RETINAL PIONEERS Poster series

The UK licensed posology for EYLEA 8 mg in nAMD is three initial monthly loading doses, followed by a treatment interval up to 16 weeks (>8 weeks). The interval may then be extended up to 20 weeks.[1] The safety and efficacy of bilateral treatment with EYLEA 8 mg has not been studied.[1]

EYLEA (aflibercept) 8 mg treat-and-extend pathway for the treatment of neovascular age-related macular degeneration (nAMD): Guidance from a UK expert panel

INTRODUCTION

The **burden of AMD** is rising due to an increase in population age and life expectancy globally[2]

AMD is projected to cause sight loss or blindness in **1.23 million** people in the UK by **2050**[2]

Many challenges are associated with medical retina and more specifically, the management of nAMD:

An **increased prevalence of AMD** and other eye conditions causes an **additional demand** for **retina services** and further **exacerbates** pre-existing **patient backlogs** and ongoing **clinic capacity challenges** in the NHS[3]

Anti-VEGF therapies that deliver robust visual outcomes while **reducing the burden of treatment** for patients with nAMD and service providers are important to help **meet this growing demand**[4]

Clinics experiencing **operational strain** (whereby demand exceeds capacity)[5] are often associated with **multiple unquantified clinic costs,** such as suboptimal control of disease; however, **durable treatment** options that can **decrease treatment burden** may **reduce the risk of strain and additional clinic costs**[4]

PATHWAY DEVELOPMENT

This consensus pathway was developed to:

- Provide expert-led **guidance** for the **use of EYLEA 8 mg** in treatment-naïve and previously treated patients with **nAMD** in UK clinical practice
- Support medical retina services with the **optimisation of clinical outcomes** and **service efficiency** using EYLEA 8 mg

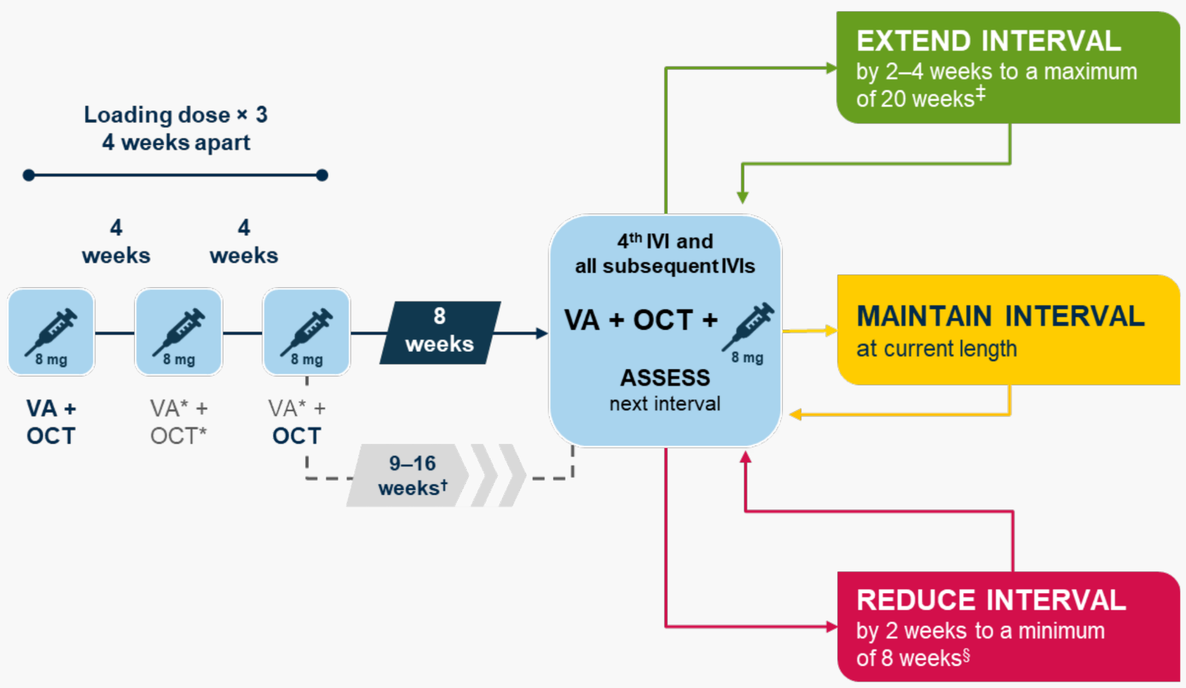
The pathways were developed by:

