NHS

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

1. Name of the proposal (policy, proposition, programme, proposal or initiative):

1930: Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over)

2. Brief summary of the proposal in a few sentences

This is a clinical commissioning policy for the use of Baricitinib as a first line treatment for adults and children 2 years and over with monogenic interferonopathies.

Monogenic interferonopathies are a group of conditions where too many interferons are produced because of a problem with a single gene. Interferons are proteins that are produced by the immune system, usually in response to viruses. There are a wide range of potential symptoms such as severe skin rashes, gangrene, arthritis, breathing difficulty and abnormal blood counts. These conditions can lead to poor quality of life, the requirement for frequent hospital admissions and can eventually be fatal. The current treatment for monogenic interferonopathies is to treat the symptoms, which is often with corticosteroids.

There are no treatments that are currently used which stop the progression of the disease. This policy suggests baricitinib as first line treatment for adults and children 2 years and over with monogenic interferonopathies. Baricitinib is given as a tablet and can slow down and stop the progression of the disease.

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
Age: older people; middle years; early years; children and young people.	Monogenic interferonopathies are more common early in life, though some may only be diagnosed in adulthood. There is currently no disease-modifying treatment for this condition. The policy is for the use of baricitinib (a disease-modifying treatment) to be used for children 2 years and over and adults with these conditions as there is insufficient safety data in children under 2 years. This policy will have a positive impact on this group.	The policy is for children 2 years and over and adults with a monogenic interferonopathy that meets the criteria set out in the document. Children under 2 years are not included due to the lack of available safety data.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	There is no change to the current treatment plans for patients with a disability. Patients with a monogenic interferonopathy may have or develop a new disease or treatment-related physical and/or cognitive disability. This policy will have a positive impact on this group as it would improve access to a wider range of treatments.	The policy is for all adults and children 2 years and over with a monogenic interferonopathy that meet the criteria set out in this document. The provision of this treatment will provide an opportunity to slow down and modify the progression of the disease for patients to improve overall quality of life.
Gender Reassignment and/or people who identify as Transgender	No impact on this group as having had gender reassignment and or identifying as a transgender has not been identified	Not applicable.

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
	as a risk factor for developing monogenic interferonopathies	
Marriage & Civil Partnership: people married or in a civil partnership.	There should be no direct negative or positive impact on this group as marital status has not been identified as a risk factor for developing monogenic interferonopathies	Not applicable.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	There may be a negative impact on people who are pregnant or breast feeding as the Summary of Product Characteristics for baricitinib states that it is contraindicated in pregnancy and should not be used whilst breastfeeding. There is no adequate data from the use of baricitinib during pregnancy.	The policy says that treatment should not be initiated during pregnancy or whilst breastfeeding due to the potential risks. These patients may be able to access standard treatment if this is not contraindicated. Patients for whom treatment cannot be initiated whilst pregnant or breastfeeding can access the treatment once pregnancy and breastfeeding have ceased if they meet the criteria set out in this document.
Race and ethnicity[1]	There is no evidence that monogenic interferonopathies are more prevalent in any particular race or ethnicity. No specific impact on this group.	Not applicable.

[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.

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
Religion and belief: 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 risk factor for developing monogenic interferonopathies.	Not applicable.
Sex: men; women	There is no evidence that monogenic interferonopathies are more prevalent in men or women. No specific impact on this group.	Not applicable.
Sexual orientation: 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 risk factor for developing monogenic interferonopathies.	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[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
Looked after children and young people	There is no change to the current treatment plans for looked after children. Monogenic interferonopathies are more common early in life. There is currently no disease-modifying treatment for this	The policy is for adults and children 2 years and over with a monogenic interferonopathy that meets the criteria set out in the document.

[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
	condition. The policy is for the use of baricitinib (a disease-modifying treatment) to be used for children 2 years and over and adults with these conditions as there is insufficient safety data in children under 2 years.	Early treatment with a disease-modifying therapy, such as baricitinib in this policy may reduce the progression of these disabilities, which would be particularly important for young people with this condition.
Carers of patients: unpaid, family members.	There is no change to the current treatment plans for carers of infants or pre-pubescent children patients. Monogenic interferonopathies are more common early in life and patients may experience a disease or treatment-related physical and/or cognitive disability and require more care. There will be a requirement for travel to appointments for blood tests and clinic appointments, which may be with a specialist outside of the local area.	The policy is a disease-modifying treatment for adults and post-pubescent children with a monogenic interferonopathy, where only symptom control is currently available. Access to a specialist centre will ensure accurate diagnosis and monitoring and appropriate recommendation for treatment due to clinical expertise and experience. Longer term impact on the quality of life could be improved through treatment of the patient, which in turn could have a beneficial impact on overall family life, work opportunities and prosperity.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	Homeless people have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.

