

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): 2204 Infliximab for refractory sarcoidosis (excluding neurosarcoidosis) (Adults)

2. Brief summary of the proposal in a few sentences

This policy refers to the use of infliximab in the treatment of refractory multisystem sarcoidosis excluding neurosarcoidosis. Sarcoidosis is a systemic inflammatory disease of unknown aetiology, that is defined by its immunological reaction, the granuloma. Commonly affected organs include the lung, skin, and eyes. Other organs and systems affected by the disease are the liver, heart, brain and other parts of the central nervous system, the gastrointestinal tract, the upper airway and the joints and bones.

First-line treatment is usually with corticosteroids such as prednisolone. Other treatments that may be added if the disease does not respond, or if a steroid-sparing agent is needed, include the conventional Disease Modifying Anti-Rheumatic Drugs (cDMARDs) including methotrexate, hydroxychloroquine, and azathioprine depending on the organ affected and disease severity.

Infliximab (IFX) is a monoclonal antibody that selectively attaches to TNF-a and blocks its action. It is delivered as an intravenous infusion. It is proposed for those with sarcoidosis (excluding neurosarcoidosis) who cannot have cDMARDs or who are refractory to cDMARD therapy.

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>Sarcoidosis is mostly diagnosed in 30–60-year-olds with the prevalence being greatest in those aged 50-80 years. Most deaths from sarcoidosis occur in those over 65 years.</p> <p>This policy provides a new treatment for those who have limited other options after cDMARD failure/ contraindication, and therefore has a potential positive prognostic impact on this group of people.</p> | <p>This policy is restricted to adults in line with the findings from the evidence review. However, as infliximab has a licenced indication in children aged six years and older for other conditions, NHS England’s Policy 170001/P Commissioning Medicines for Children in Specialised Services (commissioning medicines children) can be applied to this policy for children with refractory sarcoidosis aged six years and older if clinically eligible.</p> <p>There are very few cases of sarcoidosis in children so the restrictions as a condition of the licence should be limited.</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 sarcoidosis, however, sarcoidosis often leads to disability depending on the site the sarcoid affects.</p> <p>As this policy provides a new treatment option for those who have failed other options, it should have a positive impact on a number of aspects affecting physical and mental health. Moreover, it is hoped it will limit the development of long-term disability through the reduction in disease activity and steroid burden. This needs to be balanced against the side effect profile of the drug.</p> | <p>This policy proposes that treatment is initiated and reviewed by a specialist MDT. This will enable the appropriate selection of patients who will benefit from the intervention and mean the drug will be stopped in those gaining no benefit or where the side effect profile is too great. This should mean the greatest benefit is gained from improving physical and mental health and reducing the impact of a long-term condition.</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 |
|--|--|---|
| Gender Reassignment and/or people who identify as Transgender | Gender reassignment and being transgender are not known to be risk factors for sarcoidosis. The effects of sarcoidosis on those who identify as transgender are not well known. | All patients who meet the inclusion criteria would be considered for infliximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |
| Marriage & Civil Partnership: people married or in a civil partnership. | Marriage status is not known to be a risk factor for sarcoidosis. This policy will promote access to infliximab regardless of marriage status. | All patients who meet the inclusion criteria would be considered for infliximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |
| Pregnancy and Maternity: women before and after childbirth and who are breastfeeding. | <p>Sarcoidosis has been shown to have an impact on the risk of adverse obstetrical outcomes.¹ It is hoped that infliximab will improve control of the disease and makes sarcoid management in pregnancy easier.</p> <p>However, both some of the current treatments and the proposed infliximab treatment should be avoided in pregnancy and whilst breastfeeding as they might have an adverse impact. Access to the drug might therefore be more difficult for pregnant and breast-feeding women.</p> | Management of access to the drug and ongoing monitoring will be through an MDT. Women with sarcoid who fall into the stated category will be reviewed through this process to enable appropriate management of their sarcoid whilst having the minimum outcome on their conception, pregnancy, or postnatal experience. |

¹ Hadid V, Patenaude V, Oddy L, Abenhaim HA. Sarcoidosis and pregnancy: obstetrical and neonatal outcomes in a population-based cohort of 7 million births. J Perinat Med. 2015 Mar;43(2):201-7. doi: 10.1515/jpm-2014-0017. PMID: 24937503.

| 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 ² | <p>In the UK, sarcoidosis is more prevalent in people of Afro-Caribbean and Irish origin, due to genetic predisposition. There is also evidence from the US to suggest that Afro-Caribbean women have more extensive disease.³</p> <p>This policy provides a new treatment for those who have limited other options after cDMARD failure/ contraindication, and therefore has a potential positive impact on people of Afro-Caribbean origin. Moreover, it may limit potential development of complications or more severe disease through the reduction in disease activity.</p> | Access to the drug via an MDT will enable referral to expert advice on the management of the condition, particularly for those groups who are at risk of more extensive disease. This should improve equity of access to an effective treatment. |
| Religion and belief: people with different religions/faiths or beliefs, or none. | <p>Religion is not known to be a risk factor for sarcoidosis.</p> <p>This policy will promote access to infliximab regardless of religion.</p> | All patients who meet the inclusion criteria would be considered for infliximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |

² Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity include 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.

