Engagement Report

Topic details

Title of policy or policy statement:	Clinical Commissioning Policy (Revised): Use of defibrotide in severe veno-occlusive disease following stem cell transplant (all ages)
Programme of Care:	Blood and Infection
Clinical Reference Group:	Blood and Marrow Transplant
URN:	B04/P/c

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

Severe veno-occlusive disease (VOD) of the liver is a complication of stem cell transplantation caused by the chemotherapy and / or radiotherapy that patients receive as part of preparation for transplant. It is most likely to affect patients with certain risk factors or underlying conditions. Severe VOD is associated with a high risk of death and can cause multi-organ failure requiring long stays in hospital, often in Intensive Care. A drug called defibrotide can be given to adults or children with severe VOD to treat the condition.

This policy proposition is a revision to the current policy allowing the commencement of treatment with defibrotide after 21 days post-transplant, in line with current product licence and professional body advice.

This policy proposition recommendation is for routine commissioning and has been developed by a Policy Working Group made up of clinicians, commissioners and patient and public voice representatives.

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 not sent to stakeholder testing as a revision of current policy. However, due to the policy requiring prioritisation due to the cost pressure it presents, it was decided it would be sent for public consultation for 4 weeks from 20th

March to 18th April 2020. 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 questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact?
- Does the policy proposition accurately describe the current patient pathway that patients experience?
- 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?
- Please declare any conflict of interests relating to this document or service area.

4. Engagement Results

In total eight responses were received, all in support of the policy revision:

- 2 patients
- 3 individual clinicians
- 1 NHS trust
- 1 pharmaceutical company
- 1 patient charity

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection Programme of Care (PoC).

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

The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
One response highlighted clinical guidelines that have recently been published based on existing evidence that are more appropriate for the diagnosis of VOD in children.	The PWG have reviewed these and accepted they should be included in the policy revision. The Public Health Lead has reviewed the publications and evidence base for these paediatric guidelines and confirmed they are based on evidence already considered within the policy.
All other respondents felt relevant evidence had been taken into account	Noted
Impact Assessment	
All respondents supported the likely activity, budget and service impact	Noted
Current Patient Pathway	
All respondents responded that the policy proposition accurately describe the current patient pathway that patients experience	Noted
Potential impact on equality and health inequalities	
The respondents felt the policy proposition represents a positive step as it extends the patient criteria, extending access to defibrotide to adults or children with late onset VOD. This is important given the lack of other standard alternative treatment for VOD, a potentially life-threatening post-HSCT complication.	Noted
Changes/addition to policy	
Nil	

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

The following change(s) based on the engagement responses has (have) been made to the policy proposition: Nil.

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

Nil.