NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 19 April 2023

Intervention: Infliximab

Indication: refractory sarcoidosis (excluding neurosarcoidosis) (adults and children six years and above)

URN: 2204

Gateway: 2, Round 2

Programme: Internal Medicine

CRG: Specialised Rheumatology

Information provided to the Panel

Policy Proposition

Clinical Panel Report

Clinical Priorities Advisory Group Summary Report

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment (PIA) Report

Evidence Review by Solutions for Public Health

Evidence to Decision Making Summary

Blueteq™ Forms – Initial and continuation

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of infliximab for refractory sarcoidosis for adults and children aged six years and above. Neurosarcoidosis is excluded from this proposition as there is already an NHS England published policy in place with infliximab as the intervention. Infliximab is a biologic drug which works by reducing the effect of tumour necrosis factor-alpha (TNF-α), thus reducing the build-up of the granulomas in sarcoidosis. This would be an off-label use of the medicine.

Clinical Panel considered this proposition and supporting evidence papers at the meeting in January and considered that revisions were required.

Panel members were presented with the amendments to the documentation that had been requested and considered these in turn.

Panel members were updated that infliximab is now available in subcutaneous administration form. This was not covered within the evidence review for this indication and therefore the proposition needs to be clear that infliximab in this indication is intravenously administered only.

EHIA – no amendments requested.
PIA – no amendments requested.

Recommendation

Clinical Panel recommends this proceeds as a routine commissioning policy proposition.

Why the panel made these recommendations

Clinical Panel members considered that the amendments made have sufficiently addressed the requirements of the Panel members.

Documentation amendments required

Policy Proposition:

- Definition of refractory is still considered to be confusing and needs further review, with the avoidance of referring to 'progressive'.
- The proposition needs to be clear that infliximab in this indication is intravenous administration only.
- Page 6 – the flow diagram has an MDT decision point that only routes to treatment currently. Should there be a 'no treatment' route added?
- Audit requirements – 4th line – remove the wording 'lack of funding'.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, Medical Director, Specialised Services

Actioned Amendments:

Policy Proposition:

- Definition of refractory is still considered to be confusing and needs further review, with the avoidance of referring to 'progressive'.
  Actioned – Definition reworded slightly to avoid confusion.
- The proposition needs to be clear that infliximab in this indication is intravenous administration only.
  Actioned – Policy only refers to intravenous infliximab and intravenous added to flow diagram.
- Page 6 – the flow diagram has an MDT decision point that only routes to treatment currently. Should there be a 'no treatment' route added?
  Actioned – MDT box changed and 'not suitable' route added.
- Audit requirements – 4th line – remove the wording 'lack of funding'.
  Actioned

Clinical Panel Meeting discussion – 21 June 2023

Following the agreement in April for this proposition to progress, two weeks of stakeholder testing took place. The responses received highlighted a concern regarding one of the exclusion criteria in the proposition which is directly stated from the Summary of Product Characteristics (SmPC):

- Moderate or severe heart failure (NYHA class III/IV)

Stakeholders consider this excludes patients with refractory cardiac sarcoidosis whose disease may benefit from this treatment. This was supported by the Policy Working Group. This proposition was resubmitted to Clinical Panel for the criterion to be reconsidered and the following be recommended:

- Moderate to severer heart failure (NYHA Class III/IV) not due to cardiac sarcoidosis.

A footnote would also be included in the proposition regarding careful patient assessment, weighing benefits versus risks and management in a specialist centre only.

It was considered this change was supported by the patient population contained within two papers reported within the original evidence review.

Panel members considered that the dosing recommended in this proposition was 5mg/kg. The toxicity effects were reported originally at a dosage of 10mg/kg.

Outcome: Clinical Panel debated and concluded this change was reasonable, although should be subject to agreement with the National Clinical Director for Cardiology.