

# Policy for: Medical Retinal Treatment Pathway in Wet Age-related Macular Degeneration

Reference Number:	MO/18
Version:	V3
Name of responsible Committee and date approved or recommended to Integrated Care Board:	Finance and Performance Committee
Date approved by the Integrated Care Board (if applicable):	Nov 2025
Next Review Date:	May 2028
Expiry Date:	Nov 2028
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## VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

6/8/2025	V3	Minor suggestions around wording and formatting	Reviewer, PDG, Clinicians, deputy CMO, HCDs meeting members
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## **1. Category: Prior approval**

Prior approval from the Integrated Care Board (ICB) will be required before any treatment proceeds in secondary care unless an alternative contract arrangement has been agreed with the ICB that does not necessitate the requirement of prior approval before treatment.

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity relating to the use of medical retinal vascular treatments for the management of wet Age Related Macular Degeneration (wAMD) by the Integrated Care Board (ICB).

For patients who **DO NOT** meet the eligibility criteria, the ICB will only consider funding the treatment if an Individual Funding Request (IFR) detailing the patient's clinical presentation is submitted to the ICB.

## **2. Background**

NHS England have developed a unified national treatment pathway for wAMD, providing clear guidance on starting, switching, and stopping criteria to ensure patients receive optimal treatment at the appropriate stage. Additionally, a review of treatment data was conducted to identify the most cost-effective options while addressing ongoing capacity limitations.

The treatment pathway aims to support systems with commissioning of NICE approved treatments at the right point in the patient pathway. This will ensure patients have access to the best value treatments at the right point. The goal of developing national pathways is to reduce the considerable variation across England and to optimise use of the treatments available. This will support the should cost, should deliver approach to commissioning as highlighted in the model ICB blueprint.

This pathway was developed, in conjunction with input from a national expert working group.

Coventry and Warwickshire ICB will be adopting the national treatment pathway for wAMD to ensure equity of access across the system. Reference has been made to 'recommendations for best practice' and 'commissioning requirements'.

## **3. Indication**

Wet Age-related macular degeneration (wAMD).

## **4. Commissioning position**

Treatment is commissioned in line with the national treatment pathway as outlined in section 4.2. Commissioning requirements have been referred to under section 4.3.

#### 4.1 Key recommendations

- The ICB will only commission treatment that strictly adheres to the national treatment pathway as outlined in section 4.2. Any deviation must be supported by an approved Individual Funding Request (IFR).
- Analysis, based on both clinical trial data and real-world evidence, shows that adopting a treat-and-extend approach as standard with **aflibercept 2mg biosimilar** achieves the same patient outcomes at a lower cost. This makes it the best value option and should be used first line alongside ranibizumab biosimilar.
- This recommendation has looked at both medicines and activity costs.
- The modelling showed no significant difference in the number of injections between treatments, especially when treatment response is good. This is evidenced by real world data from a sample of Trusts (see Table 1, Appendix 2). The treat and extend regimen, with aflibercept biosimilar as first line, this best value pathway will deliver the same clinical outcomes, cost significantly less, and likely have a minimal effect on capacity.

#### Commissioning rules: summary table

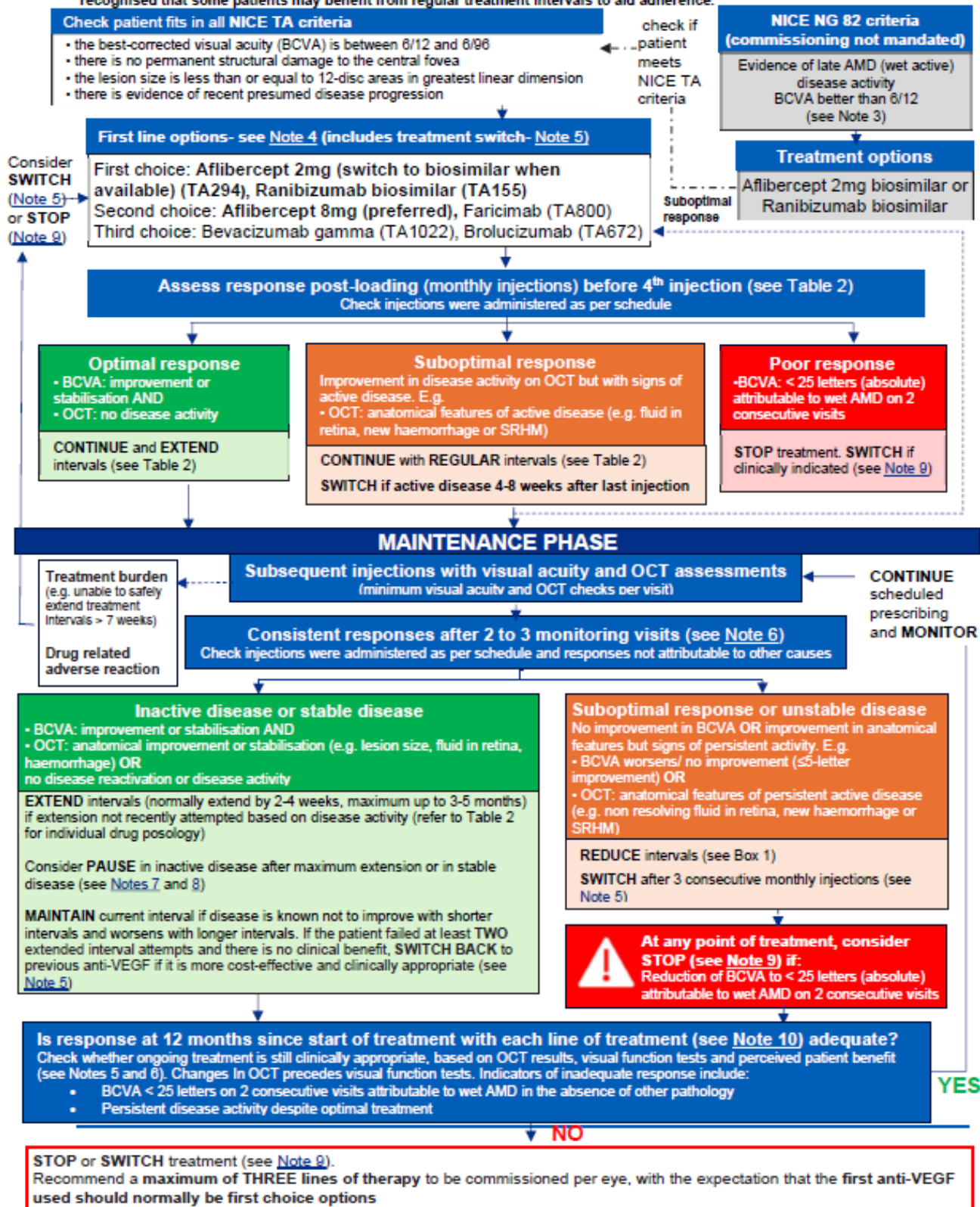
Line of Therapy	Commissioned Agents	Conditions	Prior Approval Required
First Line	Aflibercept 2mg biosimilar, Ranibizumab biosimilar	Standard	No (if criteria met)
Second Line	Aflibercept 8mg (preferred), Faricimab	Clinical justification or capacity constraints	Yes
Third Line	Brolucizumab, Bevacizumab gamma	Exceptional cases	Yes

