Engagement Report

Topic details

Title of policy or policy statement:	Sorafenib maintenance for adults with FLT3-internal tandem duplication (FLT3-ITD) acute myeloid leukaemia (AML) undergoing allogeneic haematopoietic stem cell transplantation (allo-HSCT)
Programme of Care:	Blood and infection
Clinical Reference Group:	Bone and Marrow transplantation
URN:	2262

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. During stakeholder engagement, ten responses were received which were supportive of the proposition. Changes were recommended to the draft document from stakeholder engagement.

2. Background

This policy proposition has been developed by a Policy Working Group made up of clinical specialists in haematology, Public Health, pharmacy and Commissioning Leads and a Patient and Public Voice (PPV) 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 policy proposition was sent for stakeholder testing for 2 weeks from 27th April 2023 to 11th May 2023. The comments have been shared with the Policy Working Group to enable full consideration of the feedback and to support a decision on whether any changes to the proposition might be recommended.

The Stakeholder Testing documentation was also reviewed by the Blood and Marrow Transplantation (BMT) Clinical Reference Group (CRG), the membership of which includes a representative from the Anthony Nolan charity, as well as a PPV with lived experience. The CRG was supportive of the policy proposition, with no feedback or comments provided.

A 13Q assessment has been completed following stakeholder testing.

Stakeholders were asked the following questions:

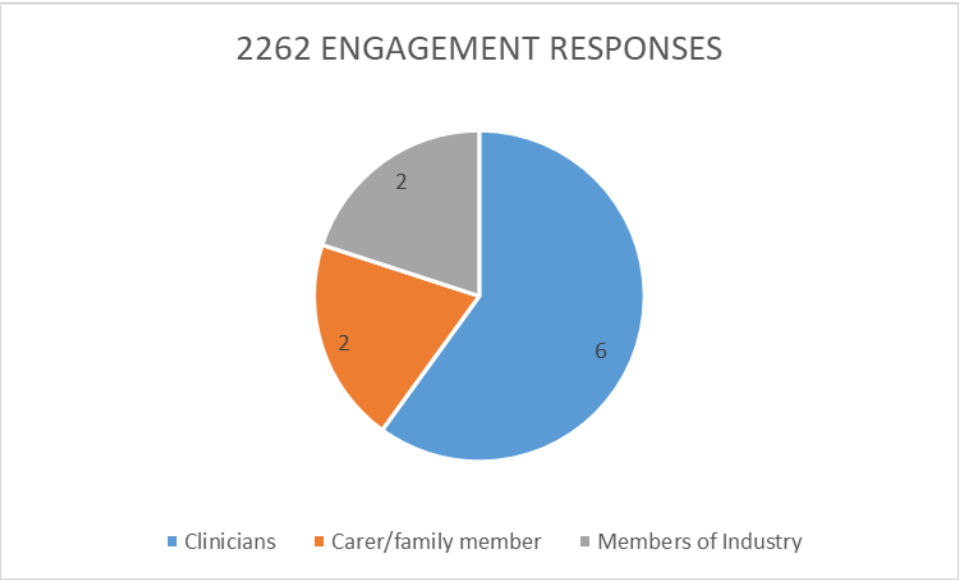
- Have you read the Policy Proposition?
- Have you read the evidence review?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Does the Patient Impact Assessment present a true reflection of the patient and carers lived experience of this condition?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Do you agree with these inclusion criteria?
- Do you agree with these exclusion criteria?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.
- Please declare any conflict of interests relating to this document or service area.

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 is not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

10 responses were received in stakeholder engagement. This included two representatives of industry, six from clinicians and two from carers/family members.

All ten responses were supportive of the Policy Proposition. Changes were recommended to the policy.



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

5. How has the feedback been considered?

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

Keys themes in feedback	NHS England Response
Clinical need	
One respondent stated the importance of this policy proposition progressing. The respondent highlighted that patients with relapsed FLT3-ITD AML post allo-HSCT configures an extremely poor prognosis, therefore, it is important to offer sorafenib, an agent that may prevent relapse.	NHS England recognises the need for maintenance therapies post allo-HSCT in this cohort to prevent relapse. This policy proposition is supportive of this.
Policy inclusion/exclusion criteria	
Comments included: • The importance of including post-pubertal children with FLT3-ITD post AML (1 comment) • A suggestion to amend commencing sorafenib no later than 6-9 months post allo-HSCT, with the current criteria being too restrictive (1 comment) • A suggestion that liver dysfunction be set as x2 ULN for ALT/AST with the current criteria being too restrictive (1 comment)	The PWG reviewed these suggestions, with the following outcomes: • This policy is applicable to adults (≥18 years) due to lack of safety data in children. Post-pubescent access is permitted as outlined in NHS England Policy 170001/P Commissioning Medicines for Children in Specialised Services. A footnote in the inclusion criteria has been added for clarity in the policy proposition. • The PWG has reviewed the suggested amendment of commencing sorafenib no later than 6-9 months post allo-HSCT. The PWG comments that this is not in line with the evidence, thus to remain with the current inclusion criteria. • The PWG have reviewed the liver dysfunction criteria and available evidence. The current inclusion criteria are in line with clinical trials.
Potential impact on equality and health inequalities	
One respondent highlighted that although the policy proposition is clear with respect to treatment should be initiated in adults, it appears incongruent with the EHIA. The EHIA summarises the policy proposition as also intending to allow for the treatment	This policy is applicable to adults (≥18 years) due to lack of safety data in children. Post-pubescent access is permitted as outlined in NHS England Policy 170001/P Commissioning Medicines for Children in Specialised Services

of post-pubescent children. The EHIA states the following: “The policy proposition recommends that sorafenib is available to adults and post-pubescent children with FLT3-ITD who meet the inclusion criteria”.	A footnote has been added to the inclusion criteria within the policy proposition to provide clearer information for inclusion of post-pubescent children via the medicines for access children's policy.

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

Changes were suggested as part of the engagement response. The viewpoints of the stakeholders were considered by the Policy Working Group and the Programme of Care and the following changes were recommended:

Policy proposition:

- Page 3 paragraph 6, addition of footnote: “This policy is applicable to adults (≥18 years) due to lack of safety data in children. Post-pubescent access is permitted as outlined in NHS England Policy 170001/P Commissioning Medicines for Children in Specialised Services”.

Equality and Health Inequalities Impact Assessment:

- No changes

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

There are no remaining outstanding concerns.