

## NHS England and NHS Improvement: 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):** Clinical Commissioning Policy proposal: 2109 Treatment of iron overload for transfused and non-transfused patients with chronic inherited anaemias (all ages)

2. **Brief summary of the proposal in a few sentences**

This clinical commissioning policy recommends a revision of the published Clinical Commissioning Policy '*Treatment of iron overload for transfused and non-transfused patients with chronic inherited anaemias*' to extend the treatment combinations available.

The following iron chelating regimes are currently commissioned:

- Desferrioxamine (DFO) monotherapy
- Deferiprone (DFP) monotherapy
- Deferasirox (DFX) monotherapy
- DFO/DFP combination

The policy is to include the following iron-chelation combination therapies:

- DFO (injectable) / DFX (oral)
- DFP (oral) / DFX (oral)

Iron is a key component of haemoglobin, which is present in red blood cells. The body has no mechanism to remove excess iron and so blood transfusion therapy can result in iron overload. Iron overload can also be non-transfusion related e.g. it can be caused from iron supplementation. Iron overload causes serious complications particularly in the liver, heart and endocrine system. Heart disease is the commonest cause of death due to iron overload. A patient who has iron overload will start chelation therapy with one agent but then may require various chelation regimens in their lifetime, dependent on tolerability, complications with the drugs, severity and location of iron burden, and lifestyle issues.



The clinical policy was developed through conducting an externally conducted evidence review and by a Policy Working Group (PWG) consisting of haematology experts, a public health specialist and a specialist commissioner for NHS England. This proposed policy is for use in people with chronic inherited anaemias who are at risk of iron overload due to their need for repeated transfusions. The treatment may also be required for patients with non-transfusion dependent iron overload that occurs due to increased gastrointestinal iron absorption.

These two proposed combination therapies will offer alternative treatment options for patients who are unable to achieve negative iron balance despite adherence to optimal doses of monotherapy or those who are unable to tolerate the currently commissioned iron chelation therapies outlined in aforementioned existing policy.

### 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><b>Age:</b> older people; middle years; early years; children and young people.</p>	<p><u>Positive impact</u></p> <p>Chronic inherited anaemias are genetic conditions that usually present in childhood. The sooner the iron overload is treated effectively, the lesser the long-term impact on a variety of organs. It also will have a positive impact on the young person's self-image and self-esteem.</p> <p>A more effective management of iron overload will enable educational engagement.</p> <p>The oral mode of delivery will also enable care to be more easily managed at home.</p>	<p>Increase positive impact by ensuring:</p> <ul style="list-style-type: none"> <li>– appropriate monitoring of condition to determine at-risk patients early</li> <li>– post-intervention monitoring to ensure drug combination is effective and to manage side-effect profile</li> </ul>

<b>Protected characteristic groups</b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
<b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions.	<p><u>Positive impact</u></p> <p>Iron overload in chronic inherited anaemias is a long-term condition. The treatment is not curative and effective treatment would improve quality of life. The condition can lead to complex medical conditions which increase an individual's risk of mortality and morbidity. This is through a direct impact on physical health and indirectly on mental health.</p>	<p>Increase the positive impact through enabling the right combination to the right patient by:</p> <ul style="list-style-type: none"> <li>– properly risk-assessing beforehand.</li> <li>– ensuring right combination is offered to the right patient.</li> <li>– monitoring physical and mental wellbeing to ensure drugs are having positive impact after starting therapy.</li> <li>– ensuring the side effects of drugs are managed effectively.</li> </ul>
<b>Gender Reassignment and/or people who identify as Transgender</b>	<p>There is no anticipated direct negative or positive impact on this group as gender reassignment and/or people who identify as transgender have not been identified as a high-risk group.</p>	<p>Not applicable</p>
<b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.	<p>There is no anticipated direct negative or positive impact on this group as marriage/civil partnership has not been identified as a high-risk group.</p>	<p>Not applicable</p>
<b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.	<p><u>Positive impact</u></p> <p>Pregnancy coupled with an inherited anaemia is a complicated scenario which can be difficult to manage due to haemodynamic changes and increased susceptibility to stress. Interventions to enable the management of iron should improve the chances of a positive outcome for both the mother and the baby.</p>	<p>Facilitate the positive impact through:</p> <ul style="list-style-type: none"> <li>• utilising the best treatment option available to the patient to ensure good iron chelation therapy ahead of trying to conceive</li> <li>• careful monitoring throughout pregnancy</li> <li>• careful monitoring throughout breastfeeding</li> <li>• reviewing therapy once breastfeeding has finished</li> </ul>

