EYLEA® 8mg
(aflibercept 114.3mg/mL, solution for injection)

OPTIMISING TREATMENT PATHWAYS WITH EYLEA (aflibercept) 8 MG FOR nAMD AND DMO: GUIDANCE FROM A UK EXPERT PANEL

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Prescribing Information and Adverse Event Reporting for EYLEA (aflibercept) 8 mg and EYLEA 2 mg is available via the QR code on the right. Click here or scan the QR code for prescribing information and adverse event reporting.

For direct access to this prescribing information, please ensure your device's browser settings have automatic PDF download enabled

DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; PDF, Portable Document Format; QR, Quick Response; UK, United Kingdom.

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nAMD and DMO are among the leading causes of blindness and vision impairment, with increasing global prevalence leading to growing demand for effective and durable treatments.[1-5] Optimising patient outcomes in these conditions requires timely intervention and personalised management strategies.[6,7]

The consensus pathways for managing nAMD and DMO with EYLEA 8 mg were developed to:[8,9]

- Provide expert-led guidance on the use of EYLEA 8 mg in treatment-naïve and previously treated patients with nAMD or DMO in UK clinical practice
- Optimise clinical outcomes and service efficiency in medical retina services

Both pathways were based on clinical data review and real-world experience to form consensus recommendations.[8,9]

For full prescribing information, refer to the SmPC.[10]

How were the pathways developed?

Expert consensus discussions at Bayer-organised and -funded non-promotional round-table meetings in Autumn 2024, attended by a group of **13 consultant ophthalmologists** from across the UK

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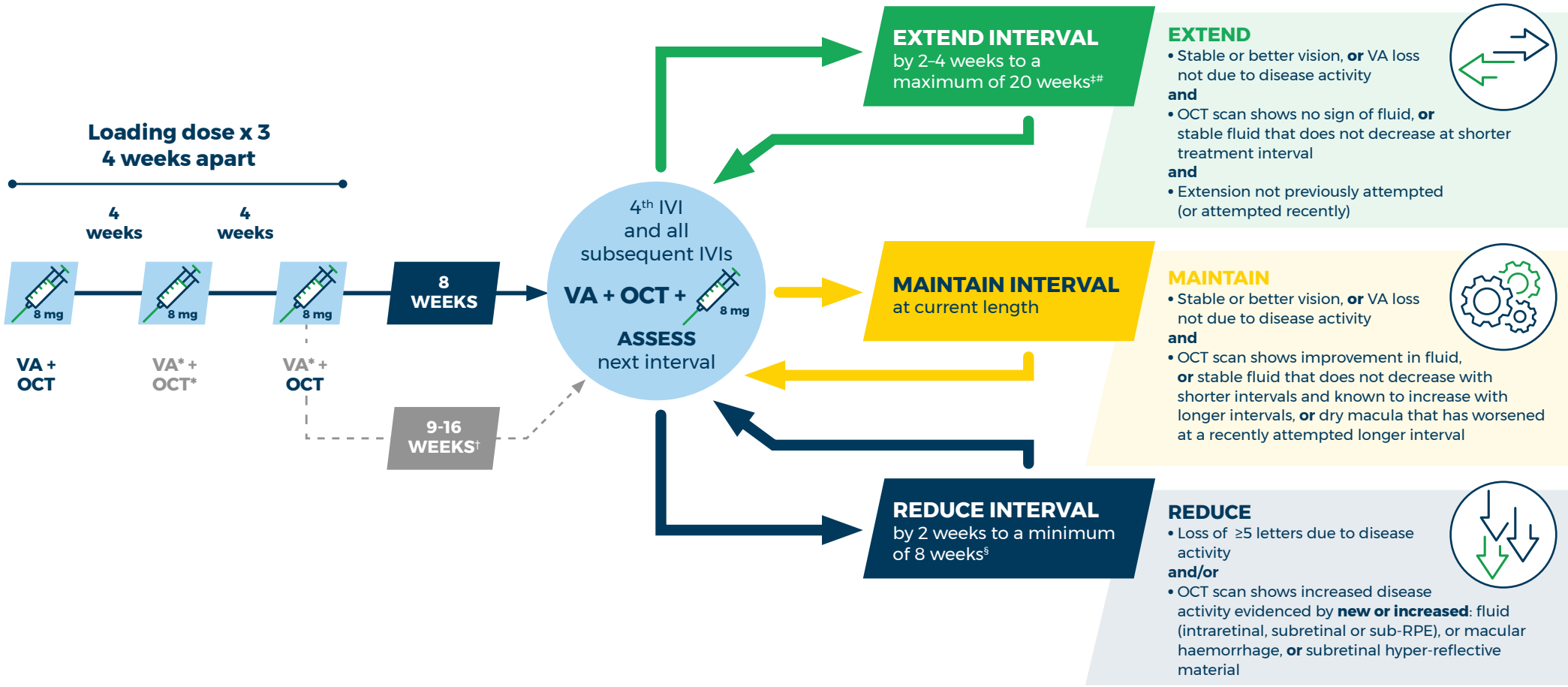
Treatment-naïve patients are those who have not received any prior anti-VEGF therapy. **Switch / previously treated patients** are those previously treated with another anti-VEGF agent.
DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; NHS, National Health Service; SmPC, Summary of Product Characteristics; UK, United Kingdom.

