Engagement Report

Topic details

Title of policy or policy statement:	**Ranibizumab in Retinopathy of Prematurity**
Programme of Care:	**Trauma**
Clinical Reference Group:	**Specialised Ear and Ophthalmology services**
URN:	**2201**

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

Retinopathy of prematurity (ROP) is a condition which can affect the eyes in preterm babies.

As the condition is preventable, all preterm (<31 weeks' gestational age) or low birth weight (<1,501g birth weight) babies are screened for it. The condition affects blood vessels (which carry blood around the body) in a part of the eye called the retina. The retina is at the back of the eye. It detects light and sends messages to the brain, which allows us to see. In severe ROP, blood vessels do not develop the way they are meant to in the retina. These abnormal blood vessels grow because of a substance called vascular endothelial growth factor (VEGF) which is produced in unusually high levels in the eyes affected by ROP. These abnormal vessels can turn into damaging scar tissue which can lead to blindness in the most severe cases.

If severe ROP is diagnosed, treatment will be offered within 48 or 72 hours depending on the severity of the diagnosis.

Severe ROP is usually treated with laser therapy. This treatment works very well and reverses severe ROP about 90% of the time. Laser therapy produces small burns to areas of the retina without good blood supply, which in turn reduces the amount of VEGF produced in the eye, and this stops abnormal blood vessels from growing further. For most babies, one treatment is enough. However, 1 in 7 to 1 in 10 babies will need re-treatment, usually around 2-3 weeks later. Babies will require several regular eye check-ups in the first four weeks after treatment and annual follow up in the eye clinic to monitor their eyesight for vision problems up to age 5.

An alternative treatment includes using injections into the eye. In these cases, a drug called ranibizumab, an anti-VEGF solution, is injected inside the eyes using a precise injection system. This temporarily stops the action of VEGF, which reduces or reverses the growth of the abnormal vessels. This treatment has been shown to work well and can be easier to perform than laser. However, it requires many months of regular eye examinations afterwards. Up to 1 in 3 (31%) babies will need a second treatment within 4 months of the first treatment taking place. Follow up following ranibizumab in the first

year is more frequent and intensive than with laser therapy, with regular follow up in the first six months followed by annual follow up to age 5.

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 was sent for stakeholder testing for 2 weeks from 1st November 2022 to 15th November 2022. 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 support the proposition for ranibizumab for retinopathy of prematurity to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- 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.

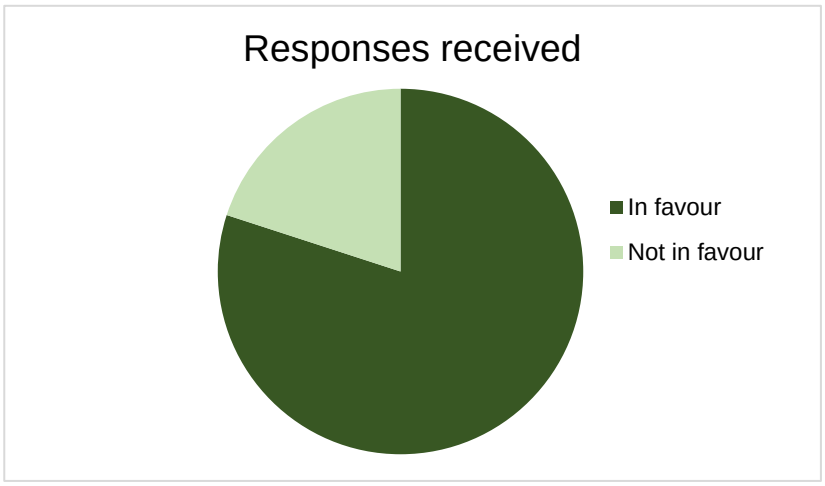
A 13Q assessment has been completed following stakeholder testing.

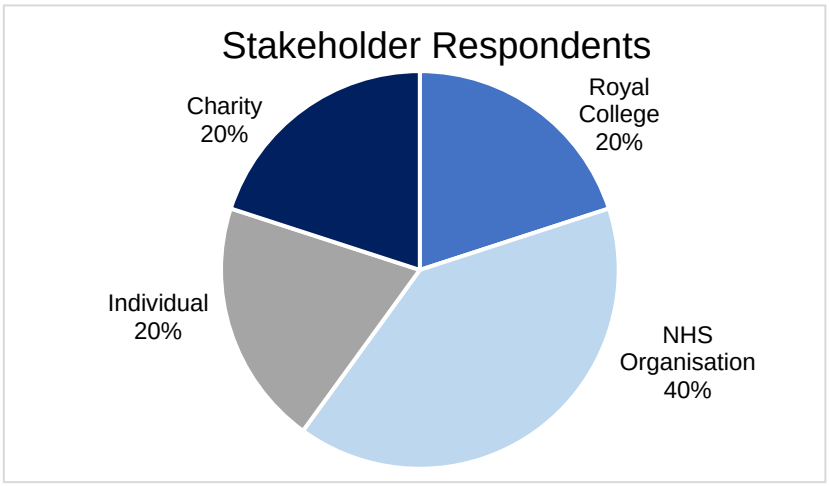
The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation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

