

NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. **Name of the proposal (policy, proposition, programme, proposal, or initiative):** Ranibizumab in retinopathy of prematurity (ROP) [2201]
2. **Brief summary of the proposal in a few sentences**

Retinopathy of prematurity (ROP) is a sight threatening condition caused by abnormal vascular development in the retina linked with vascular endothelial growth factor (VEGF) in preterm babies. The policy is to use ranibizumab for a subset of babies who may benefit from using this drug when the current standard treatment of diode laser is not clinically suitable.

For eligible babies, ranibizumab is a simpler intervention which, unlike standard laser treatment, does not require sedation with general anaesthetic and can be performed in an appropriate neonatal intensive care unit. Evidence suggests that ranibizumab is associated with a larger reduction in myopia than laser after 2 years. However, ranibizumab requires regular (weekly, twice monthly, and monthly) follow up in the first year, and annual follow up until age 5 years. By contrast, laser requires fewer follow up visits. Retreatment rates with ranibizumab are also higher than those with laser.

3. **Main potential positive or adverse impact of the proposal for protected characteristic groups summarised**

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A** if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age: older people; middle years; early years; children and young people.	This condition only occurs in preterm babies and therefore would be the cohort who stand to benefit from this policy.	Clinicians should ensure parents/carers are involved in every stage of the baby's treatment and that shared decision making is used to enable parents/carers to make informed decisions.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary by preterm age.</p> <p>Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p>	<p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>Disability: physical, sensory, and learning impairment; mental health condition; long-term conditions.</p>	<p>ROP can result in blindness and life-long visual impairment in preterm babies. This policy would be positive in reducing the impact of visual impairment with the potential to reduce life-long effects of ROP for preterm babies.</p> <p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment varies by disability or leads to disability.</p> <p>The impact of this policy is restricted by the scope to preterm babies. The intervention requires more intensive follow up than standard treatment. This would add additional burden for disabled carers of babies receiving ranibizumab who may struggle to travel to appointments.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue engaging with follow up appointments.</p> <p>Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>Gender Reassignment and/or people who identify as Transgender</p>	<p>ROP prevalence, intervention effectiveness, or patient access to treatment, is not known to vary in</p>	<p>Not applicable</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	prevalence by gender reassignment or gender identification.	
Marriage & Civil Partnership: people married or in a civil partnership.	ROP prevalence, intervention effectiveness, or patient access to treatment, is not known to vary in prevalence by marriage and civil partnership.	Not applicable
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	<p>The intervention may have a positive impact on women who have given birth to preterm babies with ROP by providing an additional treatment option for their child which may improve on medium term (2 year) clinical outcomes of the standard treatment.</p> <p>The intervention requires more intensive follow up than standard treatment and this adds additional burden for carers of children as specified in the carers section below.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Race and ethnicity ¹	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary by race/ethnicity.</p> <p>Preterm birth is more common among minority ethnic group and racial groups than amongst white groups. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>Multi-ethnic UK evidence has shown that the prevalence of severe ROP requiring treatment varies significantly by maternal ethnicity Black and Asian groups independently of birthweight and gestational age.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
Religion and belief: people with different religions/faiths or beliefs, or none.	ROP prevalence, intervention effectiveness, or patient access to treatment, is not known to vary in prevalence by religion and belief.	Not applicable
Sex: men; women	ROP prevalence, intervention effectiveness, or patient access to	Not applicable

¹ Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	treatment, is not known to vary in prevalence by gender reassignment or gender identification.	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	ROP prevalence, intervention effectiveness, or patient access to treatment, is not known to vary in prevalence by gender reassignment or gender identification.	Not applicable

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A** if your proposal will not impact on patients who experience health inequalities.

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary by looked after status. Low birthweight at delivery is more common among looked after young people. Therefore, the beneficial impacts	The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the

² Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>Specialised Ophthalmology (paediatrics) service specification.</p> <p>Clinicians should ensure a baby's parent/carers are involved in every stage of the baby's treatment and that shared decision making is used to enable parents/carers to make informed decisions.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>Carers of patients: unpaid, family members.</p>	<p>The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Clinicians should ensure parents/carers are involved in every stage of the baby's treatment and that shared decision making is used to enable parents/carers to make informed decisions.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss -</p>

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
		https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/
<p>Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.</p>	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary by children of mothers who are homeless.</p> <p>Preterm birth is more common among people who are homeless. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.</p>	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary by children of mothers who are involved in the criminal justice system.</p> <p>Preterm birth is more common among women involved in the criminal justice system. Therefore, the beneficial impacts</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the</p>