Intravitreal EYLEA 8 mg T&E pathway for the treatment of patients with nAMD[8]



Adapted from Gale R, et al. Aflibercept 8 mg treat-and-extend pathway for the treatment of neovascular age-related macular degeneration: Guidance from a UK expert panel.

*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 injection 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, and by 2 weeks in patients with previous interval reduction, or who have been switched from an alternative anti-VEGF treatment owing to suboptimal response to treatment. §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.

#The consensus pathways were developed before the EYLEA 8 mg posology was updated to allow for extensions up to 24 weeks. 24-week extensions were not part of the consensus discussion and therefore not included in the final pathway. Please refer to the EYLEA 8 mg Summary of Product Characteristics for full licensed posology.

IVI, intravitreal injection; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; RPE, retinal pigment epithelium; T&E, treat-and-extend; VA, visual acuity; VEGF, vascular endothelial growth factor.

Expert Recommendations for Managing nAMD with EYLEA 8 mg[8]

Patient Selection & Initiation

- **Treatment-Naïve Patients:**
  Consider for all adult nAMD subtypes, including all subtypes such as polypoidal choroidal vasculopathy
- **Patients receiving prior anti-VEGF treatment may be switched to:**
  EYLEA 8 mg if:
  - 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 at intervals <Q8
  - Consider switching initially to matched intervals for patients with stable disease at intervals ≥Q8 to allow for the potential future extension of treatment intervals, or to align bilateral treatment

Loading & Administration

- Prioritise the loading phase of three consecutive injections, 1 month apart, because early treatment gives the best opportunity for satisfactory long term outcomes
- Where possible, the OcuClick® pre-filled syringe should be used to administer EYLEA 8 mg. The OcuClick may provide several practical benefits compared with a vial, including precise dose delivery, facilitation of slower drug delivery, reduced chances of infection, and consequently, a lower potential risk of endophthalmitis. It also simplifies the priming procedure compared to the EYLEA 2 mg pre-filled syringe
- Perform OCT at least at the first and third loading visits to inform subsequent treatment decision-making. If possible, OCT of both eyes at every visit is ideally recommended, unless the fellow eye has end-stage disease and treatment is futile
- VA assessment should be mandatory at baseline, and ideally performed during the initiation phase as well, but this is at the discretion of the treating clinician. At all subsequent visits where a retreatment interval decision is required, OCT and VA assessments should be performed

Maintenance Phase

- At the third visit, the diagnosis of nAMD should be revisited and confirmed if there have been no clinical improvements
- At the third visit, if OCT shows disease activity is absent or improved from baseline, the fourth injection should be administered 8 weeks after the third dose. In select cases, an extended treatment interval of up to a maximum of 16 weeks may be considered after the three initial monthly injections.
- At the fourth visit (after loading), a T&E protocol would guide injections with extension of intervals by 4 weeks
- For patients with prior suboptimal anti-VEGF response or interval reductions on aflibercept 8 mg, extend by 2 weeks per interval
- If disease recurs, revert to the last stable interval (min Q8) and consider fixing the interval for at least three doses before re-extending
- For major reactivation (e.g., significant OCT changes, VA loss, or macular haemorrhage), consider reducing directly to Q8 (from any interval) or even reload with three monthly doses

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
  - Continue standard care monitoring of the fellow eye even if the affected eye is on long treatment intervals or treatment is discontinued
  - Patients on a T&E regimen receiving treatment at intervals longer than 16 weeks are not mandated 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

Managing Suboptimal Response

- If disease persists at Q8, maintain for at least one additional dose before considering a switch to another agent
- Data suggests residual low-volume subretinal fluid may not be detrimental to visual outcomes, but further studies are needed to inform clinical practice[11,12]
- It is not advised to switch to first-generation anti-VEGF agents if aflibercept 8 mg response is suboptimal
- Ensure any visual loss is due to disease activity before changing intervals or switching therapy

Bilateral Treatment Considerations

- Where appropriate, treat both eyes on the same visit using precautions such as different drug batches
- If using different anti-VEGF agents, switch both eyes to aflibercept 8 mg for consistency
- When aligning treatment intervals:
  - For small differences, use the lowest common interval
  - For larger differences, schedule the longer-interval eye at every second visit
- There are limited data on the safety of bilateral treatment with aflibercept 8 mg or with concomitant use of other anti-VEGF agents. Bilateral injections can, however, be considered and discussed with patients†