## 4.2 Treatment algorithm for wAMD

(Taken from Commissioning Guidance: Medical Retinal Treatment Pathway in Wet Age-related Macular Degeneration, NHS England, published June 2025)

If more than one treatment is suitable, use the least expensive treatment. Use best value brand available locally.

#This guideline is based on treat-and-extend protocol, which is the preferred regime for most patients and services. It is recognised that some patients may benefit from regular treatment intervals to aid adherence.



### 4.3 Notes

The following outlines notes and recommendations within the treatment pathway. These are specified as 'best practice' and/or 'commissioning requirements'. Please see Appendix 1 for associated rationale, Appendix 2 for Tables, Appendix 3 for abbreviations and Appendix 4 for definitions.

#### Note 1: Treatment goals

For most patients, the main treatment goals are:

- Preservation of visual function (e.g. BCVA improvement or stabilisation)
- Anatomical improvement from OCT (e.g. lesion size, fluid in retina, haemorrhage) with no signs of disease activity.

It is recognised that not all patients can achieve complete disease remission despite frequent and timely dosing due to the progressive nature of the disease.

#### Recommendations for best practice:

The following recommendations are intended to support decision making and do not constitute commissioning requirements unless otherwise stated.

#### Best practice: Recommendation 1.

At the beginning of the treatment, communicate with patients at treatment initiation of all treatment possibilities at the outset. This would include:

- Expected treatment outcomes and treatment burden with patients. Use real-world data to support communication, especially those with "poor" vision.<sup>3,4</sup>
- Potential treatment changes throughout their journey, including the use of best value medicines when available.
- Potential for stopping treatment if there is no further clinical benefit with continued treatment.

Communicating with patients at the beginning of treatment about all treatment possibilities is crucial for setting realistic expectations. This transparency helps patients understand the potential outcomes, benefits, and risks associated with each option, enabling them to make informed decisions about their care.

Clear communication can help mitigate anxiety and prevent misunderstandings or disappointments later on, ensuring that patients have a clear and accurate understanding of their treatment journey from the outset.

A decision support tool for wet AMD has been developed to support shared decision-making discussions with patients and is available here:

[NHS England » Decision support tool: making a decision about wet age-related macular degeneration](#)

#### Note 2: Service delivery by other healthcare professionals

Some SPCs (e.g. Ongavia<sup>®</sup>) mandate administration by "a qualified ophthalmologist experienced in intravitreal injections". However, in practice this may be administered by a

suitably trained healthcare professional (HCP). [RCOphth guidance](#) acknowledges this and recommends that 'it is essential that the HCP always has immediate access to advice from an ophthalmologist whilst giving injections and an appropriately trained clinician is available on site to deal with any very urgent complications'.<sup>1</sup>

In such circumstances, intravitreal injections performed by the HCP will be 'off-label'. Local governance processes should be in place to manage any ophthalmological or medical complications.

**Note 3: Use of anti-vascular endothelial growth factor (VEGF) outside the NICE visual acuity criteria**

NICE NG82 (not mandatory) recognise the use of anti-VEGFs outside visual acuity criteria set in NICE TAs, depending on the drug and regimen used.<sup>2</sup>

Recommendations for best practice- subject to local commissioning agreement:

**Best practice: Recommendation 2.**

Consider treating patients with "good" vision (i.e. VA  $\geq 6/12$  or  $\geq 70$  letters). Use aflibercept 2mg biosimilars or ranibizumab biosimilars as treatment options for this cohort of patients.

