Consultation Report

Topic details

Title of policy or policy statement:	Rituximab in Combination with Chemotherapy in CD20 Positive B-cell Precursor Acute Lymphoblastic Leukaemia (ALL).
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy
URN:	1748

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition.

2. Background

CD20 positive B-cell precursor acute lymphoblastic leukaemia is type of acute lymphoblastic leukaemia (ALL), which is a very rare and aggressive cancer of the blood and bone marrow. Although the condition is most common in children, teenagers and young adult, it can affect people of any age. It is estimated that approximately 300 adults are diagnosed with ALL per year.

Chemotherapy is the main treatment option and a wide range of different chemotherapy medicines are currently available. Some people may also need treatment with a targeted cancer medicine and/or a stem cell transplant. The duration of treatment for the condition is around two to three years and consists of several months of intensive multi-drug chemotherapy, followed by low intensity maintenance therapy.

This policy proposition considered whether rituximab, an unlicensed medicine in this indication, should be added to first-line standard chemotherapy. Rituximab is a medicine that works by attacking cell proteins and destroying them. The addition of rituximab to first-line standard chemotherapy is considered to reduce the rate of disease relapse and the need for further, more costly treatments.

This policy proposition is for not routine commissioning and has been subject to stakeholder testing and public consultation in line with the standard Methods.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 6 weeks from 31st May 2019 till 12th July 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 be made to this document, and why?

4. Results of consultation

There were eight responses to public consultation, of which: (i) four responses were from individual patients or members of the public; (ii) two responses were from patient charities (Leukaemia Care and Bloodwise); and (ii) two responses were from individual clinicians.

Of the eight responses received, three respondents (all individual patients/members of the public) fully supported the draft clinical commissioning policy and had no further comments. The remaining five respondents raised the following concerns:

- Respondents commented that the primary outcome measure that needed consideration in developing this policy was the impact of adding rituximab to standard chemotherapy regimes on relapse rates (demonstrated through Event Free Survival) and this evidence had not been appropriately considered by NHS England in relation to the disease. Respondents commented that in their opinion the evidence review did demonstrate a reduction in the relapse rate in CD20-positive B-ALL by a clinically meaningful and statistically significant level. In addition, respondents felt that in their opinion the primary study reviewed in developing this policy was well conducted clinical trial in the context of cancer research.
- The cost effectiveness of treatment had not been taken into account as part of the decision-making process. Respondents felt improvements in relapse rates, as a result of the addition of rituximab, would result in a reduction in the use of second line treatments which were expensive to deliver and could result in significant savings to the NHS. Respondents felt this impact had not been appropriately reflected in the consultation paperwork.
- The impact of relapse rates on patient experience and psychological outcomes also needed to be considered. Respondents referenced studies and surveys by patient charities which demonstrated the impact of relapse on psychological outcomes.
- Respondents commented that the addition of rituximab to first line chemotherapy in this indication had become the standard of care across many countries internationally.
- Respondents highlighted that in some hospitals, the addition of rituximab had already been incorporated into practice. Respondents highlighted that the policy proposition could result in health inequalities.

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.

Responses to public consultation have been graded as Level 2 or Level 3.

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 Cancer Programme of Care (PoC) Board.

As a result of feedback from public consultation and the interpretation of the clinical evidence (as per the advice of clinical experts in this field), the draft policy proposition, along with the evidence review, was reviewed once again by the Specialised Services Clinical Panel in April 2020. It has been agreed that the policy proposition will now proceed for routine commissioning, focusing on patients who are undergoing intensive treatment only.

The policy proposition and associated paperwork have now been revised for routine commissioning and will be sense-checked with stakeholders through further engagement.

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

None.