adults: 261 patients receiving treatment *Incidence (number of new cases per year) 72 – 108 patients* *Source:* BILAG-BR Post-pubertal Children: prevalence: 90 X 88% = 80 children (12% of children are under the age of 11) Incidence (number of new cases per year) 36 X 88% = 32 children (2+3+1+12+5+3+3+4+0+1+2=36) Relapse in 8 – 50% of patients, needing re-treatment Source: Letter from the PWG Click here to enter text.
A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial)	
A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Rituximab is given by IV infusion, on days 1 and 15, as a day case procedure *Source:* Interim Clinical Commissioning Policy Statement: Rituximab for the Treatment of Systemic Lupus Erythematosus in Adults August 2013, Ref. A13/PS/a

A2.2 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Choose to initiate treatment c) Comply with treatment d) Complete treatment	If not known, please specify Click here to enter text or 'Not applicable'.. a) 15% of all patients with SLE b) 5% - 10% of all patients with SLE c) 5% - 10% of all patients with SLE d) 5% - 10% of all patients with SLE *Source:* British Society for Rheumatology's Multi-region Audit on Management of SLE 2018
A3 Comparator (next best alternative treatment) Patient Pathway **(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)**	
A3.1 **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*	**Yes** Belimumab IV at 10mg/kg every 4 weeks long term, IV cyclophosphamide 10mg/kg course of 6 pulses *Source:* Policy proposition
A3.2 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?	Total estimated eligible: a) 15% of all patients with SLE b) 5% of all patients with SLE c) 5% - 10% of all patients with SLE d) 5% - 10% of all patients with SLE e) 5% - 10% of all patients with SLE *Source:* British Society for Rheumatology's Multi-region Audit on Management of SLE 2018

A4 New Patient Pathway	
A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, e.g. patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle. Include OPCS codes where applicable.	**<u>Time limited</u>** Treatment occurs on days 1 and 15 of an infusion cycle. Repeat treatment is permitted, but no more frequently than every 6 months, in line with the criteria contained within the policy proposal. *Source:* Interim Clinical Commissioning Policy Statement: Rituximab for the Treatment of Systemic Lupus Erythematosus in Adults August 2013, Ref. A13/PS/a
A5 Treatment Setting	
A5.1 How is this treatment delivered to the patient?	IV infusions as a day case
A5.2 What is the current number of contracted providers for the eligible population by region?	North East & Yorkshire Region: 4 contracted providers North West Region: 3 contracted providers Midlands Region: 6 contracted providers East of England Region: 2 contracted providers London Region: 8 contracted providers South West Region: 7 contracted providers South East Region: 2 contracted providers Total No. of Contracted Providers: 32

A5.3 Does the proposition require a change of delivery setting or capacity requirements?	*No*
A6 Coding	
A6.1 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: Click here to enter text.
A6.2 Specify how the activity related to the new patient pathway will be identified.	The pathway for both adults and children already exists and is identified using a prior approval form.

A6.3 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A6.4 **Identification Rules for Activity:** How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	**Not captured by an existing specialised service line** In line with many other drug policies, the associated day cases for the IV infusion are usually contracted and paid for by CCGs whether or not they are administered at the specialist centre or locally under shared care arrangements. Specialist adult rheumatology providers may manually map the activity to NCBPS26Z ADULT HIGHLY SPECIALIST RHEUMATOLOGY SERVICES as this is a locally defined rule.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Tertiary centres, with some networked provision: Patients must be managed at, or in shared collaboration, with a recognised centre commissioned to provide specialised rheumatology services, that has expertise in the assessment and management of SLE *Source:* Clinical Commissioning Policy Proposition
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: Click here to enter text. *Source: required*
B2 Geography & Access	

B2.1 How is the service currently accessed (e.g., self referral, referral from GP, secondary care, other)	Please specify: Secondary/Tertiary Care
B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: There will be minimal change as the current interim statement covers adults and post pubertal children.
B2.3 Is the new policy likely to improve equity[1] of access?	**No impact** *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B2.4 Is the new policy likely to improve equality[1] of access and/or outcomes?	**No impact** *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B3 Commissioning Responsibility	
B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibility), future CCG lead, devolved commissioning arrangements, STPs)	**No change - NHSE** Please specify: Click here to enter text.
Section C - Finance Impact	

[1] https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf

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 HCTED programme) – pass through	☐
	Excluded from tariff (excluding HCTED) – other	☐
	Via HCTED 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** *(to be completed by LC)*
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if

The cost of a 500mg/50ml concentrate for solution for infusion is £785.84 per vial ex-VAT (Source BNF).

applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Treatment is 1g given on day 1 and day 15 of a single treatment cycle. The total cost per patient is therefore: 2 x 500mg + VAT = £1,886 x 2 doses = £3,772. The quoted price is the NHS list price and excludes any commercial in confidence NHS discounts.
C1.3 **Device Costs***(to be completed by LC)* 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.	N/A
C1.4 **Activity Costs covered by National Tariffs** *(to be completed by Finance)* List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatients appointment etc.	The associated day case infusion for adults will group to the base HRG HD23 which is Inflammatory, Spine, Joint or Connective Tissue Disorders and has a tariff range of £367-£2,284. The weighted average is £420. The associated day case infusion for children will group to the base HRG PH34 which is Paediatric, Musculoskeletal or Connective Tissue Disorders and has a tariff range of £660-£1,089. The weighted average is £778.
C1.5 **Activity Costs covered by Local Tariff** *(to be completed by Finance)*	N/A

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.	
C1.6 **Other Activity Costs not covered by National or Local Tariff** *(to be completed by Finance)* Include descriptions and estimates of all key costs.	N/A
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	**Yes** Please specify: Regional connective tissue disease MDT meeting for ratification and Blueteq, and submission of registry data to BILAG biologics registry
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	The average cost of an adult is £4,226 (£3,772 for Rituximab biosimilar plus £420 + MFF @8% = £454 for the IV infusion) The average cost of a child is £4,612 (£3,772 for Rituximab biosimilar plus £778 + MFF @8% = £840 for the IV infusion) • Using NHS list price
C3 Overall Cost Impact of this Policy to NHS England	

<table>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.</td><td><u>Cost neutral</u><table><tr><td>Year 1</td><td>£0k</td></tr><tr><td>Year 2</td><td>£0k</td></tr><tr><td>Year 3</td><td>£0k</td></tr><tr><td>Year 4</td><td>£0k</td></tr><tr><td>Year 5</td><td>£0k</td></tr></table>The treatment is currently available to adults under the existing clinical policy statement A13/PS/a (published in August 2013) and it is anticipated that most post pubertal children will have been able to access the treatment under the Clinical Commissioning Policy 170001/P: Commissioning Medicines for Children in Specialised Services (published in March 2017) and hence why there is very limited financial impact.</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>N/A</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>N/A</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
<u>No impact on CCGs</u>

Budget impact for providers:
<u>No impact on providers</u></td></tr>
</table>

<table>
<tr><td>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</td><td><u>Cost neutral</u><table><tr><td>Year 1</td><td>£0k</td></tr><tr><td>Year 2</td><td>£0k</td></tr><tr><td>Year 3</td><td>£0k</td></tr><tr><td>Year 4</td><td>£0k</td></tr><tr><td>Year 5</td><td>£0k</td></tr></table>See C3.1</td></tr>
<tr><td>C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">C5 Funding</td></tr>
<tr><td>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.</td><td>N/A</td></tr>
<tr><td colspan="2">C6 Financial Risks Associated with Implementing this Policy</td></tr>
<tr><td>C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.</td><td>None</td></tr>
</table>

C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	N/A
C7 Cost Profile	
C7.1 Factors which impact on costs	**<u>Yes</u>** If yes, specify type and range: The costs of the policy will have reduced since the original policy statement due to the introduction of biosimilars for Rituximab.

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

		Source	*Please specify any further detail*
Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.	*109 patients a year (2010-2019). Since Sept 2013 -2019 to date under interim commissioning policy*	*BILAG -BR Registry*	*These patients would meet our policy commissioning criteria exactly* *Will have to subtract 5-12 years.*
Age group for which the treatment is proposed according to the proposed criteria	*Adults* *Post pubertal children*		

<table>
<tr>
<td>Age distribution of the patient population eligible according to the proposed criteria</td>
<td>52% - 18-40 years

42% - 41-65 years

6% - 66+years

Less than 5 patients < 18 years. It could be that paediatric patients are recruited into JSLE Cohort Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How is the population currently geographically distributed</td>
<td>Unevenly

<table><tr><td>North</td><td>26%</td></tr><tr><td>Midlands & East</td><td>37%</td></tr><tr><td>London</td><td>25%</td></tr><tr><td>South</td><td>11%</td></tr></table></td>
<td>Policy proposition (section 6)</td>
<td></td>
</tr>
<tr>
<td>What are the growth assumptions for the disease / condition?</td>
<td></td>
<td>Policy proposition (section 6)</td>
<td></td>
</tr>
<tr>
<td>Is there evidence of current inequalities in access to service or outcomes?</td>
<td>Differences probably due to differences in distribution of non - Caucasian populations, rather than inequalities of access. 40% of patients are from non-Caucasian backgrounds.</td>
<td></td>
<td></td>
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<tr>
<td>Is there evidence that implementing the service specification will improve current inequities of access or outcomes?</td>
<td>Will formalise access.</td>
<td></td>
<td></td>
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</table>