# Consultation Report

## Topic details

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| **Title of policy or policy statement:** | Rituximab for refractory Systemic Lupus Erythematosus (SLE) in adults and post-pubescent children |
| **Programme of Care:** | Internal Medicine |
| **Clinical Reference Group:** | Specialised Rheumatology |
| **URN:** | 1853 |

## 1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition. The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 23rd September until 23rd October 2019. There were 24 responses to the public consultation.

## 2. Background

Systemic lupus erythematosus (SLE), also known as lupus is a long term autoimmune condition (a condition where your immune system attacks your body) that causes swelling, soreness and inflammation in the body. It affects the whole body including the skin, joints and internal organs and results in long-term ill health. In 2012, SLE affected approximately 1 in 1000 people in the UK. It is more common in people of African-Caribbean and South Asian backgrounds and more common in women than men. SLE in children is more severe and active than in adults. Compared to adults there are higher numbers of children who have kidney and brain and spinal problems. Inadequately treated active disease causes damage to the affected systems thus increasing complications, morbidity and can lead to an early death. The aim of treatment is to suppress disease activity, prevent organ damage and improve quality of life.

Rituximab is a biological medicine that selectively targets B cells, cells that are part of the body's immune system that act to reduce the inflammatory response. It is usually given as two intravenous infusions two weeks apart. Rituximab is currently not licensed for the treatment of SLE (BNF 2018).

NHS England has carefully reviewed the evidence to treat refractory SLE with rituximab in adults and post-pubescent children. We have concluded that there is enough evidence to consider making the treatment available. For this policy proposition, patients with refractory SLE are defined as those who have used 2 or more named disease modifying anti-rheumatic drugs (DMARDs), unless contraindicated), and patients still either have: 1) ongoing moderate to severe active disease OR 2) require excessive use of glucocorticoids to maintain lower levels of disease activity.

## 3. Publication of consultation

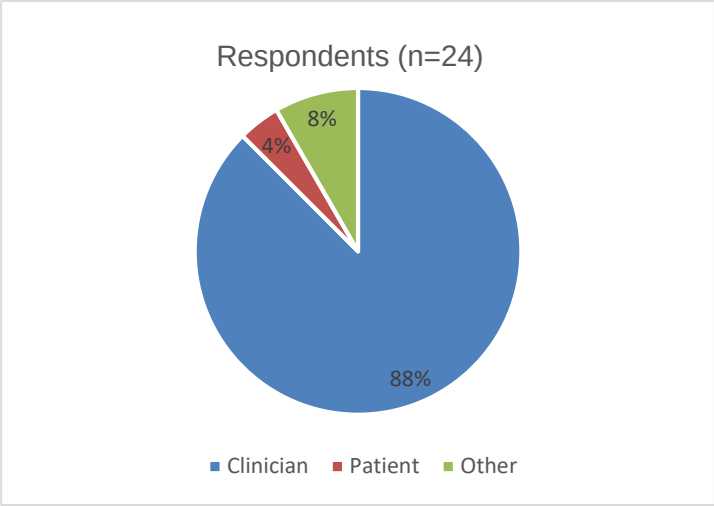
The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 23rd September until 23rd October 2019. Consultation comments have then been shared with the Policy Working Group (PWG) to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to made to this document, and why?

