

NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

- 1. Name of the proposal (policy, proposition, programme, proposal or initiative): Arsenic trioxide for the treatment of high-risk acute promyelocytic leukaemia (age 12 months and over) [2320]**
- 2. Brief summary of the proposal in a few sentences**

This policy is for arsenic trioxide in all patients with high-risk acute promyelocytic leukaemia (APML). APML is the most aggressive form of all leukaemia related conditions with a severe bleeding tendency and fatal course of only a few weeks. APML can be characterised as low-, intermediate- or high-risk defined by the presenting white blood cell count at presentation.

Arsenic trioxide is an intravenous medicine that is given in combination with all-trans retinoic acid. NICE have approved the use of arsenic trioxide in newly diagnosed low to intermediate risk acute APML and relapsed/refractory acute APML in adults. This use has been extended to children via the Cancer Drugs Fund (CDF). These indications do not include the use of arsenic trioxide in **high-risk** APML which is the subject of this policy. Its use in this indication is off-label and is considered for all ages but most commonly in children and young adults in accordance with clinical practice.

- 3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised**

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p>Age: older people; middle years; early years; children and young people.</p>	<p>APML affects people of all ages but has a slightly higher incidence in middle aged people.</p> <p>This policy is expected to have a positive effect on the overall survival and overall outcomes of both children and adults, with side-effects that are apparent but less harmful of those caused by the alternative treatments (chemotherapy) or untreated progressive disease.</p>	<p>This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible. This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.</p> <p>If this policy is adopted, a commissioning plan will set out the pathway of provision for arsenic trioxide which will include access at appropriately staffed centres.</p>
<p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>Having a disability is not a risk factor for developing APML. Following a diagnosis of cancer, the individual is defined as having a disability under the Equality Act 2010. Furthermore, patients with APML are frequently disabled by the consequences of their disease on neuropsychiatric health due to haemorrhagic stroke complications.</p> <p>The policy is expected to have a positive impact on this protected characteristic group by ameliorating symptoms and improving access to treatment.</p>	<p>This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible. This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.</p>
<p>Gender Reassignment and/or people who identify as Transgender</p>	<p>Gender reassignment and being transgender are not known to be associated with APML in any way. This policy will promote access to arsenic</p>	<p>This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible.</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	trioxide regardless of gender reassignment and being transgender.	This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.
Marriage & Civil Partnership: people married or in a civil partnership.	Marriage status is not known to be associated with APML in any way. This policy will promote access to arsenic trioxide regardless of marriage status.	<p>This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible.</p> <p>This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.</p>
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	<p>Arsenic trioxide is contra-indicated in breast-feeding and recommended against in pregnancy. Women of child-bearing age are recommended to use effective contraception during treatment and to discontinue breastfeeding prior to and throughout treatment.</p> <p>This is a potential adverse impact of the proposal but note that this restriction on use in pregnancy and breast-feeding also applies to all other chemotherapy drugs currently in use to treat APML. Therefore, the potential adverse impact of the proposal is no greater than that of the current standard of care.</p>	<p>The potential adverse impact of the proposal on this protected characteristic group cannot be reduced without compromising patient safety.</p> <p>Patients of childbearing age should discuss suitable non-hormonal contraception with their clinician for the duration of dabrafenib treatment.</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Race and ethnicity ¹	Ethnicity is not linked to the incidence of APML. The policy proposes equitable access to this treatment for all racial and ethnic groups	This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible. This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.
Religion and belief: people with different religions/faiths or beliefs, or none.	Religion is not known to be associated with APML in any way. This policy will promote access to arsenic trioxide regardless of religion.	This policy aims to make arsenic trioxide available for all patients with high risk APML if clinically eligible. This will ensure equitable access to the intervention for individuals of all ages who meet the inclusion criteria.
Sex: men; women	APML occurs at equal rates in males and females. The policy proposes equitable access to this treatment for both sexes.	All patients who meet the inclusion criteria would be considered for arsenic trioxide treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be associated with APML in any way. The policy will promote access to arsenic trioxide regardless of sexual orientation.	All patients who meet the inclusion criteria would be considered for arsenic trioxide treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

¹ Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A** if your proposal will not impact on patients who experience health inequalities.