³ Cozier YC, Berman JS, Palmer JR, Boggs DA, Serlin DM, Rosenberg L. Sarcoidosis in black women in the United States: data from the Black Women's Health Study. Chest. 2011 Jan;139(1):144-50. doi: 10.1378/chest.10-0413. Epub 2010 Jul 1. PMID: 20595459; PMCID: PMC3014690.

| 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 |
|--|---|---|
| Sex: men; women | Sex is not known to be a risk factor for sarcoidosis. This policy will promote access to infliximab regardless of sex. | All patients who meet the inclusion criteria would be considered for infliximab 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 a risk factor for sarcoidosis. This policy will promote access to infliximab regardless of sexual orientation. | All patients who meet the inclusion criteria would be considered for infliximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |

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 ⁴ | 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 policy might have an adverse impact of children aged under six years as the drug is not licensed in this group. As a long-term condition that can be difficult to treat, access to a more effective treatment will improve the life | Refractory Sarcoid is rare in children and very rare in those aged under six years old. The impact of this restriction is therefore limited. The specialist MDT will include clinicians who manage children and young people. The individual health, physical, mental, emotional, educational, and developmental needs of the patient will be taken into consideration if infliximab was proposed |

⁴ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

| Groups who face health inequalities ⁴ | 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 |
|---|--|---|
| | chances of looked after children and young people. | as a treatment option. Access to an injected treatment will need managing for those in care who need special arrangements. |
| Carers of patients: unpaid, family members. | <p>Carers may be indirectly affected by this policy.</p> <p>Infliximab has the potential to improve an individual's health status and reduce morbidity and mortality. Infliximab should reduce or eliminate the care needs of patients, allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with sarcoidosis by reducing 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 sarcoidosis.</p> <p>However, the use of infliximab may increase ongoing carer support to enable attendance at hospital.</p> | <p>The existence of a clear referral process into an MDT should enable access to the drug.</p> <p>The policy recommends that the suitability of infliximab as an intervention is assessed by the MDT team. This includes considering the support, care, and follow-up mechanisms a patient would require undergoing the intervention. The ability to attend regular hospital appointments for infusions needs to be part of that consideration.</p> |
| Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs. | This group may be less likely to enter the patient pathway due to access issues e.g., not registered with a General Practitioner. They may also find it more | <p>NHS England is producing the infliximab policy to increase access for anyone who may benefit from the intervention.</p> <p>Commissioned providers and their specialised rheumatology/respiratory Teams should work with</p> |

| Groups who face health inequalities⁴ | 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 |
|--|---|--|
| | difficult to maintain engagement with a course of treatment. | 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. |
| People involved in the criminal justice system: offenders in prison/on probation, ex-offenders. | <p>Being in the criminal justice system is not known to be a risk factor for sarcoidosis.</p> <p>However, the risk of tuberculosis (TB) is higher in this population. The SmPC states that untreated TB is a contraindication to infliximab. This would therefore have the potential to either impede or delay access to infliximab in this population.</p> <p>This policy will promote access to infliximab regardless of criminal status.</p> | The policy would facilitate access to infliximab if approved (as it is not currently available in the NHS). These issues of the population being higher risk of TB or viral infections should be considered by a specialist MDT. |
| People with addictions and/or substance misuse issues | <p>Addiction and substance misuse is not known to be a risk factor for sarcoidosis.</p> <p>People with addiction/and or substance misuse issues might find it harder to maintain engagement with the course of treatment.</p> <p>Additionally, patients with substance misuse are higher risk of tuberculosis (TB) and opportunistic infections. The</p> | The policy will facilitate access to infliximab 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 should be considered by a specialist MDT. |

| Groups who face health inequalities ⁴ | 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>SmPC states that untreated TB is a contraindication to infliximab. This would therefore have the potential to either impede or delay access to infliximab in this population.</p> <p>This policy will promote access to infliximab regardless of addiction issues.</p> | |
| <p>People or families on a low income</p> | <p>Economic status is not known to be a risk factor for sarcoidosis, although statistics from the British Lung Foundation show that those with higher income are more likely to be diagnosed with sarcoidosis, which might indicate a barrier to healthcare access for people of lower income.⁵</p> <p>Travel to hospital for infusions, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement.</p> <p>By providing an extra treatment option, this policy may have a positive impact on this patient.</p> | <p>NHS England is producing the infliximab policy to increase access for anyone who may benefit from the intervention.</p> <p>Commissioned providers should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to ensure adequate referral, access and attendance support for people or families on a low income.</p> |