- **13 expert UK consultant ophthalmologists** convened at Bayer-organised and fully funded roundtable meetings in October 2024*
- Reviewing **clinical trial data** and sharing **real-world experiences** to form **consensus recommendations**

Safety profile of EYLEA 8 mg[1]

- Serious adverse reactions were cataract (8.2%), retinal haemorrhage (3.6%), intraocular pressure increased (2.8%), vitreous haemorrhage (1.2%), cataract subcapsular (0.9%), cataract nuclear (0.6%), retinal detachment (0.6%), and retinal tear (0.5%).
- The most frequently observed adverse reactions in patients treated with EYLEA 114.3 mg/mL were cataract (8.2%), visual acuity reduced (4.4%), vitreous floaters (4.0%), conjunctival haemorrhage (3.8%), vitreous detachment (3.7%), retinal haemorrhage (3.6%), intraocular pressure increased (2.8%) and eye pain (2.0%).
- The safety profile observed in the 3 clinical studies (CANDELA, PULSAR, PHOTON) was similar in patients treated with EYLEA 114.3 mg/mL (N=1,217) and EYLEA 40 mg/mL (N=556), and in patients with nAMD and DMO.
- A total of 1,217 patients treated with EYLEA 114.3 mg/mL constituted the safety population in 3 clinical phase II/III studies (CANDELA, PULSAR, PHOTON).
- **Please refer to the EYLEA 8 mg SmPC for more information, including the list of adverse reactions.**

CONSENSUS PATHWAY



*Optional.
†Extending the interval between the 3rd and 4th injections **beyond 8 weeks** is at the discretion of the clinician and in consultation with the patient, providing the OCT at the 2nd and 3rd visit indicate **no disease activity** or **disease activity is controlled**. **Interim monitoring** with OCT may be required.
‡Increase interval by **4 weeks** in treatment-naïve patients. Increase treatment interval by **2 weeks** in patients with **previous interval reduction**, or who have been **switched** from an alternative anti-VEGF treatment due to suboptimal response to treatment. Treatment intervals greater than 20 weeks between injections have not been studied.
§Treatment intervals of shorter than 8 weeks between injections **have not been studied**. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, **aflibercept 8 mg should be discontinued**.

nAMD retreatment criteria

EXTEND

Stable or better vision, **or** VA loss not due to disease activity
AND OCT scan shows:

- No signs of fluid **OR**
- Stable fluid that does not decrease at shorter treatment interval

AND

Extension not previously attempted (or attempted recently)

MAINTAIN

Stable or better vision, **or** VA loss not due to disease activity
AND OCT scan shows:

- Improvement in fluid **OR**
- Stable fluid that does not decrease with shorter intervals **AND** is known to increase with longer intervals **OR**
- Dry macula, which has worsened at a recently attempted longer interval

REDUCE

Loss of ≥5 letters of VA due to disease activity **AND/OR** OCT scan shows increased disease activity evidenced by **new or increased**:

