Engagement Report

Topic details

Title of policy or policy statement:	**Infliximab for sarcoidosis (excluding neurosarcoidosis) (adults)**
Programme of Care:	**Internal Medicine**
Clinical Reference Group:	**Specialised Rheumatology**
URN:	**2204**

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Sarcoidosis (also known as sarcoid) is a condition where cells in the body clump together to make small lumps called granulomas. If these develop in organs in the body, they can stop the organ working correctly. The disease can affect more than one organ system in a patient so there are several types of sarcoidosis. Sarcoidosis mainly affects the lungs (more than 90% of patients have lung involvement including both the lymph nodes and the lung tissue), skin and eyes. However, it can also affect other organs, including the heart, liver, and brain.

The cause of sarcoidosis is unknown and there is currently no cure for the condition. The symptoms of the disease vary and partially depend on the body part affected. General symptoms can include cough, breathlessness, red or painful eyes, swollen glands, rashes, muscle and joint pain or numbness in the face, arms, or legs. Patients may also feel tired, suffer from weight loss or experience fevers and night sweats. Some patients do not have any symptoms at all.

Most patients with sarcoidosis do not require treatment. However, around a third have more serious disease and require therapies such as steroids and drugs that suppress the immune system. The overall death rate (mortality) in sarcoidosis is 1-5% usually due to lung, heart or brain involvement and their associated complications.

Refractory disease is defined as sarcoid disease that has failed to respond to standard treatments (for example corticosteroids and/or at least one conventional Disease Modifying Anti Rheumatic Drug (cDMARD)) or the standard treatments are contraindicated.

Infliximab belongs to a group of medicines called ‘biological drugs’. It is a type of drug which works by reducing the effect of a chemical called tumour necrosis factor-alpha (TNF-α). TNF- α is released in response to a disease or infection as part of the body’s immune response. Infliximab is used to treat several medical conditions including Crohn’s disease, ulcerative colitis and certain types of arthritis such as rheumatoid arthritis and ankylosing spondylitis. Infliximab is used as both to prevent the disease

from getting worse, and to reduce the dose of steroids individuals with severe, refractory sarcoidosis are taking.

The proposition is for infliximab to be given intravenously as an outpatient day-case once every eight weeks after the patient has completed an initial loading regimen. The treatment is given until the patient stops responding.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent a two-week stakeholder testing between 27th April and 11th Mary 2023 with registered stakeholders from the following Clinical Reference Groups:

- Specialised rheumatology
- Hepatobiliary and pancreas
- Cardiac services
- Renal Services
- Specialised Dermatology
- Paediatric Medicine
- Specialised ophthalmology
- Specialised Respiratory

The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following consultation questions:

- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you support the inclusion criteria set out in the policy proposition?
- Do you support the exclusion criteria set out in the policy proposition?
- Do you have any further comments on the proposal?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Summary present a true reflection of the patient and carers lived experience of this condition?
- Please declare any conflict of interests relating to this document or service area.

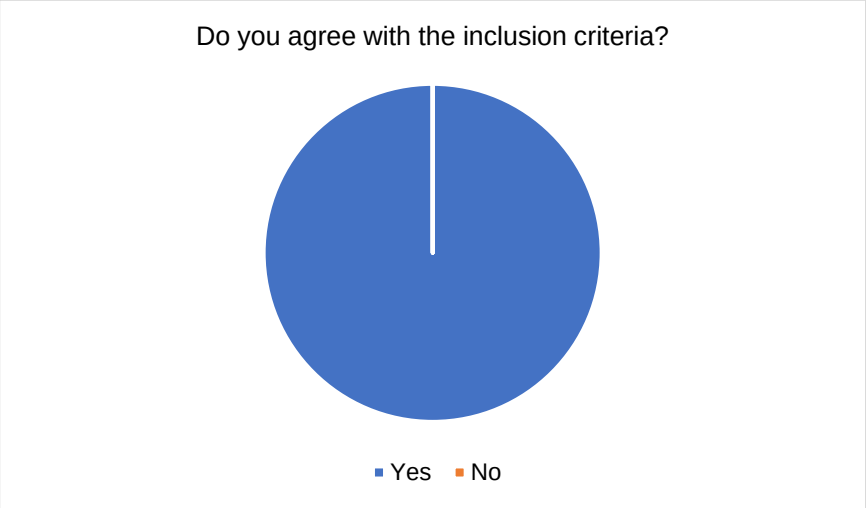
A 13Q assessment has been completed following stakeholder testing.