⁵ Statistics.blf.org.uk. 2022. *Sarcoidosis statistics | British Lung Foundation*. [online] Available at: <<https://statistics.blf.org.uk/sarcoidosis#statistic186>> [Accessed 6 September 2022].

| Groups who face health inequalities⁴ | 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 |
|---|---|---|
| | This policy will promote access to infliximab regardless of economic status. | |
| 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 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. | <p>The existence of a clear referral process into an MDT should enable access to the drug.</p> <p>Shared decision making should be used using appropriate mediums including verbal, written shared decision-making tools, translated, and Easy Read materials.</p> <p>The provision of treatment should be provided in a way to assist those with poor health or literacy skills. A holistic assessment of an individual should be undertaken by the prescribing physician to assess their suitability and understanding of compliance barriers for infliximab.</p> |
| People living in deprived areas | Deprivation is not known to be a risk factor for sarcoidosis but may be a risk factor for delayed diagnosis. | <p>The existence of a clear referral process into an MDT should enable access to the drug. The policy will increase geographic access of providers of infliximab which is not currently available.</p> <p>Patients' socio-economic circumstance will be considered by an appropriately constituted MDT. This will help to ensure treatment is provided as close to the home location of the patient as possible. Access to travel arrangements provided by Integrated Care Boards (ICBs) needs to be part of this.</p> |

| Groups who face health inequalities ⁴ | 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 | <p>This policy attempts to ensure there is equal access to treatment regardless of location.</p> <p>As infliximab requires intravenous infusion, this may be difficult for people living in remote, rural or island locations as it may require travel to the nearest delivering centre.</p> | <p>The existence of a clear referral process into an MDT should enable access to the drug. The policy will increase geographic access of providers of infliximab which is not currently available.</p> <p>If adopted, a commissioning plan will provide guidance for local service arrangements, which may include specialist oversight, to improve travel access for patients but with the necessary arrangements in place for reimbursement.</p> |
| Refugees, asylum seekers or those experiencing modern slavery | <p>Being a refugee, asylum seeker or experiencing modern slavery are not known to be risk factors for sarcoidosis.</p> <p>This policy will promote access to infliximab regardless of economic status.</p> | <p>The existence of a clear referral process into an MDT should enable access to the drug.</p> |
| Other groups experiencing health inequalities (please describe) | N/A | N/A |

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 testing (planned) | There was a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods. | 26th April- 11th May 2023 |
| 2 | Public consultation (planned) | Not formally required | |
| 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. | Cost effectiveness of treatment Larger and longer-term studies on the effect of the intervention |
| Consultation and involvement findings | Stakeholder testing. | |
| Research | No pending research is known. | Cost effectiveness of treatment Larger and longer-term studies on the effect of the intervention based in the UK |
| 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 sarcoidosis specialists, a range of medical clinicians, 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? | X | X | |
| The proposal may support? | | | 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? | 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 Cost effectiveness of intervention versus usual care | research |
| 2 Clearer understanding of the demographics of the group with refractory sarcoid compared with rest of the patient group with sarcoid | research |
| 3 | |

10. Summary assessment of this EHIA findings

This policy aims to make infliximab available for all adults with refractory sarcoidosis (excluding neurosarcoidosis) if clinically eligible. The policy is restricted to adults in line with the findings of the evidence review. Access for children aged six years and above can be sought via NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services ([commissioning medicines children](#)) in line with the licensing for infliximab in other indications. It is not thought to adversely impact on any other individuals from protected characteristic groups. The policy could provide a treatment option for patients who are currently experiencing the consequences of refractory sarcoidosis for which there are currently limited or no treatment options to control the

disease. With the constitution of an MDT, the policy should enable equity of access to expert advice and intervention for a long-term condition with limited effective treatment options. **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. At present some trusts have agreed to fund the treatment for the occasional patient but other trusts have not agreed to do so.

11. Contact details re this EHIA

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|-------------------------------------|--|
| Team/Unit name: | Internal Medicine Programme of Care |
| Division name: | Specialised Commissioning, NHS England |
| Directorate name: | Chief finance officer |
| Date EHIA agreed: | |
| Date EHIA published if appropriate: | |