It would be better value to treat "good" vision patients with biosimilars because they retain this level of vision based on the NOD AMD audit.<sup>3</sup> This cohort of patients tend to respond better therefore reduce the need to switch to other more expensive therapies.

Patients who do not respond to both aflibercept 2mg biosimilars and ranibizumab biosimilars would not have the option to switch to other treatments, unless BCVA deteriorates and meets NICE TA criteria.

**Note 4: Choice of therapy**

If more than one treatment option is suitable and service capacity allows for timely treatment, choose the least expensive (taking into account administration costs, frequency and commercial arrangements) unless an order of preference is stated in the TAs or by the local commissioner.

Clinicians are advised to consider the patient's medical history, existing treatment in the other eye (if receiving treatment) and patient factors. [Medicines and Healthcare Regulatory Agency \(MHRA\)](#) recommends brand name prescribing.<sup>6</sup> If more than one biosimilar brand is available, choose best value brand available locally.

**Recommendations for best practice and commissioning requirements**

The following statements represent recommendations for best practice or commissioning requirements (please see individual boxes):

**Commissioning requirement: Recommendation 3.**

Where clinically appropriate, use aflibercept 2mg (switch to biosimilar once available) and ranibizumab biosimilar as first choice options.

Examples of specific clinical considerations where aflibercept or ranibizumab may not be appropriate:

- Non-responder to ranibizumab/ aflibercept in fellow eye previously
- Ranibizumab-specific contraindications: subretinal bleed >50% of lesion, idiopathic polypoidal choroidal vasculopathy [PCV]<sup>7</sup>.

**Commissioning requirement: Recommendation 4.**

Use aflibercept 8mg (preferred) and faricimab as second choice options. This is usually when high injection frequency is not acceptable with first choice options.

Examples where use may be appropriate:

o Capacity constraints

- Capacity constraints are normally represented by inability within a service to deliver treatment in a timely way to patients as part of business as usual (BAU). This could be represented by frequent insourcing and outsourcing in order to meet intravitreal treatment demand. Definition of capacity constraints needs to be agreed locally between providers with commissioners.
- Providers are robustly encouraged to transform their services to create the capacity which their service demands, using some of the savings generated by first-choice agents.

o Patient factors

- The following patient groups may be better managed with the least number of injections which will outweigh the cost:
  - learning difficulties
  - dementia
  - hospital transport
  - requiring treatment in the operating theatre under sedation/deep sedation/general anaesthesia
  - frequent inpatient hospital admissions or other regular attendance (e.g. chemotherapy)

o Clinical factors

- Non-responder to first-line choices in fellow eye previously
- Treatment harmonisation (see recommendation 6 below)

**Commissioning requirement: Recommendation 5.**

Use brolocizumab and bevacizumab gamma (licensed) as third choice options.

**Commissioning requirement: Recommendation 6.**

Where one eye is already on treatment, but the other eye qualifies for another treatment, prioritise treatment harmonisation by choosing the best treatment options for both eyes (i.e using only one drug for both eyes).

**Note 5: Consider treatment switch if:**

- suboptimal response after loading phase or (post-loading) at any other injection point due to resistance to current agent after 3 consecutive monthly intravitreal injections<sup>4</sup> AND there is still potential for improvement in vision, or improved stabilisation at 6/96 or

better, with further treatment

- symptoms of allergy or presumed tachyphylaxis<sup>4</sup>
- adverse events related to drug<sup>1</sup>
- frequent injections (e.g. < 8-week intervals) required to maintain disease stability and treatment burden not acceptable to either patient or service delivery<sup>4</sup>
- when patient injection burden is highlighted
- where treatment harmonisation is required (see Note 4, recommendation 6 for details)

**Commissioning requirement: Recommendation 7.**

If the patient failed at least TWO extended interval attempts and there is no clinical benefit, switch back to previous anti-VEGF if it is more cost-effective and clinically appropriate.

Consider switching to an alternative anti-VEGF if this is the patient's second anti-VEGF.

**Commissioning requirement: Recommendation 8.**

The ICB will commission a maximum of THREE lines of therapy per eye. The first line must be aflibercept 2mg biosimilar or ranibizumab biosimilar. Second and third line therapies may be considered only under the conditions outlined in section 4.2 and must be agreed locally.

The following scenarios should not count as a line of therapy:

- Switch from branded to biosimilar and vice versa, biosimilar to biosimilar switches for the same agent
- Switch back to a previous anti-VEGF (i.e. those who did not experience clinical benefit after failed extended interval attempts with newer agents)
- Switch due to adverse drug events or allergy

**Note 6: Confounding factors in response assessments**

Be aware that responses can be affected by other causes and may require further assessments to confirm a true suboptimal or poor response. Examples include, but not limited to:

- not consistently wearing vision correction equipment at each visual assessment
- in early dementia patients where comprehension may fluctuate at each visit
- development of cataracts (see also Note 11)

**Note 7: Disease activity in the long term**

Some patients will have stable disease activity or persistent subretinal fluid despite frequent and timely dosing. This is due to the progressive nature of wet AMD. Consider early review (i.e. at 2 weeks to confirm a lack of further response).