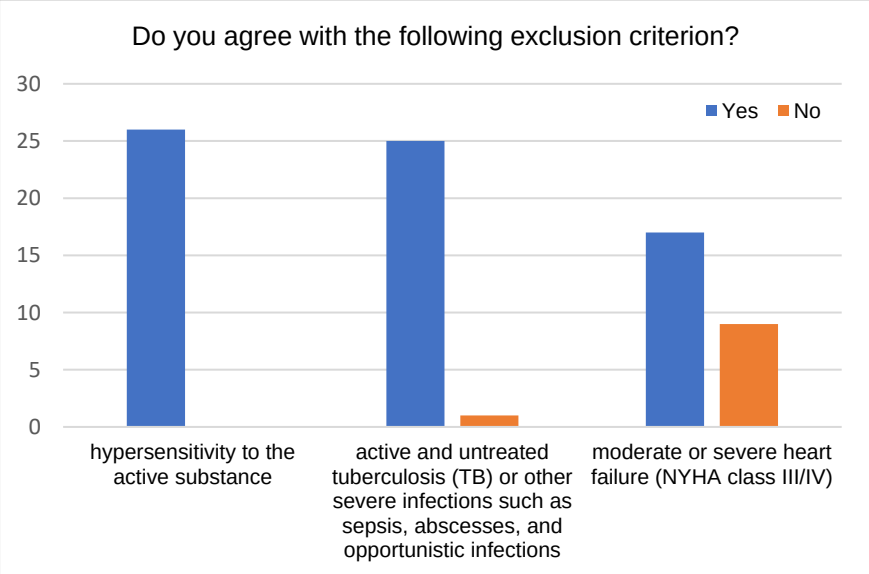
The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

27 stakeholders responded:

- 15 clinicians
- 2 patients
- 1 Royal College
- 1 Society
- 7 NHS Trusts
- 1 commissioner





In line with the 13Q assessment it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the (insert PoC) PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
All stakeholder agreed with the findings of the evidence review. No additional evidence was identified.	Noted.
Equalities and health inequalities impact assessment	
All stakeholders supported the equalities and health inequalities impact assessment.	Noted.
Policy inclusion criteria	
Most stakeholders agreed with the inclusion criteria. One stakeholder commented that ocular sarcoidosis can sometimes be a diagnostic challenge.	The inclusion criteria are based off evidence findings. Sarcoidosis is a multisystem disease which can have many manifestations. The policy proposition has been made as concise as possible whilst attempting to cover as broad a range of diagnostic criteria as possible.
Policy exclusion criteria	
Most stakeholders agreed with all exclusion criteria. A few stakeholders felt that the exclusion criteria '*moderate or severe heart failure (NYHA class III/IV)'* was restricting as patients may have heart failure stage III/IV due to cardiac sarcoidosis.	Noted. The exclusion criterion 'moderate to severe heart failure (NYHA Class III/IV)' has been amended and reviewed by Clinical Panel on the 21st June.
Patient impact assessment	
All stakeholders felt the patient impact assessment represented the experience of patients. One stakeholder mentioned that the impact of ocular sarcoidosis was not highlighted in the impact assessment.	Noted.
Further comments	
All stakeholders felt that this policy proposition would be a welcomed addition to the patient pathway and offer an alternative treatment option to patients who needed it. Some stakeholders felt that the response to treatment should be assessed at 12 months instead of 6 months to allow patients more time to respond to treatment.	Noted. Response evaluation at 6 months was based off the evidence review, as most outcomes were first reported at 6 months. This indicates that a treatment

	effect can be seen from six months onwards.
One stakeholder commented on the lack of option for subcutaneous anti-TNF treatment options.	The independent evidence review did not identify any evidence pertaining to subcutaneous infliximab. The policy proposition is only for intravenous infliximab in this population. A new PPP for an alternative subcutaneous anti-TNF would need to be submitted.
One stakeholder felt the policy should be combined with NHS England's policy for infliximab in neurosarcoidosis.	The policies have been kept separate as the neurosarcoidosis policy has an extended 'progressive' population that is not applicable to this policy proposition. The policies were therefore kept separate to avoid confusion.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change based on the engagement responses has been made to the policy proposition:

- Patient impact assessment updated to reflect impact on vision.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

The following change based on the engagement responses was returned to Clinical Panel for a final decision on whether a change was needed for the exclusion criterion '*moderate or severe heart failure (NYHA class III/IV)*'.

Clinical Panel decided that there was sufficient evidence to extend the use of infliximab to patients with severe cardiac sarcoidosis and the exclusion criterion has been amended accordingly and now reads:

moderate or severe heart failure (NYHA class III/IV) not due to cardiac sarcoidosis[1].

[1] If infliximab is used to treat cardiac sarcoidosis, careful assessment weighing the benefits versus the risks needs to be made to treat a patient, and treatment needs to be managed in a specialist cardiac centre.