- Fluid – IRF, SRF or sub-RPE **OR**
- Macular haemorrhage **OR**
- SHRM

*Expert clinicians included: Mahmoud Awad, Swansea Bay University Health Board; Clare Bailey, University Hospitals Bristol and Weston NHS Foundation Trust; Peter Cackett, NHS Lothian; Romi Chhabra, Manchester University NHS Foundation Trust; Louise Downey, Hull University Teaching Hospitals NHS Trust; Richard Gale, York and Scarborough Teaching Hospitals NHS Foundation Trust; Faruque Ghanchi, Bradford Teaching Hospitals NHS Foundation Trust; Ajay Kotagiri, South Tyneside and Sunderland NHS Foundation Trust; Niro Narendran, The Royal Wolverhampton NHS Trust; Ian Pearce, NHS University Hospitals of Liverpool Group; Tunde Peto, Queen's University Belfast; Sobha Sivaprasad, Moorfields Eye Hospital NHS Foundation Trust; Saad Younis, Imperial College Healthcare NHS Trust. AMD, age-related macular degeneration; DMO, diabetic macular oedema; IRF, intraretinal fluid; OCT, optical coherence tomography; RPE, retinal pigment epithelium; SHRM, subretinal hyperreflective material; SmPC, summary of product characteristics; SRF, subretinal fluid; VA, visual acuity; VEGF, vascular endothelial growth factor.

**Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.
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The consensus roundtables were organised and fully funded by Bayer UK.
Prescribing information and adverse event reporting information for EYLEA (aflibercept) 2 mg and EYLEA 8 mg can be accessed by clicking here or via the QR code located on the last page of this document.

The UK licensed posology for EYLEA 8 mg in nAMD is three initial monthly loading doses, followed by a treatment interval up to 16 weeks (>8 weeks). The interval may then be extended up to 20 weeks.[1] The safety and efficacy of bilateral treatment with EYLEA 8 mg has not been studied.[1]

Expert recommendations for the use of EYLEA 8 mg for nAMD in UK clinical practice[6]

Patient consent:

- Patients should be consented in line with local policy when switched to EYLEA 8 mg from another agent
- The posology and injection volume of EYLEA 8 mg should be discussed with the patient during the consenting process as this differs from EYLEA 2 mg
- Risk of IOP spikes in patients with glaucoma and risk of worsening optic disk cupping in patients with advanced disc cupping should be discussed with patients during the consenting process if necessary

Initiation in treatment-naïve patients

- EYLEA 8 mg can be used to treat all nAMD subtypes, including those with PCV
- EYLEA 8 mg is contraindicated in the presence of hypersensitivity, ocular or periocular inflammation and active, severe IOI[1]
- Patients with glaucoma should be managed per local practice, informed by national recommendations[2,7]
- When considering safety profiles prior to treatment initiation, it is notable that EYLEA 8 mg and EYLEA 2 mg have comparable safety profiles[1]

Loading phase

- The loading phase for EYLEA 8 mg consists of three initial monthly loading doses as per the licensed posology[1]
- To best inform future decision-making:
  - Pre-injection OCT imaging is recommended at the first and third injection visit
  - VA assessment should be mandatory at the baseline visit but is at the discretion of the treating clinician at Weeks 4 and 8
  - OCT and VA assessments should be conducted at all visits involving a retreatment interval decision
- FFA and ICGA may be considered if suboptimal response to treatment is observed
- In the event of no clinical improvement in anatomic or visual outcomes at the third injection visit, the diagnosis of nAMD should be reassessed

Discontinuation

- EYLEA 8 mg treatment should be continued indefinitely even when patients are maintained on q20 treatment intervals with no disease activity
- In the case of a diagnosis of late AMD (wet inactive disease) and/or no prospect of visual improvement, it may be appropriate to discontinue treatment[2]

Recording VA and OCT

- VA and CST (on OCT) should always be accurately recorded each time they are taken and documented in a location that allows easy reference in the future
- Accurate CST measurements require OCT images to be centred correctly, and the segmentation algorithm applied appropriately to prevent imaging artefacts

