Engagement Report

Topic details

Title of policy or policy statement:	Obinutuzumab for systemic lupus erythematosus with secondary non-response to rituximab (adults and post-pubescent children) 2121
Programme of Care:	Internal medicine
Clinical Reference Group:	Specialised Rheumatology
URN:	2121

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Systemic lupus erythematosus (SLE, also known as lupus) is a long-term autoimmune condition (a condition where your immune system attacks the 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 can cause different symptoms in different people. Patients are prone to flares of their disease. SLE can cause arthritis, kidney inflammation, rashes, heart and lung inflammation, central nervous system abnormalities and blood disorders. Renal (kidney) disease occurs in up to 40% of people with SLE and significantly contributes to long-term ill health, including kidney failure requiring dialysis and death in some lupus patients.

Inadequately treated active disease causes damage of the affected systems/organs 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.

Four drugs are currently licensed and available for use in adults with SLE: hydroxychloroquine (an anti-malarial), azathioprine (a conventional DMARD (Disease Modifying Anti Rheumatic Drugs)), prednisolone (a corticosteroid), and belimumab (a biological DMARD). Treatment regimens for SLE vary depending on disease severity, which can be mild, moderate, or severe. For mild disease, standard therapy is usually a combination of non-steroidal anti-inflammatory drugs (NSAIDs), hydroxychloroquine and low dose steroids e.g., an occasional intramuscular corticosteroid injection. The current NHS England treatment pathway for moderate or severe SLE is for conventional immunosuppressants. First line options include oral medications such as azathioprine, methotrexate, mycophenolate, or hydroxychloroquine. Cyclophosphamide is also a first

line option, and this is usually given intravenously. These immunosuppressants are associated with potential side effects and toxicity.

For patients with refractory SLE (high disease activity scores, high doses of steroids and have failed 2 other immunosuppressant therapies), they may be eligible for treatment with rituximab (an anti-CD20 drug), as per the NHS Clinical Commissioning Policy for this. In a small minority of patients who have previously responded to rituximab, later cycles become ineffective – this is called secondary non-response. There is some evidence in SLE that in this clinical scenario switching to an alternative similar therapy (namely a fully humanised anti-CD20 drug) restores clinical response. Obinutuzumab is being proposed as this alternative similar therapy.

Obinutuzumab 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 an intravenous infusion. Obinutuzumab is currently not licensed for the treatment of SLE (BNF 2022).

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for two weeks from 14th November 2022 to 28th November 2022. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following consultation questions:

- Do you support the proposition for obinutuzumab for systemic lupus erythematous with secondary non-response to rituximab to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you have any further comments on the proposal?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Summary present a true reflection of the patient and carers lived experience of this condition?
- Please declare any conflict of interests relating to this document or service area.

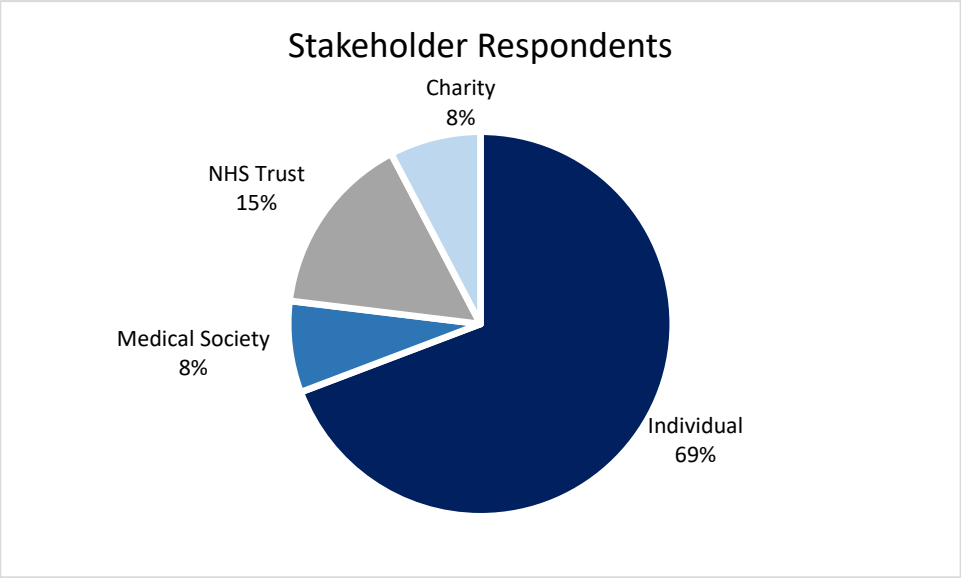
A 13Q assessment has been completed following stakeholder testing.