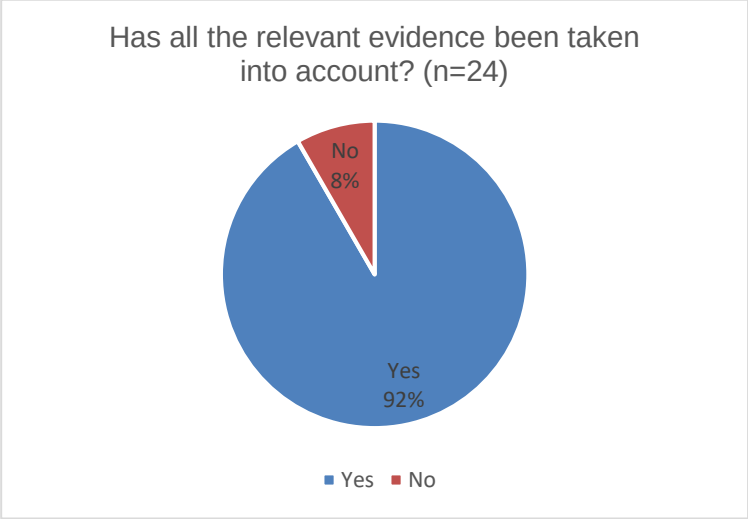
## 4. Results of consultation

There were 24 responses to the consultation:




The 2 'other' respondents consisted of 1 specialist nurse (responding on behalf of an NHS Trust) and 1 non-profit professional.

### 4.1. Relevant evidence

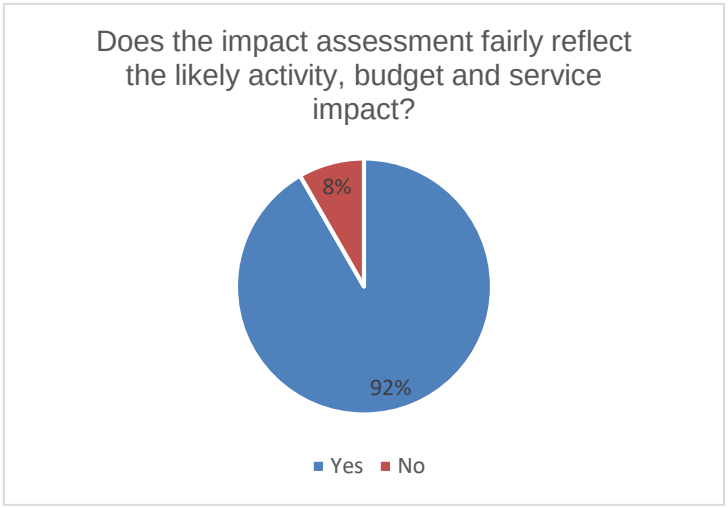



22 out of 24 respondents agreed that the relevant evidence had been taken into account in developing this policy proposition.

One clinician highlighted that their centre is in the process of publishing data on 165 patients treated with rituximab for SLE. As this was not published prior to when the evidence review was conducted, this was not considered. Two other published papers were identified, one peer reviewed cohort study of 50 patients assessing the response to rituximab in those with severe active cutaneous lupus erythematous. The second paper assessed the impact of rituximab in SLE patients on long term steroid use.

Another clinician identified that his team had published their experience of using repeat rituximab dosing in 147 SLE patients. This was not published prior to the original evidence review being conducted. The published evidence has been reviewed and found to be low grade evidence identified that does not materially affect the conclusions of the original evidence review.

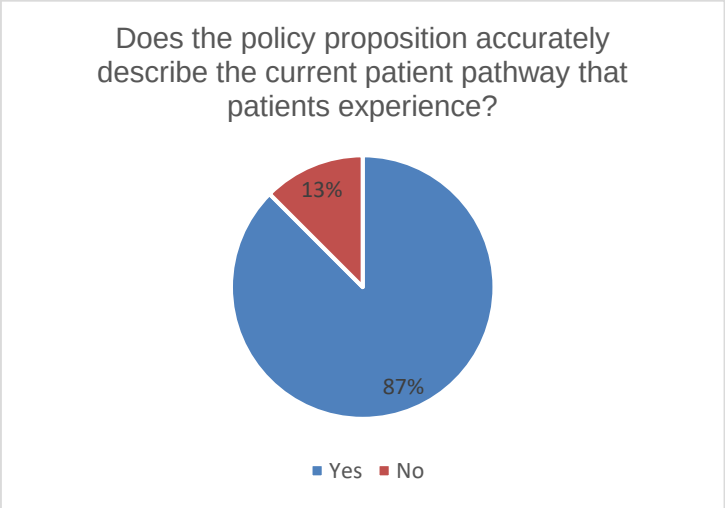
### 4.2. Impact assessment



22 respondents agreed that the impact assessment fairly reflected the likely activity, financial and service impact. One clinician highlighted that costs are likely to be lower with the introduction of biosimilars and their increasing availability.