**Note 8: Treatment pause**

Clinicians may consider temporarily withholding treatment if:

- no disease activity [i.e. disease has become inactive on maximum extension (usually 3 to 5 month intervals depending on the drug- see Table 2 for details) after 2-3 doses]

[RCOphth guidance \(section 10.4\)](#) recommends monitoring with visual acuity and OCT for disease reactivation. Although there is no data on length of monitoring period required, there is consensus that patients should be monitored for at least 2 years after disease stability is

achieved.<sup>4</sup> If there is recurrence of disease activity, treatment is reinstated until disease stabilisation is achieved, as indicated by best corrected visual acuity and/or lesion morphology.

### **Note 9: Stopping treatment (e.g. permanent discontinuation)**

#### **Commissioning requirement: Recommendation 9.**

#### **REVIEW with consideration to stop treatment if:**

- visual acuity < 25 letters (absolute) on 2 consecutive visits despite optimum treatment (see also Note 6 and 11) AND
- attributable to wet AMD in the absence of other pathology AND
- structural results (e.g. OCT) suggest no prospect of visual improvement with continued treatment.

Questions to be considered when deciding whether further treatment is beneficial (discontinue treatment if yes to all the below):

- Has the patient completed loading phase?
- Is the patient's treatment optimised (i.e. they have been receiving adequate injections at optimal intervals on time)?

*On average, a patient initiated on treatment would require 6 injections in the first year and 5 injections in the second year. From the third year, an average of 5 injections are required to prevent decrease in vision due to inadequate treatment.<sup>4</sup>*

- Has the patient exhausted a reasonable number of treatment options (maximum of THREE lines of anti-VEGFs are recommended)?
- Is the treated eye the WORSE seeing eye?
- Does the patient agree that they DO NOT receive continuing benefits from treatment?

#### **Commissioning requirement: Recommendation 10.**

#### **Treatment STOP recommended if:**

- ⊖ visual acuity < 15 letters (absolute) on 2 consecutive visits despite optimum treatment (see also Note 6 and 11) AND
- attributable to wet AMD in the absence of other pathology

Where a decision is made to discontinue treatment permanently where risks of giving injections outweigh its potential benefits, no further monitoring is required for that eye. These patients may be discharged from the hospital eye service (refer to [RCOphth guidance](#) section 10.5 for further information).<sup>4</sup>

A decision support tool for wet AMD has been developed to support shared decision-making discussions with patients and is available here:

<https://www.england.nhs.uk/publication/decision-support-tool-making-a-decision-about-wetage-related-macular-degeneration/>

### **Note 10: Initial 12-month and annual response assessments**

After 12 months of intravitreal injections, most patients are expected to have:

- Stabilisation of visual function (improvement or preservation)
- Anatomical improvement from OCT (e.g. lesion size, fluid in retina, haemorrhage)

Changes in OCT precedes visual function tests.<sup>4</sup>

#### **Commissioning requirement: Recommendation 11.**

Consider treatment switch (see Note 5) or permanent discontinuation (see Note 9) if:

- BCVA < 25 letters on 2 consecutive visits attributable to wet AMD in the absence of other pathology (see also Note 6 and 11) OR
- Persistent disease activity despite optimal treatment

#### **Commissioning requirement: Recommendation 12.**

The management of the patient should be reviewed by a senior specialist annually to consider if continuation of treatment is in patient's best interest.

### **Note 11: Cataracts**

#### **Best practice: Recommendation 13.**

If a patient is scheduled for a cataract operation within the next 3 months and if it is anticipated that vision will improve due to the procedure, discontinuation criteria may no longer apply, and patient may continue treatment.

## 5. References

### Based on Commissioning Guidance: Medical Retinal Treatment Pathway in Wet Age-related Macular Degeneration, NHS England, published June 2025

#### Specific references outlined below:

1. The Royal College of Ophthalmologists (2018). Ophthalmic service guidance: intravitreal injection therapy. Revised Aug 2018. Accessed 22/07/24 via <https://curriculum.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf>
2. National Institute for Health and Care Excellence (2018). [NICE guideline 82 \(NG82\): Age-related macular degeneration](#).
3. The Royal College of Ophthalmologists (2024). National ophthalmology database audit: the second report of age-related macular degeneration audit (AMD). Accessed 22/07/24 via <https://nodaudit.org.uk/publications-news-and-events>
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8. Gale et al (2019). Anatomical and functional outcomes following switching from aflibercept to ranibizumab in neovascular age-related macular degeneration in Europe: SAFARI study. *Br J Ophthalmol*. 0:1-7.
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11. Kioke et al (2019). Results of switchback from ranibizumab to aflibercept in patients with exudative age-related macular degeneration. *Clin Ophthalmol*. 13:1247-1251.
12. Baumal et al (2023). Efficacy and safety of brolocizumab in age-related macular degeneration: A systematic review of real-world studies. *Acta Ophthalmol*. 101(2):123-139
13. Rush et al (2022). Intravitreal faricimab for aflibercept-resistant neovascular age-related macular degeneration. *Clin Ophthalmol*. 16:4041-4046
14. Ali et al (2023). Real-world use of faricimab: from the IRIS® Registry. Presented at the Hawaiian Eye and Retina 14-20 January 2023.
15. Sim et al (2025). Real-world 1-year outcomes of treatment-intensive neovascular age-related macular degeneration switched to faricimab. *Ophthalmol Retina*. 9(1):22–30.