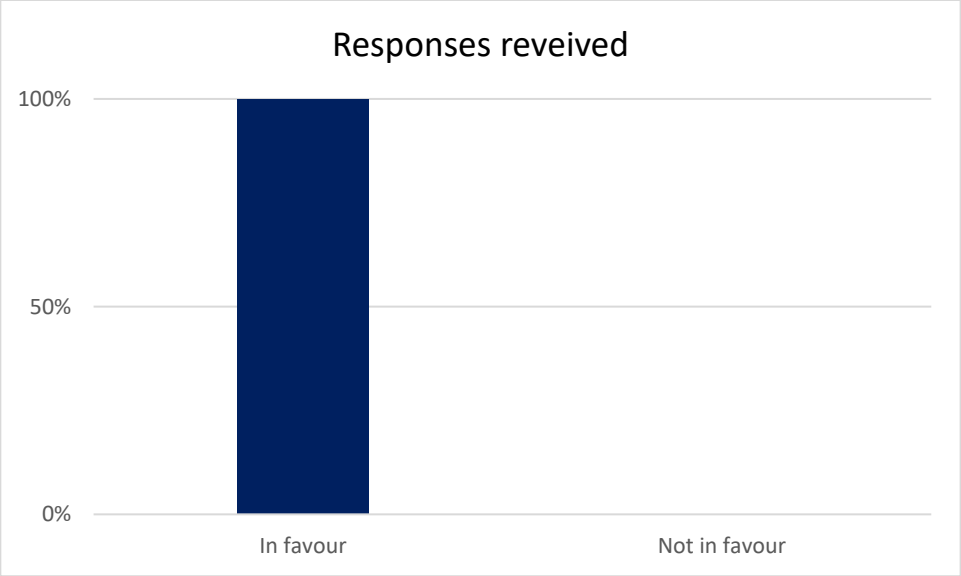
The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

Thirteen responses were received:

- Nine individuals
- One society
- Two NHS Trusts
- One patient charity for patients with lupus





In line with the 13Q assessment it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Internal Medicine PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
General agreement that there is enough evidence to support making the treatment available at this time. No extra evidence was identified. One stakeholder recommended supporting data from trials looking at rituximab in patients with SLE.	Noted. These papers do not use obinutuzumab as the intervention and therefore are outside the scope of the evidence review.
Potential positive and negative impacts on patient care	
All stakeholders felt there would overall be a positive impact on patients. One stakeholder raised concerns over pre-pubescent children being excluded from the policy proposition.	Noted. The policy proposition is limited to adults and post-pubescent access via the Medicines for Children policy as there is no safety evidence or license in pre-pubescent children.
Further comments	
A few stakeholders requested the inclusion criteria to be extended to patients with an allergic reaction to rituximab. Another stakeholder reiterated the concerns of excluding pre-pubescent children from the policy proposition. One stakeholder suggested amending the wording to include post-pubescent access in the policy proposition summary. One stakeholder asked for patients with renal lupus to be allowed access to obinutuzumab under the policy proposition. Finally, one stakeholder pointed out some typographical errors in the definitions section of the policy proposition.	Noted. Patients with an allergy to rituximab were not included in the evidence review, and therefore this is beyond the scope of this policy proposition. The policy proposition is limited to adults and post-pubescent access via the medicines for children policy as there is no safety evidence or licence in pre-pubescent children. Patients with SLE who go on to develop renal lupus and have shown secondary non-response to rituximab would be eligible for treatment with obinutuzumab under this policy proposition. Typographical errors noted.
Patient impact assessment	
The overall response from the stakeholders was that they agreed with the lived experience of patients and carers of this condition described in the patient impact summary.	Noted.
Potential impact on equality and health inequalities	
The overall response from the stakeholders was that they agreed with	Noted.

equality and health inequalities impact assessment.	

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following changes based on the engagement responses have been made to the policy proposition:

- Amend wording of policy proposition summary to make it clearer that post-pubescent children can access obinutuzumab via the Medicines for Children policy.
- Amend typographical errors.

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

No.