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	The incidence of APML is similar in children to adults. This policy is expected to have a positive effect on the overall survival and overall outcomes of looked after children and young people, with side-effects that are apparent but less harmful of those caused by chemotherapy or untreated progressive disease.	This policy will potentially have a positive impact on looked after children and young people, by improving overall survival and outcomes. The less harmful side effects could reduce the assistance required to complete personal tasks and reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced cancer. If this policy is adopted, a commissioning plan will set out the pathway of provision for arsenic trioxide which will include access at appropriately staffed centres.
Carers of patients: unpaid, family members.	Arsenic trioxide has the potential to improve an individual's health status and reduce morbidity. Arsenic trioxide may reduce the care needs of patients, allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with APML by reducing	All patients who meet the inclusion criteria would be considered for arsenic trioxide treatment. The policy will facilitate access to arsenic trioxide if approved (as it is not currently available in the NHS).

² Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	the assistance required to complete work, family and personal tasks and reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced cancer.	
<p>Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.</p>	<p>This group may be less likely to enter the patient pathway due to access issues e.g., not registered with a General Practitioner. In addition, chronic ill-health such as that caused by histiocytic neoplasms, is associated with homelessness. They may also find it more difficult to maintain engagement with a course of treatment.</p> <p>Arsenic trioxide reduces the length of hospital stay but does require regular attendance for infusions. This group may struggle to attend infusion appointments regularly, although the only current alternative is chemotherapy which requires more frequent appointments.</p>	<p>NHS England is producing the arsenic trioxide policy to increase access for anyone who may benefit from the intervention.</p> <p>Commissioned providers and their specialised teams should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for homeless patients and facilitate access to the drug, as well as clinical monitoring and follow-up appointments.</p>
<p>People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.</p>	<p>This policy will promote access to arsenic trioxide regardless of involvement in the criminal justice system.</p> <p>People involved in the criminal justice system would be able to access</p>	<p>All patients who meet the inclusion criteria would be considered for arsenic trioxide treatment. The policy will facilitate access to arsenic trioxide if approved (as it is not currently available in the NHS).</p>

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>treatment through prison and community healthcare services. Being in the criminal justice system is not known to be a risk factor for APML.</p> <p>Arsenic trioxide reduces the length of hospital stay but does require regular attendance for infusions. This group may struggle to attend infusion appointments regularly, although the only current alternative is chemotherapy which requires more frequent appointments.</p>	
People with addictions and/or substance misuse issues	<p>Addiction and substance misuse can be an increased risk in patients who experience a high level of chronic pain as is often the case in APML</p> <p>Addiction and substance misuse is not known to be a risk factor for APML.</p> <p>This policy will promote access to arsenic trioxide in the context of holistic care and attention to addiction issues.</p>	<p>The policy will facilitate access to arsenic trioxide if approved (as it is not currently available in the NHS). These issues of addiction and substance misuse and any impact on drug interactions, compliance and need for carer and inter-agency support and assistance will be considered by the APML.</p>
People or families on a low income	<p>Socioeconomic factors are not known to be linked to incidence of APML. Cancer treatment is known to have a financial impact on patients with cancer with 4 in 5 people are affected by financial difficulties and incurring, on average, costs of £570 per month (Macmillan</p>	<p>Patient convenience is a key consideration and particularly important for patients with recurrent disease. This policy will potentially have a positive impact on this patient group, as arsenic trioxide treatment would reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced cancer.</p>

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>Cancer Care, 2017). However, it is anticipated that treatment with arsenic trioxide would reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced cancer. This could positively impact patients or families on a low income due to a reduction in costs associated with hospital visits. This may confer an additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS).</p> <p>Arsenic trioxide reduces the length of hospital stay but does require regular attendance for infusions. This group may struggle to attend infusion appointments regularly, although the only current alternative is chemotherapy which requires more frequent appointments.</p>	<p>This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS)</p> <p>Healthcare Travel Costs Scheme (HTCS) - NHS.</p>
<p>People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).</p>	<p>The policy is specifically for people with a confirmed cancer diagnosis and already accessing healthcare. It is important to ensure that patients are aware of all treatment options available to them and</p>	<p>The provision of arsenic trioxide involves face-to-face assessment and delivery with verbal instruction. This can assist those with poor health or literacy skills.</p>