16. Goodchild et al (2024). Real world efficacy and durability of faricimab in patients with neovascular AMD (nAMD) who had sub-optimal response to prior anti-VEGF therapy. *Eye (Lond)*. 38(16):3059-3064.
17. National Institute for Health and Care Excellence (2008). [NICE TA155: Ranibizumab and pegaptanib for the treatment of age-related macular degeneration](#).
18. National Institute for Health and Care Excellence (2022). [NICE TA800: Faricimab for treating wet age-related macular degeneration](#).
19. National Institute for Health and Care Excellence (2013). [NICE TA294: Aflibercept solution for injection for treating wet age-related macular degeneration](#).
20. National Institute for Health and Care Excellence (2021). [NICE TA672: Brolucizumab for treating wet age-related macular degeneration](#).
21. National Institute for Health and Care Excellence (2024). [NICE TA1022: Bevacizumab gamma for treating wet age-related macular degeneration](#).
22. Electronic Medicines Compendium. Individual drug summary of product characteristics. Available at <https://www.medicines.org.uk/emc>
23. IPD Analytics. Individual molecule pages. Accessed 19/05/2025 via <https://www.ipdanalytics.com/>

## Appendix 1

### Rationale for notes/recommendations:

#### Note 1/recommendation 1: Treatment goals

NOD AMD 2024 audit<sup>3</sup> identified that at 12 months:<sup>3</sup>

- 77.7% of eyes who received treatment with “good” vision” at the start of treatment retained this level of vision. This corresponds to driving vision according to DVLA standards, provided there are no compounding factors.<sup>5</sup>
- Patients with “poor” vision (i.e.  $\leq 35$  letters) at the start of treatment rarely (6.3%) achieved “good” vision.

#### Note 3/recommendation 2: Use of anti-vascular endothelial growth factor (VEGF) outside the NICE visual acuity criteria:

NOD AMD 2024 audit<sup>3</sup> identified that at 12 months:<sup>3</sup>

- 77.7% of eyes who received treatment with “good” vision” at the start of treatment retained this level of vision. This corresponds to driving vision according to DVLA standards, provided there are no compounding factors.<sup>5</sup>
- For patients with baseline vision of 35-55 letters and 56-69 letters, 19.7% and 47.1% achieve “good” vision at 12 months respectively.

#### Note 4/recommendation 3: Choice of therapy

- These are the cheapest options (taking into account administration costs, frequency and drug cost per annum) according to NHSE modelling based on real world data and projected biosimilar savings. At the time of writing, branded aflibercept 2mg is one of the more expensive options but there are opportunity savings to be made once aflibercept 2mg biosimilars become available (loss of exclusivity expected end of November 2025).

#### Recommendation 4: Rationale:

- More expensive than aflibercept 2mg biosimilar and ranibizumab biosimilar (taking into account administration frequency and drug cost per annum) according to NHSE modelling based on real world data. Our modelling showed no significant difference in number of injections between treatments, provided there is good response to treatment. This is evidenced by real-world data from a random sample of Trusts (See Table 1, Appendix 2).

#### Recommendation 5 Rationale:

- Bevacizumab licensed is the most expensive choice (taking into account administration frequency and drug cost per annum) according to NHSE modelling.
- Risk of intraocular inflammation with brolocizumab.

#### Recommendation 6 Rationale:

- To minimise drug administration error
- Allows easy identification of adverse drug reactions of a single drug compared to administering two different drugs.

**Note 5/Recommendation 7 Rationale: Consider treatment switch**

This is based on feedback from commissioners to ensure best value medicines are used appropriately in the patient's treatment journey.

When switching to a different anti-VEGF, it would be a clinical decision to determine whether reloading is required. [RCOphth guidance](#) recommends the following: <sup>4</sup>

Loading with new agent recommended (within product license):

- those in whom the treatment interval cannot be extended beyond 7 weeks with the current agent.

Loading with new agent may not be required (off label use):

- those managed on longer intervals (8 or more weeks) to reduce treatment burden.

These patients may be switched to new agent on a matched treatment interval followed by a treat-and-extend interval post-initial dose

*This approach may be easier for patients, but it is not known whether loading these patients may increase the chances of further extension so reload may also be considered.*

**Recommendation 8 Rationale:**

There are no randomised controlled trials or head-to-head trials which compare the treatment outcomes for switching between different anti-VEGFs. Real-world cohort studies have shown that patients do benefit from switching to an alternative anti-VEGF. It is established clinical practice to switch to a different anti-VEGF for sub-optimal responders.<sup>8-16</sup> The maximum number of treatments recommended is based on expert opinion consensus from the working group. There are no studies which evaluates clinical efficacy when patients are switched between multiple anti-VEGFs. The upper limit aims to encourage biosimilar use, recognising the need to provide alternatives with the limited treatment options available whilst ensuring affordability for commissioners.

**Recommendation 10 Rationale: Treatment STOP:**

The cut off points for visual acuity were based on collective expert opinion from the expert working group.