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>of this policy I may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>People with addictions and/or substance misuse issues</p>	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers with addictions and/or substance misuse issues.</p> <p>Preterm birth is more common among women with addictions and/or substance misuse issues. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. A documented discussion between available multi-disciplinary team members should take place to support this decision.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p>People or families on a low income</p>	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers from low income households.</p> <p>Preterm birth is more common among women from low income households. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
<p>People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).</p>	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers with poor literacy or health literacy.</p> <p>Women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p>

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
		Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/
People living in deprived areas	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers living in deprived areas.</p> <p>Preterm birth is more common among women living in deprived areas. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
People living in remote, rural and island locations	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers living in remote, rural or island locations.</p> <p>Women from this group often experience challenges accessing healthcare. The intervention requires more intensive</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable</p>

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
Refugees, asylum seekers or those experiencing modern slavery	<p>There is no evidence to suggest that clinical outcomes of ranibizumab versus laser treatment vary for children of carers refugees, asylum seekers or those experiencing modern slavery.</p> <p>Preterm birth is more common among women living in deprived areas. Therefore, the beneficial impacts of this policy may positively benefit those groups proportionate to that need.</p> <p>This said, women from this group often experience challenges accessing healthcare. The intervention requires more intensive follow up than standard treatment and as such the intervention may present more challenges for carers from this group than standard care.</p>	<p>The policy recommends that the suitability of ranibizumab as an intervention is assessed by the treating physician. This includes considering the support and care mechanisms a patient's carers would require to continue to engage with follow up appointments. Commissioned providers should ensure appropriate support is put in place to enable equitable access to the service, as outlined in the Specialised Ophthalmology (paediatrics) service specification.</p> <p>Ensure that women and their partners are referred to appropriate support groups such as Bliss - https://www.bliss.org.uk/ or Spoons - https://spoons.org.uk/</p>
Other groups experiencing health inequalities (please describe)	None identified	Not applicable

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	No x	Do Not Know
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b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	Stakeholder testing	The policy was sent for stakeholder testing for 2 weeks from 1 st November 2022 to 15 th November 2022. Five responses were received: One charity relating to blindness, two NHS Organisations, one Royal College, and one individual. In line with the 13Q assessment it was deemed that further public consultation was not required.	November 2022
2			
3			

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	Adams GG, Bunce C, Xing W, Butler L, Long V, Reddy A, et al. Treatment trends for retinopathy of prematurity in the UK: active surveillance study of infants at risk. BMJ Open. 2017;7(3):e013366.	Cost-effectiveness, evidence on differential effectiveness.
Consultation and involvement findings	No additional evidence was provided.	Long term effects of ranibizumab on the developing child. Patients receiving ranibizumab will be added to a local or international database and outcomes will be followed up to assess long term effects and inform future revisions to this policy.
Research	No bespoke research commissioned	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The EHIA was reviewed by a Policy Working Group (PWG) including clinical specialists and patient and public representative from the Spoons neonatal support group	The PWG has reviewed and identified no gaps in evidence. Suggested revisions to the document by the PWG have been incorporated.

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?	x	x	x
Uncertain whether the proposal will support?			

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?		
The proposal may support?	x	x
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research, or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1 Not applicable	
2 Not applicable	
3 Not applicable	

10. Summary assessment of this EHIA findings

The findings of this assessment are that this policy will support a cohort of babies to receive an improved treatment for a sight threatening condition when standard of care treatment is not suitable. Preterm birth is more common in socio-economically disadvantaged groups. Therefore, by giving national access to this treatment across the population, it would in theory narrow social inequalities by improving ocular outcomes for those children. As has been highlighted throughout, the treatment requires more extensive and repeated engagement with healthcare over a long period and has a higher retreatment rate than current standard of care, and this is often observed to be challenging for disadvantaged families. As such, to ensure that it does narrow inequalities, there needs to be careful consideration of whether the clinical benefits outweigh the access issues for families, and if it is decided that they do, that families for whom access is likely to be a particular issue are provided with support to ensure continued engagement with follow up appointments.

11. Contact details re this EHIA

Team/Unit name:	Clinical Policy Team
Division name:	Specialised Commissioning
Directorate name:	
Date EHIA agreed:	
Date EHIA published if appropriate:	