NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 17 August 2022

Intervention: Ranibizumab

Indication: Retinopathy of prematurity

URN: 2201

Gateway: 2, Round 1

Programme: Trauma Programme of Care

CRG: Specialised Ear and Ophthalmology Services

Information provided to the Panel

Policy Proposition

Clinical Priorities Advisory Group Summary Reports

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Report

Evidence Reviews by Solutions for Public Health

Evidence to Decision Making Summary

Blueteq™ Form

Summary of Product Characteristics (SmPC) Lucentis® Licence information

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of ranibizumab in retinopathy of prematurity (ROP) in preterm babies. ROP is a potentially blinding condition caused by abnormal vascular development in the retina linked with vascular endothelial growth factor (VEGF) in preterm babies. The current standard treatment for ROP is diode laser treatment (retinal laser photocoagulation) to areas of avascular retina. The proposed intervention, ranibizumab, is an alternative first line intervention to laser. Ranibizumab is a VEGF inhibitor administered via an intravitreal injection into the eye. The treatment is licensed in the UK for this indication.

Panel members were informed that that the licensed indication of 'aggressive posterior ROP' has been replaced in the most recent international classification of the disease (updated in 2021) to a broader category of 'aggressive ROP'. This wider category is what is being recommended for consideration, therefore off label use of the medicine.

Clinical Panel were presented with the evidence review supporting the proposition which included seven studies published in nine papers, including two randomised controlled trials (RCT) and five retrospective cohort studies. In high myopia one RCT extension study provided low certainty evidence of statistically significantly less myopia for 0.2mg ranibizumab compared to laser therapy at age 20-28 months. Regarding Quality of Life (QoL) one study provided low certainty evidence in vision related QoL at age 20-28 months between ranibizumab and laser therapy.

Panel members discussed the proposition. It had been considered whether to restrict the proposition to specific subgroups within the licensed indication however, the PWG did not believe that the subgroup analysis supported restricting the proposition to these groups and hence have proposed that a broader inclusion criterion broadly in line with the licensed indication should be used. Panel members agreed that the licenced indication should be referred to and then state the one indication that is off-label.

It was noted in the EHIA that this treatment may help reduce inequalities and improve safety.

Panel noted this treatment is already in use as has been provided free of charge since 2020 but this will expire at the end of this year.

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:

- In the inclusion criteria the licenced indication should be referred to and then state the one indication that is off-label.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, National Director, Specialised Services

PWG post panel revisions

Policy proposition:

- In the inclusion criteria the licenced indication should be referred to and then state the one indication that is off-label. **Actioned**