## Appendix 2

Table 1. Injection frequency comparison across treatments

Number of injections								
First choice drug	ranibizumab	afibercept 2mg	faricimab	afibercept 8mg	ranibizumab	afibercept 2mg	faricimab	afibercept 8mg
Response during maintenance phase	<b>Stable disease</b> <i>Regular dosing required to maintain disease activity</i>				<b>Inactive disease</b> <i>Dose intervals can be extended without affecting disease activity</i>			
Average treatment intervals post-loading	4 weeks	8 weeks	8 weeks	8 weeks	Treat and extend			
Year 1	13	8	7	8	7	6	6	6
Year 2	13	6	7	6	4	3	3	2
Year 3	13	7	6	7	5	3	3	3

Table 2: Drug dosing details according to SPC

Drug	Cost tier	Posology post-loading		Treat-and-extend dose increment intervals	Maximum treatment intervals	Minimum dose intervals
		No disease activity	Disease activity			
<b>First choice</b>						
Ranibizumab biosimilar	£	Treat-and-extend	Continue monthly	2 weeks	12 weeks	4 weeks
Aflibercept 2mg	£££		Continue 2-monthly	2-4 weeks	16 weeks	4 weeks
Biosimilar once available	£					
<b>Second choice</b>						
Aflibercept 8mg	££	Treat-and-extend	Clinical decision	Not specified	16 weeks, can be further extended to 20 weeks	8 weeks (max once weekly for 3 consecutive doses in used studies)
Faricimab	£££		Continue 8-12 weekly	4 weeks	16 weeks	21 days
<b>Third choice</b>						
Bevacizumab	£££	Treat-and-extend	Continue monthly	Not specified	12 weeks	4 weeks
Brolucizumab	NE	Every 3 months	Every 2 months	Not specified	12 weeks	8 weeks

### Appendix 3: Abbreviations

Abbreviation	Explanation
AMD	Age-related Macular Degeneration
BCVA	Best Corrected Visual Acuity
ICB	Integrated Care Board
LoE	Loss of Exclusivity. Date where generic competitors may enter the market.
MHRA	Medicines and Healthcare Regulatory Agency
NHS	National Health Service
NICE	National Institute of Healthcare and Excellence
NG	NICE Guidance. Recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales. Commissioning of medicines recommended in NICE guidance is not mandatory.
NOD	National Ophthalmology Database
OCT	Optical Coherence Tomography
RCOphth	The Royal College of Ophthalmologists
SHRM	Subretinal Hyper-reflective Material
SPC	Summary of Product Characteristics
TA	Technology Appraisal. The NHS is legally obliged to fund and resource medicines and other treatments recommended by NICE's technology appraisals
VA	Visual Acuity
VEGF	Vascular Endothelial Growth Factor
wAMD	Wet Age-related Macular Degeneration

## Appendix 4: Definitions

Term	Explanation
Fellow eye	The eye opposite the one being treated
Line of therapy	<p>The order in which different therapies are given to people as their disease progresses. The following scenarios should not count as a line of therapy:</p> <ul style="list-style-type: none"> <li>• Switch from branded to biosimilar and vice versa, biosimilar to biosimilar switches for the same agent</li> <li>• Switch back to a previous anti-VEGF (i.e. those who did not experience clinical benefit after failed extended interval attempts with newer agents)</li> <li>• Switch due to adverse drug events or allergy</li> </ul> <p>Worked examples</p> <p>One line of therapy:</p> <ul style="list-style-type: none"> <li>• Patient switched from branded drug A to biosimilar drug A</li> <li>• Patient switched from drug A to B due to adverse drug events</li> </ul> <p>Two lines of therapy:</p> <ul style="list-style-type: none"> <li>• Patient had suboptimal response to drug A, now on drug B</li> <li>• Patient had suboptimal response to drug A, switched to drug B and had a good clinical response. Unable to extend dose intervals beyond 7 weeks so switched to drug C. Still unable to extend dose intervals on drug C and no clinical benefit, so switchback to drug B because it is more cost-effective.</li> </ul> <p>Three lines of therapy:</p> <ul style="list-style-type: none"> <li>• Patient who had suboptimal responses to drugs A and B, now on drug C</li> <li>• Patient had suboptimal response to drug A, then switched to drug B. Unable to extend dose intervals beyond 7 weeks on drug B so switched to drug C. Remains on drug C because has added clinical benefit compared to drug B even though unable to extend dose intervals further.</li> </ul>
Recommendations for best practice	Recommendations made by the expert working group following review of real-world evidence or based on consensus from expert working group. These are subject to local commissioning agreements.
Stopping treatment/permanent discontinuation	A point in the patient's treatment journey where clinicians decide to stop treatment permanently. This is usually when further treatment is unlikely to benefit the patient.
Treatment harmonisation	The act of using only one drug for both eyes. Usually occurs when one eye is already on treatment, but the other eye qualifies for another treatment.
Treat and extend protocol	A standard treatment regimen for treating wAMD, where the interval for the next anti-VEGF injection is extended by 2 to 4 weeks up to a maximum of 20 weeks depending on the anti-VEGF used.
Treatment pause	A point in the patient's treatment journey where clinicians decide to temporarily withhold treatment. This is usually when the disease has become inactive whilst the patient is on a drug with maximum dose extension intervals.
Worse-seeing eye	Also known as the weaker eye. This occurs when one eye sees significantly better than the other eye.