4. Engagement Results (stakeholder testing)

Five responses were received:

- One charity relating to blindness
- Two NHS Organisations
- One Royal College
- One individual





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 Trauma PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
General agreement that there is enough evidence to support making the treatment available at this time. No extra evidence was identified. One stakeholder suggested the policy proposition should be in line with the Royal College of Ophthalmology's guidelines for the use of ranibizumab in ROP and the need to refer to the College's guidelines in the policy. Another stakeholder expressed concern that the policy proposition does not mention	This policy proposition is based on available peer reviewed published evidence from the independent evidence review. Guidelines are not considered in the evidence base in line with published methods. The policy proposition is specifically for ranibizumab and other drugs within the drug class are outside the scope of the policy proposition. A preliminary policy proposition can be submitted for other

other forms of anti-VEGF drugs that are available, and the opportunity to use alternative therapies within the policy. There was also concern about the unknown side effects of the drug on the child as they develop.	treatments supported by peer reviewed published evidence. Noted. It is not possible to comment in the policy proposition on unknown side effects. The MHRA yellow card system should be used to report suspected side effects to medicines. Furthermore, the policy proposition includes that the commission position may be reviewed as a result of newly published evidence.
Potential positive and negative impacts on patient care	
Most stakeholders felt there would overall be a positive impact on patients. One stakeholder felt this would have an overall positive outcome on patients but expressed concerns over the unknown systemic and long-term effects on the developing child. One stakeholder felt this policy would have a negative impact on patients due to the following issues: - Restricts the use of other anti-VEGF drugs - Ease of access - Additional follow-up required - Need for re-treatment - Need for repeat general anaesthetic	Noted. It is not possible to comment in the policy proposition on unknown side effects. The MHRA yellow card system should be used to report suspected side effects to medicines. Furthermore, the policy proposition includes that the commission position may be reviewed as a result of newly published evidence. This policy proposition is for ranibizumab, and other anti-VEGF drugs are out of scope. If the use of other anti-VEGF is supported by peer reviewed published evidence, then a preliminary policy proposition can be submitted. This is not felt to negatively impact patients, as the policy proposition provides an alternative treatment to the current commissioned standard of care. Follow up for ranibizumab has been considered in the impact assessment. The PWG consensus was that most centres will not use general anaesthetic to deliver ranibizumab. Additionally, this was felt to be an acceptable risk to patients as the alternative option is laser therapy with general anaesthetic or, if laser is not appropriate, potential blindness.
Further comments	
One stakeholder noted that biosimilars are available which have not been studied, but which are cheaper. However, as the dose of ranibizumab is so small, a highly accurate syringe (only supplied by the ranibizumab drug company) needs to be	Biosimilars that are not licenced for ROP and therefore cannot be used ahead of a licenced product. Noted.

used. The concern is that other preparations may be prone to inaccuracy. Another stakeholder wanted to highlight the importance of involving the baby's parents/carers in every stage of the treatment and ensure shared decision making and clear discussions are in place at every stage.	
Patient Impact Assessment	
The overall response from the stakeholders was that they agreed with the lived experience of patients and carers of this condition described in the patient impact summary. One stakeholder noted that treatment is not always successful, and the condition can still lead to blindness. Another stakeholder felt that whilst the health and physical impacts were mentioned in the impact summary, it fails to address the mental wellbeing and social impacts such as schooling, learning, and accessing support.	Noted. Noted. The patient impact assessment reflects the impact of the condition and does not take into account the treatment. Noted. This is stated in the policy.
Potential impact on equality and health inequalities	
The overall response from the stakeholders was that they agreed with equality and health inequalities impact assessment. One stakeholder felt this policy would have a negative impact on patients due to the following issues: - Restricts the use of other anti-VEGF drugs - Ease of access - Additional follow-up required - Need for re-treatment - Need for repeat general anaesthetic	Noted Follow up for ranibizumab has been considered in the impact assessment. The PWG consensus was that most centres will not use general anaesthetic to deliver ranibizumab. This is stated in the EHIA. Additionally, this was felt to be an acceptable risk to patients as the alternative option is laser therapy with general anaesthetic or potential blindness.

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

The following changes based on the engagement responses have been made to the policy proposition:

- The policy proposition wording has been amended to specify that ranibizumab is an option when treatment with laser is not suitable.

- A sentence has been added to encourage contribution of data to the European data registry to monitor the outcomes, and the mandating for local data collection to monitor for outcomes such as neurodevelopmental problems. This can be mandated and any costs can be included in the Impact Assessment and Finance Model.
- The wording of the EHIA has been amended to add a sentence about shared decision making in the '*carers of patients'*, '*age'* and '*looked after children'* sections. A similar sentence has been added to the policy proposition.
- The patient impact assessment has been updated to include the impact of ROP on patient's and carer's mental wellbeing and social outcomes.

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

No