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>to obtain informed consent for treatment. If additional resources are required for this purpose- e.g., use of an interpreter, then this should be made available to patients.</p> <p>Poor literacy or health literacy is an increased risk in patient with APML who may experience neurocognitive disturbances due to haemorrhagic stroke complications.</p> <p>Although this group may find it hard to understand their condition and the benefits and risks associated with different treatment options, the proposal has a very high potential positive impact on this inequality group.</p>	<p>It is proposed that the developmental stage and a holistic assessment of an individual is undertaken to assess their suitability and understanding of compliance barriers for arsenic trioxide.</p>
People living in deprived areas	<p>Socioeconomic factors are not known to be linked to incidence of APML.</p> <p>Arsenic trioxide reduces the length of hospital stay but does require regular attendance for infusions. This group may struggle to attend infusion appointments regularly, although the only current alternative is chemotherapy which requires more frequent appointments.</p>	<p>Patients adverse socio-economic circumstance and impact on treatment delivery, monitoring and follow-up will be considered by the MDT. This will help to ensure, where practicable, treatment is provided as close to the home location of the patient as possible, with priority given to those in deprived areas who may find it challenging to arrange travel, or that travel arrangements are provided by ICBs. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment,</p>

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
		including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS).
People living in remote, rural and island locations	Arsenic trioxide reduces the length of hospital stay but does require regular attendance for infusions. Fewer and less frequent infusions are required for arsenic trioxide than for the alternative chemotherapy treatment. This group may struggle to attend infusion appointments regularly, although the only current alternative is chemotherapy which requires more frequent appointments.	Patient convenience is a key consideration and particularly important for patients with recurrent disease. This policy will potentially have a positive impact on this patient group, as arsenic trioxide treatment requires fewer and less frequent infusions than other IV chemotherapy options. This would make access easier for patients living in remote, rural and island locations who may find it more difficult to access services. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS) Healthcare Travel Costs Scheme (HTCS) - NHS .
Refugees, asylum seekers or those experiencing modern slavery	Being a refugee, asylum seeker or experiencing modern slavery are not known to be associated with APML in any way. This policy will promote access to arsenic trioxide regardless of refugee status.	If adopted, a commissioning plan will provide guidance for local service arrangements, which may include specialist oversight, to improve travel access for patients highlighting available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS) Healthcare Travel Costs Scheme (HTCS) - NHS .
Other groups experiencing health inequalities (please describe)	Not applicable	

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	X	No	Do Not Know
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b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	PPV Representation	A PPV representative was on the working group of this policy.	
2	Stakeholder testing	Stakeholder testing for this policy took place for 14 days in March 2024, following a successful outcome at Clinical Panel	
3			

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An external review of available clinical evidence was undertaken to inform this policy.	
Consultation and involvement findings	Planned	
Research	No pending research is known	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which included AMPL specialists, a public health specialist, a pharmacist and a patient and public voice representative.	

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?	X	X	
Uncertain whether the proposal will support?			X

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	X	X
The proposal may support?		
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1	
2	
3	

10. Summary assessment of this EHIA findings

This policy aims to make arsenic trioxide available to all patients with high-risk acute promyelocytic leukaemia (APML) if clinically eligible. It is not thought to adversely impact on any other individuals from protected characteristic groups. The policy could reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced cancer and the duration and frequency for attendance at chemotherapy suites. It also improves overall survival and overall outcomes of both children and adults and has side-effects that are apparent but less harmful of those caused by the alternative treatments (chemotherapy) or untreated progressive disease. This policy is informed by the evidence base and the clinical expertise of the policy working group.

A national commissioned policy will reduce variation in clinical practice promoting an equity of care nationally for those in which this intervention is indicated.

11. Contact details re this EHIA

Team/Unit name:	National Cancer Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Chief Finance Office

Date EHIA agreed:	
Date EHIA published if appropriate:	