# 1 Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

*Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.*

Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

## Quality Impact Assessment

### Quality and Equality Impact Assessment

<b>Scheme Title:</b>	Medical Retinal Treatment Pathway in Wet Age-related Macular Degeneration (wAMD)		
<b>Project Lead:</b>	Jas Sagoo	<b>Senior Responsible Officer:</b>	Altaz Dhanani
		<b>Quality Sign Off:</b>	Quality EQIA Panel
<b>Intended impact of scheme:</b>	<ul style="list-style-type: none"> <li>Align with national NHS E recommendations</li> <li>Consistency across the ICS departments &amp; Independent Sector Providers</li> <li>Promote best practice and use of cost-effective treatments thereby leading to efficiencies</li> <li>Create capacity within ophthalmology departments</li> </ul>		
<b>How will it be achieved:</b>	<ul style="list-style-type: none"> <li>This will set out a clear policy for the criteria and approval process for the use of medicines in the management of wAMD.</li> <li>Off label use of licensed preparation: clinical teams to seek patient consent and document in patient notes.</li> <li>Publication &amp; implementation of this policy</li> <li>Mapping Blueteq forms over to local policy</li> </ul>		

<b>Name of person completing assessment:</b>	Jas Sagoo
<b>Position:</b>	Lead Pharmacist – Medicines Optimisation
<b>Date of Assessment:</b>	29/09/2025 updated 15/10/2025

<b>Quality Review by:</b>	QIA panel
<b>Position:</b>	Quality Team Members
<b>Date of Review:</b>	16 10 2025

### High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
<b>Duty of Quality</b> Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	√			Patients to be treated in line with national pathway, with the aim of preserving eyesight/prevent eyesight from deteriorating. Outcome captured via Blueteq. Policy to implement access for eligible patients to receive clinically effective NHS funded treatment.				
	Patient experience	√			Policy to implement access for eligible patients who will be assured that they are accessing evidenced based practice to receive clinically effective NHS funded treatment. The aim is to preserve eyesight/prevent eyesight from deteriorating. Patients will obtain the service delivered by the policy in a timely and consistent manner, delivered by trained registered				

				healthcare professionals.				
	Patient safety	√		Implement policy in a safe and consistent manner.  The provider will follow the Patient Safety Incident Response Framework (PSIRF) national guidance on reporting incidents via the Learning from Patient Safety Events (LFPSE) system as per individual policy/procedures to protect patients and maintain safety.				
	Parity of esteem	√		Policy allows access for patients to receive clinically appropriate treatment which includes access to mental health and physical health support within the Tier 1-4 services				
	Safeguarding children or adults	√		Maintenance of current safeguarding arrangements as per ICB Local Authority and/or Provider safeguarding policies and procedures. A systemwide approach to care with a collaborative, integrated approach, will enable learning from incidents to be shared across the system.				
<b>NHS Outcomes Framework</b> Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	√		Policy allows access for patients to receive clinically appropriate treatment which will reduce the risk of disease and/or improve outcomes. Namely treatment aims to enhance/preserve eyesight and/or prevent eyesight from deteriorating.				

	Ensuring people have a positive experience of care	√			Policy allows access for patients to receive clinically appropriate treatment. Increased opportunity for patients to access the service locally and nationally via patient choice.				
	Preventing people from dying prematurely			√	Policy allows access for eligible patients to receive clinically appropriate treatment which will reduce the risk of disease and/or improve outcomes.				
	Helping people recover from episodes of ill health or following injury	√			Policy allows access for patients to receive clinically appropriate treatment which will reduce the risk of disease and/or improve outcomes. Namely treatment aims to enhance/preserve eyesight and/or prevent eyesight from deteriorating. Patients eligible for this NHS funded treatment will be able to receive appropriate medication to manage their wAMD symptoms.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm	√			Policy allows access for patients to receive clinically appropriate treatment in a safe environment that has measures to protect from avoidable harm. The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality of care in line with the Care Quality Commission (CQC) "quality statements".				

<b>Patient services</b> Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors	√			This policy has an integrated care approach to ensure patients receive clinically appropriate treatments.				
	Access to the highest quality urgent and emergency care			√	This policy has an integrated care approach to ensure patients have access to urgent and emergency care services which can direct patients, including those most complex and unwell patients, and their carers appropriately. This policy is intended to be delivered in an appropriate setting including acute and accredited Independent Sector Provider settings.				
	Convenient access for everyone	√			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive NHS funded treatment.				
	Ensuring that citizens are fully included in all aspects of service design and change			√	Patients invited to participate in current providers National/Local staff/patient satisfaction surveys.				
	Patient Choice	√			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment.				
	Patients are fully empowered in their own			√	Patients must consent to treatment since this is off label use. Informed				

	care				consent and shared decision making will be part of the delivery.				
	Wider primary care, provided at scale			√	Policy to implement evidence based guidance for eligible patients to receive clinically effective NHS funded treatment within the Secondary Care services under patient choice.				
<b>Access</b> Could the proposal impact positively or negatively on any of the following:	Patient choice	√			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment.				
	Access	√			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment within the Secondary Care services under patient choice.				
	Integration	√			Improved collaboration across the ICS – delivering consistent care to patients.				
<b>Compliance with NHS Constitution</b>	Quality of care and environment	√			Better utilisation of treatments to maintain or enhance patient's eye sight in relation to wAMD. This in turn will lead to improved access for more complex conditions. The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality				

					of care in line with the Care Quality Commission (CQC) "quality statements".				
	Nationally approved treatment/drugs	√			Policy to implement access for eligible patients to receive clinically effective NHS funded treatment. Aligned to NHS E national treatment pathway for wAMD.				
	Respect, consent and confidentiality	√			All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply.				
	Informed choice and involvement	√			Patients will be fully involved in their care planning through shared decision-making, personalised care, and support planning.				
	Complain and redress	√			Usual ICB and/or Provider compliment, complaint and redress policies and mechanisms will apply.				

\*Risk score definitions are provided in the next section.

