

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

1. **Name of the proposal (policy, proposition, programme, proposal or initiative)¹:**
Peginterferon alfa-2 and ropeginterferon alfa-2b to treat myeloproliferative neoplasms [2420]

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

Myeloproliferative neoplasms (MPNs) are a group of diseases in which the bone marrow makes too many cells that are either released into the blood stream or build up inside bone marrow. This includes polycythaemia vera (PV) where too many red blood cells are made, essential thrombocythemia (ET) where too many platelets are made, and myelofibrosis, where abnormal blood cells are made and build up inside the bone marrow. Complications of these conditions can include thromboembolic events (such as strokes and heart attacks), increased risk of bleeding or infection (due to low levels of blood cells) and in some cases, progression to blood cancers such as acute myeloid leukaemia. Interferons such as peginterferon alfa-2 is indicated in the treatment of chronic hepatitis B (HBV) and chronic hepatitis C (HCV). However, its use in in these conditions has reduced significantly due to other treatments being available. There is still some usage of peginterferon alfa-2 in certain scenarios, including HBV-HDV super-infection. Peginterferon alfa-2 is also used off-label to treat MPN, such as PV, myelofibrosis and ET. Roppeginterferon alfa-2b is indicated as monotherapy in adults for the treatment of PV without symptomatic splenomegaly. The use of roppeginterferon alfa-2b in other MPNs is off-label.

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.**

¹ Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.

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
Age: older people; middle years; early years; children and young people.	MPNs have a median onset age of 60-65, although some children and young people are affected.	Provision of treatment will be available to people over the age of three years for peginterferon and post-pubescent children for ropeginterferon, subject to eligibility criteria.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	MPNs can cause debilitating symptoms and can cause thromboembolic events like strokes which can lead to disability. The use of peginterferon alfa-2a/ropeginterferon alfa-2b is expected to have a positive impact on patients and aims to reduce the complications of disease.	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of any disability.
Gender Reassignment and/or people who identify as Transgender	No impact	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of gender identity/reassignment.
Marriage & Civil Partnership: people married or in a civil partnership.	No impact	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of marital status.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The Summary of Product Characteristics (SmPC) states there are no or limited amount of data from the use of peginterferon alfa-2a in pregnant women and it recommends it is to be used during	The prescribing clinician should be aware of the special warnings and precautions, including pregnancy and breast-feeding, for use of interferon alpha as detailed in the.SmPC.

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>pregnancy only if the potential benefit justifies the potential risk to the foetus.</p> <p>Regarding breastfeeding, it is unknown whether peginterferon alfa-2a/metabolites are excreted in human milk. Because of the potential for adverse reactions in breastfed infants, breastfeeding should be discontinued prior to initiation of treatment.</p>	
Race and ethnicity ²	MPNs have similar incidence rates across different races and ethnicities.	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of ethnicity.
Religion and belief: people with different religions/faiths or beliefs, or none.	No impact	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of religion/belief
Sex: men; women	There is a roughly equal gender balance. However it affects different groups differently. For example, young women in their 30s with ET tend to have worse symptoms (headaches/migraine/aura). Also, the people who have SVT	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of sex.

² 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
	(splanchnic vein thrombosis) tend to be younger women with PV and lower Janus kinase 2 (JAK2).	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	No impact	This policy proposition aims to make interferon alpha available for all patients with who meet the implementation criteria, regardless of sexual orientation.

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 inequalities³	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	Post-pubescent children can access ropeginterferon and children over three can access peginterferon under the Commissioning Medicines for Children Policy. This will likely have a positive impact for looked after children and young people, by providing a treatment that can be administered by themselves or carers in the community.	Children outside of these parameters are not covered by this policy given the unavailability of safety data in this age group and children not being included in the drug's marketing authorisation. Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
Carers of patients: unpaid, family members.	Potentially positive impacts as treatments may improve patients' symptoms and ability to carry out activities of daily living (ADLs) and reduces carer burden.	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	These treatments require refrigerated storage which may be difficult to achieve if the patient is homeless, so the use of peginterferon alfa-2a/ropeginterferon alfa-2b does not negate the potential disadvantage to this group.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.

³ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities³	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
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Being in the criminal justice system is not known to be a risk factor for MPNs.	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.
People with addictions and/or substance misuse issues	Addiction and substance misuse is not known to be a risk factor for MPNs.	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.
People or families on a low income	<p>Both potentially positive and negative impacts. Economic status is not known to be a risk factor for MPNs.</p> <p>Travel to hospital for treatment, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement. However, as peginterferon/ropeginterferon is available subcutaneously, most patients will be able to have treatment from home and avoid this potential barrier to treatment.</p> <p>Most patients will already be receiving treatment and will likely continue their regular appointments for follow-up and monitoring. As such, apart from 2-3 training visits, additional visits may not be required. This treatment may provide</p>	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient, maximise the positive impact of this policy proposition and minimise any potential negative impacts.

Groups who face health inequalities ³	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
	better symptom control and better health, allowing people to continue to work.	
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This group may find it hard to understand literature regarding their condition and the benefits and risks associated with different treatment options. This might impact on their ability to access treatment or maintain involvement in a treatment regime.	Provision of training and support regarding administration to patients and carers is essential. This includes offering verbal and written mediums of treatment information and training tools and providing translated and Easy Read materials.
People living in deprived areas	<p>Travel to hospital for treatment, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement. However, as peginterferon/ropeginterferon is available subcutaneously, most patients will be able to have treatment from home and avoid this potential barrier to treatment.</p> <p>Most patients will already be receiving treatment and will likely continue their regular appointments for follow-up and monitoring. As such, apart from 2-3 training visits, additional visits may not be required. This treatment may provide better symptom control and better health, allowing people to continue to work and carry out their ADLs.</p>	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.

Groups who face health inequalities³	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
People living in remote, rural and island locations	Potentially positive impacts as peginterferon/ropeginterferon is given subcutaneously, so should be able to be self-administered in the community.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
Refugees, asylum seekers or those experiencing modern slavery	Both potentially positive and negative impacts. Refugees, asylum seekers or those experiencing modern slavery might have difficulty accessing healthcare. However, peginterferon/ropeginterferon can be self-administered in the community.	Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient, maximise the positive impact of this policy proposition and minimise any potential negative impacts.
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.

	No	
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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
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1	No engagement has been undertaken due to the urgency required to publish the policy due to the severe supply disruption of peginterferon/		
2			
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	4 three paper summaries completed externally to inform this proposition.	Hard to draw clear conclusions on clinical and cost effectiveness.
Consultation and involvement findings	Not undertaken due to the urgency of the issue being addressed	
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Expert working group assembled including clinicians and pharmacists with experience in this area.	

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?		
The proposal may support?	x	x

Uncertain if the proposal will support?		
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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	Cost effectiveness	Further research
2	Clinical effectiveness	Further research about the equivalence of ropeginterferon to peginterferon in MPNs.
3		

10. Summary assessment of this EHIA findings

This assessment should summarise whether the findings are that this proposal will contribute to advancing equality of opportunity and reducing health inequalities for those patients with the highest disease risk. Due to the supply shortage from the manufacturer there may be an inequity of access for patients with a lower risk of disease or those who wish to get pregnant. The shortage is expected to be in place until June 2025.

11. Contact details re this EHIA

Team/Unit name:	Cancer Programme of Care
Division name:	Specialised Commissioning
Directorate name:	CFO
Date EHIA agreed:	

Date EHA published if appropriate:

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