Engagement Report

Topic details

Title of policy or policy statement:	Clinical Commissioning Policy: Addition of rituximab to first-line standard chemotherapy for CD20 positive B-cell precursor acute lymphoblastic leukaemia.
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy
URN:	1748

1. Summary

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

2. Background

The policy recommends that rituximab should be made routinely available as an addition to standard chemotherapy to treat adults with CD20 positive B-cell precursor acute lymphoblastic leukaemia (ALL).

The policy was first reviewed by the Specialised Commissioning Clinical Panel in November 2018 and as a result of this discussion, was initially proposed for not routine commissioning. However, the draft policy was not supported at either stakeholder testing or public consultation. Following a review of the feedback from stakeholders by the Cancer Programme of Care, the evidence was re-considered by the Specialised Services Clinical Panel. The policy has now been revised for routine commissioning, and specifically for adults undergoing intensive chemotherapy.

The primary purpose of engagement has been to sense-check the revised policy, and in particular the proposed clinical criteria.

Development of the policy has been supported by a Policy Working Group (PWG), established in line with the standard Methods and involving clinical experts, Public Health England and a patient and public voice representative.

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 revised policy was sent for stakeholder testing for a period of two weeks from 2nd July 2020 to 17th July 2020. The comments have then been shared with the PWG 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 questions:

- Do you support the proposal for the addition of rituximab to first line standard chemotherapy for the treatment of CD20 positive B-cell precursor acute lymphblastic leukaemia 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 negative impacts on patient care as a result of making this treatment option available?
- 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?

A 13Q assessment has not been completed following stakeholder testing. This is because the policy has been previously subject to public consultation (as per the standard Methods for developing clinical commissioning policies) and the purpose of stakeholder testing was to 'sense-check' the revised policy proposition following this feedback at public consultation.

4. Engagement Results

There were four responses to engagement, of which (i) one response submitted on behalf of an NHS organisation; (ii) two responses were from individual members of the public; and (iii) one response was submitted by the pharmaceutical company that manufactures the drug.

Of the 4 responses received, all respondents fully supported the draft policy proposition. Furthermore, all respondents supported the draft Equality and Health Inequalities Impact Assessment and agreed that the Patient Impact Form represented a true reflection of the patient and carers lived experience of this condition.

However, one respondent queried the following:

- The pharmaceutical company queried the exclusion criteria included in the policy proposition and suggested that the criteria are the same as for the Summary of Product Characteristics (SmPC).
- The pharmaceutical company also suggested the addition of "severe skin reactions" under the "Stopping Criteria" section to align with the product SmPC.

5. How has feedback been considered?

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

Keys themes in feedback	NHS England Response
Amendments to the exclusion and stopping criteria in line with the product SmPC.	The policy proposition includes some of the key exclusion and stopping criteria for the treatment. The PWG agree that the policy should reference the SmPC for the full list of contra-indications and that skin reactions should be added to the stopping criteria as suggested.

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

As a result of engagement, the following changes have been to the policy:

- Under the 'Eligibility Criteria – Stopping Criteria', severe skin reactions have been included. A reference to the SmPC has also been included.
- Under the 'Eligibility Criteria – Exclusion Criteria', a reference to the SmPC has been added.

No other changes have been made to the policy or any of the other supporting documents as a result of this engagement exercise.

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

None.