

## Engagement report

### Topic details

<b>Title of policy or policy statement:</b>	Arsenic trioxide in combination with all-trans retinoic acid for the treatment of high-risk acute promyelocytic leukaemia (age 12 months and over) [2322]
<b>Programme of Care:</b>	Cancer
<b>Clinical Reference Group:</b>	Chemotherapy
<b>URN:</b>	2320

### 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

APML is a form of white blood cell cancer (leukaemia) and is the most aggressive form of leukaemia. Patients with high-risk APML have a high bleeding tendency and the condition causes early mortality in 30% due to bleeding complications. APML can be categorised as low-, intermediate- and high-risk depending on the level of white blood cells at presentation. significantly higher risk of relapse compared to intermediate or standard risk patients. A greater proportion of children than adults have the high-risk form of the disease at diagnosis.

Arsenic trioxide is a chemotherapy drug that causes cell death of leukemic cells. It is licensed, in combination with all-trans retinoic acid, in adults for low- and intermediate-risk APML. Arsenic trioxide is given intravenously over a 40-week regimen.

In high-risk APML, arsenic trioxide, in combination with all-trans retinoic acid, is proposed to be given in place of anthracycline chemotherapy in combination with all-trans retinoic acid. It is given with a small amount of anthracycline chemotherapy during induction (the first few weeks of treatment) to reduce the bleeding risk. The use of arsenic trioxide, in combination with all-trans retinoic acid, in both adults and children with high-risk APML is off-label.

APML is a rare disease. Whilst APML can affect patients of all ages, it tends to have a peak incidence in children and then again in older adults. It occurs equally in males and females and there is no identified ethnic predisposition for APML.

It is estimated that the total annual incidence of patients with high-risk APML is 12 patients a year, of which 3 are estimated to be children and 9 adults.

### 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 underwent a two-week stakeholder testing between the 13<sup>th</sup> and 28<sup>th</sup> March 2024 with registered stakeholders from the following Clinical Reference Groups:

- Chemotherapy
- Children and young people's cancer services

Respondents were asked the following consultation questions:

- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you support the inclusion criteria set out in the policy proposition?
- Do you support the exclusion criteria set out in the policy proposition?
- Do you have any further comments on the proposal?
- 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?
- Please declare any conflict of interests relating to this document or service area.

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.

A 13Q assessment has been completed following stakeholder testing.

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

## **4. Engagement Results**

The policy proposition received 10 stakeholder responses:

- 2 NHS Foundation Trusts
- 2 Cancer Groups
- 6 Clinicians

This was deemed to be a significant stakeholder response, given the rarity of the condition. All stakeholders agreed with the policy proposition and felt this offered patients a positive change.

## **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
<b>Relevant Evidence</b>	
Most stakeholders agreed that the relevant evidence had been identified. One stakeholder identified an additional paper.	Noted. The additional paper has been reviewed separately in the public health evidence report.
<b>Policy proposition</b>	
All stakeholders supported the policy proposition and agreed with the inclusion and exclusion criteria.	Noted.
<b>Potential impact on equality and health inequalities</b>	
All stakeholders agreed with the equalities and health inequalities impact assessment.	Noted.
<b>Patient impact assessment</b>	
All stakeholders agreed with the patient impact assessment.	Noted.
<b>Changes/addition to policy</b>	
One stakeholder suggested delivery of arsenic at an enhanced level B POSCU, in addition to principal treatment centres (PTC).	Noted. Arsenic trioxide must be initiated in a PTC in accordance with the service specification for commissioned cancer services for children and teenage and young adults. Once initiated, treatment may then be continued in a Paediatric oncology shared care unit. (POSCU).

**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:

None.

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

No.