Consultation 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 & Infection Programme of Care
Clinical Reference Group:	BMT
URN:	B04/P/c

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the update to the NHS England published policy on the use of defibrotide in severe veno-occlusive disease following stem cell transplant (all ages).

2. Background

Severe veno-occlusive disease (VOD) of the liver is a rare 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 an update of current policy allowing the commencement of treatment with defibrotide after 21 days post-transplant, in line with current product licence and professional body advice.

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 20th March 2020 to 18th April 2020. Consultation 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 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

8 responses were received:

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

All responses were supportive of the updated policy proposition, citing the positive improvement this will bring to patients who experience late onset VOD and how the amendment brings the commissioning position in line with the latest evidence and licencing of defibrotide. Most respondents felt the evidence was appropriate and the policy proposition reflected this.

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.

6. Has anything been changed in the policy as a result of the consultation?

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 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 and therefore no material change to policy.

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

There are no remaining concerns.