NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 19 October 2022

Intervention: Obinutuzumab

Indication: refractory systemic lupus erythematosus (adult and post-pubescent children)

URN: 2121

Gateway: 2, Round 1

Programme: Internal Medicine

CRG: Specialised Rheumatology

Information provided to the Panel

Policy Proposition

Clinical Priorities Advisory Group Summary Report

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Report (PIR)

Evidence Review by NICE

Evidence to Decision Making Summary

Blueteq™ Forms – Adult and Medicines for Children

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of obinutuzumab to treat patients with systemic lupus erythematosus (SLE) with secondary non-response to rituximab (adults and post pubescent children). This is an off-label use of the medicine.

Some patients who have previously responded to rituximab (an anti-CD20 monoclonal antibody), later treatment cycles may become ineffective - secondary non-response. This is related to the development of anti-rituximab antibodies, which neutralise the drug and stop it from depleting B cells, a key mediator in the development of SLE. There is some evidence that switching to an alternative anti-CD20 therapy restores clinical response.

Clinical Panel was presented with the evidence review supporting the proposition which included one retrospective non-comparative case series with 9 patients across 6 centres in England. The evidence, of very low certainty, demonstrated statistically significant improvement in disease activity scores from baseline over 6 months. It also reported an improvement in lupus nephritis renal disease. No evidence was identified for quality of life. No evidence identified on cost effectiveness.

Panel members discussed the proposition which they considered required a couple of amendments.

EHIA – a couple of amendments required.

FINAL

Patient Impact report – more detail required to strengthen understanding of impact.

Recommendation

Clinical Panel recommends this progresses as a routine commissioning proposition.

Why the panel made these recommendations

Clinical Panel members considered the evidence base presented supported the commissioning position.

Documentation amendments required

Policy proposition:

- The title needs to be clearer to specify this is secondary non-response rather than using the broad term 'refractory'.
- Retreatment criteria – bullet point 3, the word 'above' is currently in superscript and needs reviewing.
- Pathway – 'Exits the Pathway' box needs an asterix to link it with the 'Exits the Pathway' statement below it.

EHIA:

- Section 3 – Race and ethnicity – the summary explanation is currently clinically focused and should be reviewed / revised to include non-clinical factors relating to this protected characteristic, such as language barriers and access barriers.
- Section 10 – remove last sentence.

PIR:

- More detail required on the definition of secondary non-responders at the beginning to understand impact.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, National Director, Specialised Services

PWG post panel revisions
Policy proposition:

- The title needs to be clearer to specify this is secondary non-response rather than using the broad term 'refractory'. **Actioned**
- Retreatment criteria – bullet point 3, the word 'above' is currently in superscript and needs reviewing. **Actioned**
- Pathway – 'Exits the Pathway' box needs an asterix to link it with the 'Exits the Pathway' statement below it. **Actioned**

EHIA:

- Section 3 – Race and ethnicity – the summary explanation is currently clinically focused and should be reviewed / revised to include non-clinical factors relating to this protected characteristic, such as language barriers and access barriers. **Actioned**
- Section 10 – remove last sentence. **Actioned**

PIR:

- More detail required on the definition of secondary non-responders at the beginning to understand impact. **Actioned**

FINAL