## Equality Impact Assessment

### Project / Policy Details

#### What is the aim of the project / policy?

- Align with national NHS E recommendations
- Consistency across the ICS departments & Independent Sector Providers
- Promote best practice and use of cost-effective treatments thereby leading to efficiencies
- Create capacity within ophthalmology departments

#### Who will be affected by this work? e.g staff, patients, service users, partner organisations etc.

The proposed ICB policy reflects national NHS E recommendations, which in turn align with mandated NICE guidance and clinical guidelines. Ophthalmology Specialists already treat patients in accordance with NICE guidance. This will promote consistency & parity across the ICS departments and Independent Sector Providers, in terms of managing patients with Wet Age-related Macular Degeneration (wAMD).

#### Is a full Equality Analysis Required for this project?

Yes ✓	Proceed to complete this form.	No	Explain why further equality analysis is not required.
If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.			

### Equality Analysis Form

#### Evidence used

**What evidence have you identified and considered?** This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

[Commissioning Guidance - Medical Retinal Treatment Pathway in Wet Age-related Macular Degeneration - The NHS Biosimilar Hub - Futures](#) accessed Sept 2025

The National Institute for Health and Care Excellence (NICE) summarises the available evidence and provides recommendations for use of different products for each drug:

1. National Institute for Health and Care Excellence (2008). [NICE TA155: Ranibizumab and pegaptanib for the treatment of age-related macular degeneration](#).
2. National Institute for Health and Care Excellence (2022). [NICE TA800: Faricimab for treating wet age-related macular degeneration](#).
3. National Institute for Health and Care Excellence (2013). [NICE TA294: Aflibercept solution for injection for treating wet age-related macular degeneration](#).
4. National Institute for Health and Care Excellence (2021). [NICE TA672: Brolucizumab for treating wet age-related macular degeneration](#).
5. National Institute for Health and Care Excellence (2024). [NICE TA1022: Bevacizumab gamma for treating wet age-related macular degeneration](#)
6. National Institute for Health and Care Excellence (2018). [NICE CG 82: Age-related macular degeneration](#)

In addition, specialists across the Integrated care System support the principles/framework within the national recommendations.

<b>2. Impact and Evidence:</b>
In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.
<b>Age:</b> A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. However, many of the medical retinal vascular conditions are more common with age. For example, within the NG 82; the following is stated:  <i>'The prevalence of late AMD in the UK among people aged 50 years or over is 2.4% (from a meta-analysis applied to UK 2007–09 population data). This increases to 4.8% in people aged 65 years or over, and 12.2% in people aged 80 years or over'.</i>  This policy will be applied equally to all patients, irrespective of age.
<b>Disability:</b> A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. Overall, this policy has a positive impact in terms of loss of eyesight, since the treatment pathway aims to preserve eyesight/prevent eyesight from deteriorating.
<b>Gender reassignment (including transgender):</b> Where a person has proposed, started or completed a process to change his or her sex.
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.
<b>Marriage and civil partnership:</b> A person who is married or in a civil partnership.
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.
<b>Pregnancy and maternity:</b> A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.
<b>Race:</b> A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.
<b>Religion or belief:</b> A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

<b>Sex:</b> A man or a woman		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
<b>Sexual orientation:</b> Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
<b>Carers:</b> A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
<b>Other disadvantaged groups:</b>		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
<b>3. Human Rights</b>		
<b>FREDA Principles / Human Rights</b>	<b>Question</b>	<b>Response</b>
<b>Fairness</b> – Fair and equal access to services	How will this respect a person's entitlement to access this service?	To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.  The policy for Medical Retinal Treatment Pathway in wAMD supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
<b>Respect</b> – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	The patient will not be contacted by the ICB. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
<b>Equality</b> – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	This policy is applied to all patients of the NHS Coventry and Warwickshire Integrated Care Board to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
<b>Dignity</b> – the right not to be treated in a	How will you ensure that individuals are not being	All communication, written or verbal, will be provided in a confidential, clear, understandable, format.

degrading way	treated in an inhuman or degrading way?	
<b>Autonomy</b> – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Individuals will have the opportunity to discuss their healthcare with the requesting clinician.  If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Right to <b>Life</b>	Will or could it affect someone's right to life? How?	No
Right to <b>Liberty</b>	Will or could someone be deprived of their liberty? How?	No

<b>4. Engagement, Involvement and Consultation</b>		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	Protected Characteristic/ Group/ Community	Date
N/A	N/A	N/A
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us .... So we will .....):		
N/A		

<b>5. Mitigations and Changes</b>
Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the <b>recommendations</b> and any <b>changes</b> to the proposal arising from the equality analysis.
N/A

<b>6. How will you measure how the proposal impacts health inequalities?</b>			
e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities.			
You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.			
Activity will be monitored and reported eg via the HCDs data feed/system wide HCDs meeting on a regular basis/as appropriate.			
<b>7. Is further work required to complete this assessment?</b>			
Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).			
Work needed	Section	When	Date completed
N/A	N/A	N/A	N/A

**8. Sign off**

The Equality Analysis will need to go through a process of **quality assurance** by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.

<b>Requirement</b>	<b>Name</b>	<b>Date</b>
Senior Manager Signoff	Altaz Dhanani	15/10/2025
Which committee will be considering the findings and signing off the EA?	Finance & Performance	12/11/2025
Approved by the Policy Procedure and Strategy Assurance Group.		16/10/2025

Once complete, please send to the ICB's Governance Team.