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
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	People involved in the criminal justice system have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.
People with addictions and/or substance misuse issues	As this drug is contraindicated in those with severe hepatic impairment there is an indirect risk for those with substance misuse (alcohol and intravenous drug use) issues which can be a common cause of impairment.	The drug is contraindicated in those with severe hepatic impairment due to the potential risks. These patients may be able to access standard treatment if this is not contraindicated. Patients for whom treatment cannot be initiated due to severe hepatic impairment can access the treatment once the impairment is resolved if they meet the criteria set out in this document.
People or families on a low income	Homeless people have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Poor literacy or health literacy have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.
People living in deprived areas	People living in deprived areas have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.

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
People living in remote, rural and island locations	People living in remote, rural and island locations have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly.	Not applicable.
Refugees, asylum seekers or those experiencing modern slavery	Refugees, asylum seekers or those experiencing modern slavery have not been identified as being at higher risk of developing monogenic interferonopathies. The policy will not impact this group directly	Not applicable.
Other groups experiencing health inequalities (please describe)	There should be no further direct negative or positive impacts on any other groups experiencing health inequalities not previously described.	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~~

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	There was a two-week stakeholder engagement period with key stakeholders as per NHS England's standard methods. There were 10 responses to this, 9 of which supported the policy progressing as developed. One respondent did not support the policy progressing due to it excluding children under 2 years. The most common theme from stakeholder testing was the exclusion of children under 2. Four of the ten respondents stated the children under 2 should not be excluded. Unfortunately, there is limited efficacy data for children under 2 and very limited safety data. Baricitinib is not licensed for any indication in children. Until further safety data has been published for the use of baricitinib in children under 2, the inclusion of this age group is not possible. This was reviewed at Clinical Panel and the decision to include over 2 years was agreed.	9 – 23 December 2020
2	Policy working group	The policy working group that is developing the policy is made up of specialist clinicians, a public health consultant, pharmacist, two patient public voice representatives, a commissioner and a clinical policy fellow to offer a wide range of opinions and backgrounds.	Throughout the policy development process
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	Adang, L., Gavazzi, F., De Simone, M…et al. (2020) Developmental outcomes of Aicardi-Goutières syndrome. Journal of Child Neurology. 35(1): 7-16. Casazza, R.L., Lazear, H.M., Miner, J.J. (2020) Protective and pathogenic effects of interferon signaling during pregnancy. Viral Immunology. 33(1): 3-11. Eleftheriou, D., Brogan, P.A. (2017) Genetic interferonopathies: an overview. Best Practice & Research. Clinical Rheumatology. 31(4): 441-459. Kim, H., Brooks, K.M., Tang, C.C.et al. (2018) Pharmacokinetics, pharmacodynamics, and proposed dosing of the oral JAK1 and JAK2 inhibitor baricitinib in pediatric and young adult CANDLE and SAVI patients. Clinical Pharmacology and Therapeutics. 104(2): 364-373. Sanchez, G.A.M., Reinhardt, A., Ramsey, S….et al. (2018) JAK1/2 inhibition with baricitinib in the treatment of autoinflammatory interferonopathies. Journal of Clinical Investigation. 128(7): 3041-3052.	

Evidence Type	Key sources of available evidence	Key gaps in evidence
Consultation and involvement findings	Stakeholder testing from 9-23rd December 2020.	
Research	Not applicable.	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Through the Blood and Infection Programme of Care and its Clinical Reference Group structures supporting the Policy Working Group, with its expert knowledge regarding the incidence and treatment of monogenic interferonopathies.	

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	X
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?		
The proposal may support?	x	x
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	N/A	
2		
3		

10. Summary assessment of this EHIA findings

Monogenic interferonopathies are more common in children and can lead to poor quality of life, with increased requirement for care and frequent hospital admissions. The policy supports the use of a disease-modifying treatment in adults and children 2 years and over where no treatment of this type is currently available. The policy and clinical criteria defined in this policy are based on the result of an external evidence review. Children under 2 are not included due to insufficient safety data.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Finance, Performance and Planning
Date EHIA agreed:	16 February 2021
Date EHIA published if appropriate:	July 2021