NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 21 August 2024

Intervention: Tocilizumab

Indication: neuromyelitis optica spectrum disorder (NMOSD) and myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD) refractory or intolerant to previous lines of therapy (adults)

URN: 2334

Gateway: 2, Round 1

Programme: Trauma

CRG: Neurology

Information provided to the Panel

Policy Proposition

Evidence Review completed by Solutions for Public Health

Clinical Priorities Advisory Group (CPAG) Summary Report

Evidence to Decision (EtD) Summary

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment

Blueteq® Forms – adult and Medicines for Children

Policy Working Group (PWG) Appendix

This Policy Proposition recommends the use of tocilizumab for the treatment of neuromyelitis optica spectrum disorder (NMOSD) and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). NMOSD and MOGAD are two subtypes of a severe inflammatory neurological condition which typically presents as severe optic neuritis and longitudinally extensive myelitis often followed by further severe attacks which usually result in permanent disability or death. Tocilizumab is proposed as a third line option for patients who continue to relapse after first- and second-line treatment. The use of tocilizumab in NMOSD and MOGAD is recommended for adults and is off label.

An evidence review was completed which included three studies a phase 2, open-label, randomised trial, and two retrospective, observational, before and after studies.

Outcomes that were considered critical and important to decision making were presented to Panel members. The evidence was of moderate to very low certainty for all reported outcomes. The studies demonstrated a statistically significant reduction in relapse rate compared with azathioprine, and the measures of disability (EDSS score) showed improvement in the reduction of disability progression.

Panel members noted that the Policy Working Group's commentary in the EtD focused more on the statistical effect rather and it would have been helpful to have more of a clinical view from them.

The proposition and the supporting documentation were presented to Clinical Panel members. A few points were debated and it was agreed some amendments were required.

EHIA – no amendments requested.

PIA – no amendments requested.

Recommendation

Clinical Panel recommends that this proposition proceeds as a routine commissioning policy proposition, once amendments have been made and approved through Chair's action in consultation with the presenter.

Why the panel made these recommendations

Panel members agreed that the evidence base does demonstrate clinical benefit.

Documentation amendments required

Policy Proposition:

- The proposition needs to be worded in line with the Medicines for Children policy.
- *What have we decided* section – page 2. The first sentence needs to be re-written as it reads like patients have received tocilizumab before.
- Page 4 – states there is no licensed treatments available. This needs to be reworded as there are licensed treatments in UK however they have been subject to terminated NICE Technology Appraisals.
- *About Tocilizumab* section – first paragraph is missing and 'and' between giant cell arteritis and severe COVID-19 infection.
- It would be helpful to explain the scales measuring disability within the proposition and their meaningfulness to aid interpretation.
- Pathway – page 7:
    - tocilizumab is positioned as an alternative to intravenous immunoglobulin. Check with the PWG to clarify. The PWG should refer to the published Immunoglobulin policy to make sure all aligns.
    - lower right hand side box – Is patient suitable for IVIg – Yes or No. Would there ever be a stage where they need to be reconsidered for tocilizumab and so need an arrow going back to allow for that?

Declarations of Interest of Panel Members: None received.

Panel Chair: Anthony Kessel, Deputy Medical Director, Specialised Services

Post Panel Amendments

Policy Proposition		
Panel Comment	**Amendment**	**Page number (if applicable)**
The proposition needs to be worded in line with the Medicines for Children policy.	Footnote 1 edited to reflect the changes: Tocilizumab may be used in children aged two years and above via NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services. M4C prior approval form updated to reflect this. EHIA updated to reflect this change. EtD updated to reflect this change.	P2
What have we decided section – page 2. The first sentence needs to be re-written as it reads like patients have received tocilizumab before.	This sentence has been amended.	P2
Page 4 – states there is no licensed treatments available. This needs to be reworded as there are licensed treatments in UK however they have been subject to terminated NICE Technology Appraisals.	This sentence has been amended. It now reads: There are currently no licensed treatments available for NMOSD or MOGAD with a positive recommendation from NICE.	P4
About Tocilizumab section – first paragraph is missing and 'and' between giant cell arteritis and severe COVID-19 infection.	This sentence has been amended.	P4
Pathway – page 7: tocilizumab is positioned as an alternative to intravenous	The IVIG guidelines will need to be updated, suggested wording has been provided by the PWG and passed on	n/a

immunoglobulin. Check with the PWG to clarify. The PWG should refer to the published Immunoglobulin policy to make sure all aligns.	to the National Programme of Care Manager for Blood and Infection. The amended wording will reflect that tocilizumab needs to have been trailed prior to initiating IVIG in NMOSD and in MOGAD.	
Pathway – page 7: lower right hand side box – Is patient suitable for IVIg – Yes or No. Would there ever be a stage where they need to be reconsidered for tocilizumab and so need an arrow going back to allow for that?	Patient pathway amended to allow patient to be reconsidered for tocilizumab at annual review or with change in patient circumstances.	P7
Evidence to Decision Summary		
It would be helpful to explain the scales measuring disability within the proposition and their meaningfulness to aid interpretation.	Footnote 2 explains the expanded disability status scale (EDSS).	P3