Treatment interval extension

- In the case of absence or improvement (compared with baseline) of disease activity on OCT at the third visit, the fourth injection should be administered 8 weeks after the third dose
  - In certain cases, clinicians may discuss with the patient extending the treatment interval by ≥9 weeks up to 16 weeks, if there is no disease activity at the third visit
- From the fourth visit, a T&E protocol can be implemented:
  - Treatment intervals can be extended by 4-week increments, up to a maximum treatment interval of 20 weeks, in line with the UK licence for EYLEA 8 mg[1]
  - In patients with a previous suboptimal response to an alternative anti-VEGF agent, interval extension by 2-week increments is recommended

Treatment interval reduction

- If active disease reoccurs during the extension phase, the interval should be reduced to the last known interval that offered disease stability (minimum q8)
  - Treating clinicians should consider fixing the interval for three further doses before any subsequent attempt to extend
- Clinicians may reduce the next interval directly to a minimum of every 8 weeks or reload patients with three consecutive monthly doses in the following cases:
  - If new, unexpected disease activity occurs during a 16- or 20-week treatment interval
  - If patients experience major disease reactivation at any interval, as determined by multiple OCT findings, significant vision loss or large macular haemorrhage
- Treatment intervals shorter than 8 weeks with EYLEA 8 mg in the maintenance phase have not been studied

Switching to EYLEA 8 mg

- Patients receiving prior anti-VEGF treatment may be switched to EYLEA 8 mg, if:[2]
  - Complete control of disease activity is not achieved (suboptimal response)
  - Disease control is achieved but the injection interval is not suitable for the patient
- EYLEA 8 mg may be initiated in previously treated patients with:
  - Three initial monthly loading doses for patients with persistent disease activity despite treatment at the smallest permitted dosing interval, or patients who are receiving treatment intervals shorter than q8
  - Matched intervals may be considered for patients with stable disease receiving treatment at intervals ≥q8 to allow for future extension to longer treatment intervals or to align bilateral treatment
- When evaluating a switch from EYLEA 2 mg to EYLEA 8 mg, consider the differences in dose and posology

OcuClick pre-filled syringe

- Where possible, OcuClick should be used to administer EYLEA 8 mg
- In general, there are fewer opportunities for an injection solution to become contaminated when injected using a pre-filled syringe compared with a vial, reducing the potential risk of endophthalmitis[8,9]

Switching from EYLEA 8 mg

- If patients show signs of disease activity while receiving EYLEA 8 mg at q8 intervals it is advisable to continue at this interval for at least one further dose before a switch to an alternative agent is considered
- Ensure any loss in vision is due to disease activity before changing treatment interval or agent
- The management of patients requiring 8-weekly dosing with residual low-volume fluid is guided by clinician discretion following informed discussion with the patient
- It is not advisable to switch patients with a suboptimal response to EYLEA 8 mg to first generation anti-VEGF agents

Bilateral disease

- Treating both eyes at the visit should be considered and discussed with patients, in line with current expert recommendations for anti-VEGF treatment in general[2,10,11]
- Patients receiving EYLEA 8 mg in their primary eye and an alternative anti-VEGF in their secondary eye should be switched to receive EYLEA 8 mg in both eyes
- Aligning treatment intervals between the eyes should be discussed with the patient to minimise treatment burden and ensure efficient service provision

Monitoring

OCT monitoring

- Both eyes should undergo OCT monitoring at every visit unless the fellow eye has end-stage disease and any treatment would be futile
- Patients on a T&E regimen receiving treatment at intervals longer than 16 weeks are not required to undergo additional monitoring in the affected eye

IOP monitoring

- Pre-injection IOP should be recorded at baseline and at 12 months as a minimum, or more frequently in high-risk patients
- Clinicians should refer to local and national guidelines for measuring and managing post-injection IOP in high-risk patients, those experiencing pain and those with reduced VA immediately after an injection

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CST, central subfield thickness; FFA, fundus fluorescein angiography; ICGA, indocyanine green angiography; IOI, intraocular inflammation; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; PCV, polypoidal choroidal vasculopathy; q8, every 8 weeks; T&E, treat-and-extend; VA, visual acuity; VEGF, vascular endothelial growth factor

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