Another clinician commented on the use of rituximab in pre-pubescent children with SLE, and stated they considered there is sufficient evidence available to recommend this in younger children.

### 4.3. Current patient pathway




21 respondents agreed that the policy proposition accurately represented the current patient pathway. Points raised included a request to clarify current pathways of treatment which exist outside a specialised rheumatology service (e.g. nephrology) and the role of belimumab in the current pathway.

### 4.4. Potential impact on equality and health inequalities

Points raised included:

- A concern that mandatory participation in the BILAG Biologics Register (BILAG BR) may be a barrier for some centres who do not have a process in place to enrol patients with the registry or where patients do not want their data included.
- A concern that the model of having ‘expert’ centres and shared care sites may disadvantage patients in poorly functioning networks.
- A concern about lack of access to treatment for pre-pubescent children.

### 4.5. Changes/addition to policy

10 respondents commented on potential changes/additions. These focused on:

- Considering use of rituximab at time of diagnosis to maximise benefit
- Having a lower age cut off for initiation of rituximab
- Removing the mandatory enrolment of patients in BILAG BR

The additional evidence identified was considered and one new paper was suggested that had not been previously considered.

## 5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

## 6. Has anything been changed in the policy as a result of the consultation?

Responses to public consultation have been reviewed by the PWG and the Internal Medicine Programme of Care (PoC). The following change has been made to the policy proposition:

A sentence has been included in the policy proposition that:

> Advises clinicians that having taken into account the clinical presentation, that the rituximab with the lowest acquisition costs should be used. This is likely to be a rituximab biosimilar.

Feedback from the PWG is as follows:

- Access to treatment for pre-pubescent children / having a lower age cut off for initiation of rituximab: The PWG supports the use in pre-pubescent children; however, NHS England bases policy proposition recommendations on an assessment of the published evidence in line with the NHS England Specialised Commissioning Methods document: At this time, there is insufficient evidence in this group to make rituximab available for pre-pubescent children for refractory SLE. It was noted the policy proposition can be reviewed when new evidence is published which is anticipated when the UK Juvenile SLE (JSLE) Cohort Study is published. The policy proposition does not contain a lower age cut off as pubescence occurs in children at different ages. It is normal for puberty to begin at any point from the ages of 8 to 14 years old.

- Removing the mandatory enrolment of patients in BILAG BR: The requirement to enter data into the registries is to enable measurement of outcomes and monitor whether the treatment is effective to inform future policy revisions. This has been amended to should from must. It is noted that any patient has a choice on whether to have their data submitted to registries.

- Considering use of rituximab at time of diagnosis to maximise benefit**:** This requires the submission of a new preliminary policy proposition.
- Addressing the issue of access to 'expert' centres which may disadvantage patients in poorly functioning networks: The requirement to work with specialised centres is covered in the Service Specification with the aim to reduce the development of disease-related morbidity and mortality, through a commitment to ensure early identification of patients with complex multisystem disease and ensuring that they have timely access to specialist care. It was noted the view of one respondent is that shared care is less acceptable to patients from ethnic minorities, who they suggest are more likely to be concerned about being seen in shared care. The specialised service specification for rheumatology is being updated and regional networks which are already well developed in most Regions will be referenced. The concern that offering care within shared care may be a barrier will be addressed during policy implementation so that Networks consider these concerns when agreeing pathways.

  The inclusion of access through renal services has been included in the policy.
- Additional evidence paper: The paper was reviewed by the Public Health Lead and found to be low grade evidence identified by stakeholders that does not materially affect the conclusions of the existing evidence reviews.

## 7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

None.