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
	The proposed combination therapies are not suitable for use in pregnancy because DFP and DFX are not safe for use in pregnant women. However, robust iron chelation prior to conception minimises the chance of subfertility and reduces complications in pregnancy.	
<b>Race and ethnicity</b> <sup>1</sup>	<p><u>Positive impact</u></p> <p>The majority of patients with chronic inherited anaemias are of African, Afro-Caribbean, Asian or Mediterranean descent. An intervention to minimize the impact of the treatment of the condition would have a wide-ranging positive impact of the population groups affected by chronic inherited anaemias.</p>	Both thalassaemia and sickle cell diseases are screened for during the antenatal/neonatal period to improve case ascertainment and improve the identification of patients most at risk of intervention.
<b>Religion and belief:</b> people with different religions/faiths or beliefs, or none.	There should be no direct negative or positive impact on this group as religion and belief has not been identified as a high-risk group.	Not applicable
<b>Sex:</b> men; women	There should be no direct negative or positive impact on this group as sex has not been identified as a high-risk group.	Not applicable

<sup>1</sup> 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.

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
<b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.	There should be no direct negative or positive impact on this group as sexual orientation has not been identified as a high-risk group.	Not applicable

#### 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 inequalities <sup>2</sup>	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
<b>Looked after children and young people</b>	<p><u>Positive impact</u></p> <p>This is a condition that often affects children and young adults. Anything that enables a child/young person to look after their health independently improves the outcomes. Likewise treatment that reduces the need for hospital attendances to manage the consequences of iron overload will have a positive impact for a group who often struggle to engage positively with the health sector for a number of different reasons e.g. multiple changes in place of residence, poor previous interactions, complex social situations.</p>	<p>Increase the identified positive impact through careful engagement of the young person in defining their drug treatment and treatment regime to enable lifelong compliance and minimise adverse effects.</p> <p>Decrease the identified negative impact through considering the value of face to face visits for different patient groups. Healthcare professionals would need to account for this in their decision making when commencing or switching iron chelation therapies.</p>

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

Groups who face health inequalities <sup>2</sup>	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><u>Negative impact</u></p> <p>One of the proposed combination therapies is purely oral and therefore treatment will require less in-person visits. This may negatively impact vulnerable individuals due to the reduction in face to face visits. It may be challenging to assess patients holistically in a virtual consultation environment.</p>	
<p><b>Carers of patients:</b> unpaid, family members.</p>	<p><u>Positive impact</u></p> <p>The morbidity from iron overload involves complex medical conditions /chronic disease which needs repeated engagement with all sectors including health, social and educational establishments. This may involve carers having to take time off work or be unable to maintain a steady job, both of which can have a detrimental effect on the family members and the social situation. An intervention to improve the management would improve the situation of carers physically, mentally, socially and financially.</p>	<p>Maximise the positive impact through:</p> <ul style="list-style-type: none"> <li>• Good quality risk assessment pre- and post-treatment initiation of all aspects of care including the needs of carers</li> <li>• Support from social and educational establishments to minimise the impact of the condition however well it is managed</li> </ul>
<p><b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&amp;Bs.</p>	<p><u>Negative impact</u></p> <p>One of the proposed combination therapies is purely oral and therefore treatment will require less in-person visits. This may negatively impact vulnerable individuals due to the reduction in face</p>	<p>Decrease the identified negative impact through considering the value of face to face visits for different patient groups. Healthcare professionals would need to account for this in their decision making when commencing or switching iron chelation therapies.</p>

Groups who face health inequalities <sup>2</sup>	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
	to face visits. It may be challenging to assess patients holistically in a virtual consultation environment.	
<b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.	There is no identified impact of this policy on this group who face health inequalities.	Not applicable
<b>People with addictions and/or substance misuse issues</b>	There is no identified impact of this policy on this group who face health inequalities.	Not applicable
<b>People or families on a low income</b>	<p><u>Positive impact</u></p> <p>For families, improved management of iron overload should reduce the need for multiple attendance at, or admission to, hospital which can be costly and inconvenient.</p> <p>For adult patients, better iron overload management should enable improved engagement in the work sector by reducing the time off work for hospital attendance or illness.</p>	Some people on low incomes will be eligible for help with the transport costs to get them to the specialist centre for their care ( <a href="https://www.nhs.uk/using-the-nhs/help-with-health-costs/healthcare-travel-costs-scheme-htcs/">https://www.nhs.uk/using-the-nhs/help-with-health-costs/healthcare-travel-costs-scheme-htcs/</a> )
<b>People with poor literacy or health Literacy:</b> (e.g. poor understanding of health services poor language skills).	<p><u>Negative impact</u></p> <p>One of the proposed combination therapies is purely oral and therefore treatment will require less in-person visits. This may negatively impact vulnerable individuals due to the reduction in face to face visits. It may be challenging to assess patients holistically in a virtual consultation environment.</p>	Decrease the identified negative impact through considering the value of face to face visits for different patient groups. Healthcare professionals would need to account for this in their decision making when commencing or switching iron chelation therapies.

<b>Groups who face health inequalities<sup>2</sup></b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
<b>People living in deprived areas</b>	There is no identified impact of this policy on this group who face health inequalities.	Not applicable
<b>People living in remote, rural and island locations</b>	<p><u>Positive impact</u></p> <p>The oral medication regime would enable self-management at home for people who require iron chelation therapy. This would benefit people who live in remote, rural and island locations because they may not need to travel to clinic appointments as frequently.</p>	Increase the positive impact by discussing the additional iron chelation therapy options with patients and following shared care decision making principles.
<b>Refugees, asylum seekers or those experiencing modern slavery</b>	<p><u>Negative impact</u></p> <p>One of the proposed combination therapies is purely oral and therefore treatment will require less in-person visits. This may negatively impact vulnerable individuals due to the reduction in face to face visits. It may be challenging to assess patients holistically in a virtual consultation environment.</p>	Decrease the identified negative impact through considering the value of face to face visits for different patient groups. Healthcare professionals would need to account for this in their decision making when commencing or switching iron chelation therapies.
<b>Other groups experiencing health inequalities (please describe)</b>	Not applicable	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 <b>x</b>	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	Stakeholder engagement (planned)	There will be a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods.	30 March 2022 – 13 April 2022
2	Discussion with the clinical lead and public health lead for the policy	Advice sought from the clinical lead in regard to the use of iron chelation in pregnancy and breastfeeding. General advice sought from the public health lead in the completion of the EHIA.	October 2021
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.	n/a
Consultation and involvement findings	Planned – stakeholder testing	n/a
Research	No pending research is known.	n/a
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A PWG with a clinical lead was assembled which includes specialist haematology clinicians, a public health specialist, specialist haematology pharmacist and a patient representative from UK Thalassaemia society.	n/a

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?	X	X	X
The proposal may support?			
Uncertain whether the proposal will support?			

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   Impact of the condition on cases in the UK to enable direct applicability to NHSE	Research (most research is from overseas)
2   Assessing the impact of the condition on quality of life	Research
3   Cost effectiveness of interventions	Research

## 10. Summary assessment of this EHIA findings

This policy does not unfairly discriminate those with a protected characteristic. The policy could provide additional treatment options for patients who are currently experiencing sub-optimal iron chelation therapy and are at risk of iron overload. This policy is informed by the evidence base and the clinical expertise of the PWG.

Extending the treatment options in the current national commissioned policy will promote an equity of care for those in which this intervention is indicated.

## 11. Contact details re this EHIA

Team/Unit name:	Specialised Commissioning
Division name:	Blood and Infections Programme of Care
Directorate name:	Finance
Date EHIA agreed:	
Date EHIA published if appropriate:	