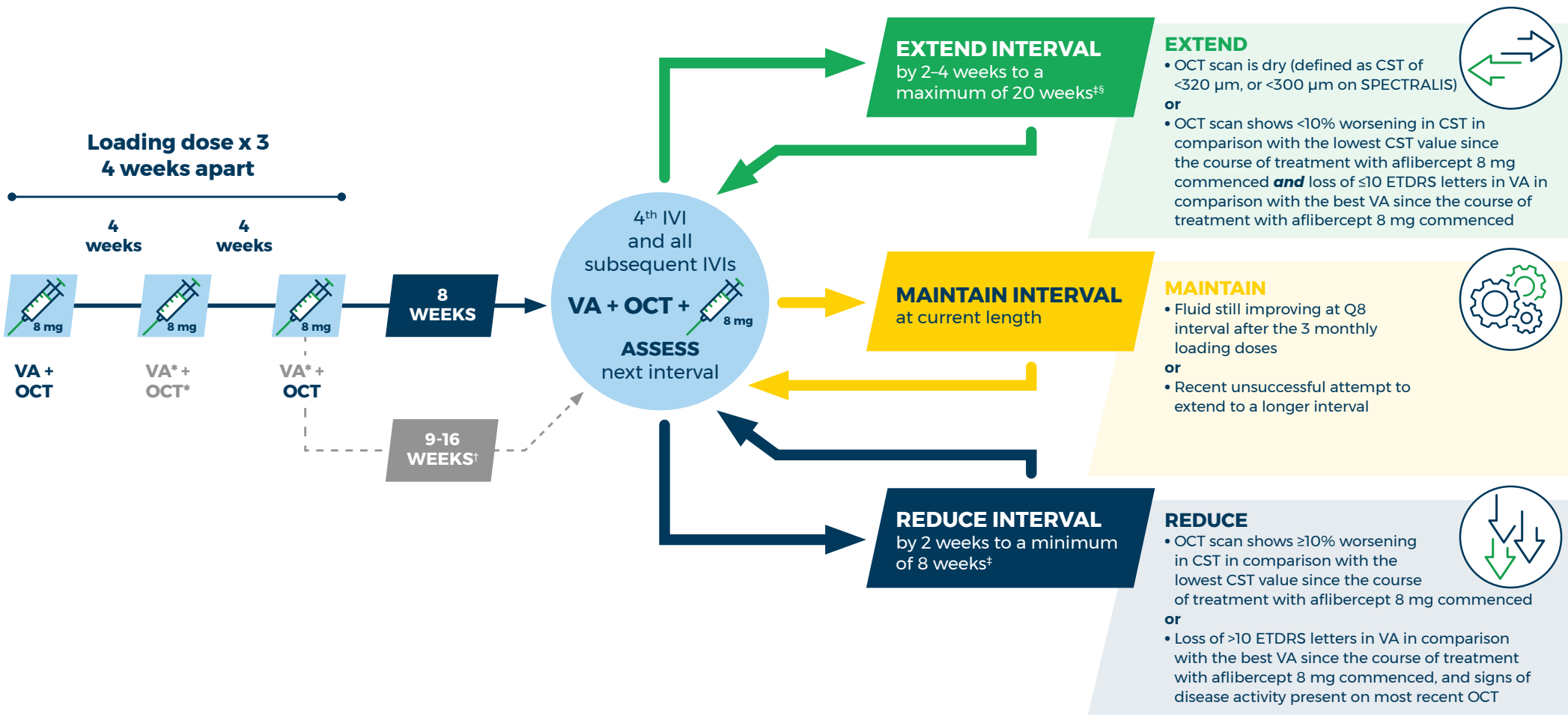
Discontinuing Treatment & Long-Term Planning

- It is advisable that treatment should continue indefinitely, even at Q20* with no signs of disease activity. However, discontinuation of treatment and regular follow-up may be considered after informed discussions between clinician and patient
- Discontinuation may be considered in late AMD (wet inactive) disease and/or if there is no prospect of visual improvement

*The consensus pathways were developed before the EYLEA 8 mg posology was updated to allow for extensions up to 24 weeks. 24-week extensions were not part of the consensus discussion and therefore not included in the final pathway. Please refer to the EYLEA 8 mg Summary of Product Characteristics for full licensed posology. †The safety and efficacy of bilateral treatment with Eylea 114.3 mg/ml per eye have not been studied (see section 5.1). If bilateral treatment is performed at the same time this could lead to an increased systemic exposure, which could increase the risk of systemic adverse events.[10]

AMD, age-related macular degeneration; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; Q8, every 8 weeks; Q20, every 20 weeks; T&E, treat-and-extend; VA, visual acuity; VEGF, vascular endothelial growth factor.

Intravitreal EYLEA 8 mg T&E pathway for the treatment of patients with visual impairment due to DMO[9]



Adapted from Bailey C, et al. Aflibercept 8 mg treat-and-extend pathway for the treatment of visual impairment due to diabetic macular oedema: Guidance from a UK expert panel.

*Optional. †An injection interval of 12–16 weeks can be considered between the third and fourth injections for eyes that are dry (defined as CST of <320 µm, or <300 µm on SPECTRALIS) on OCT at the third loading visit. ‡Interval extensions or reductions of 2 weeks are recommended in patients who have previously required an interval reduction with aflibercept 8 mg or have demonstrated a suboptimal response to treatment with an alternative anti-VEGF agent. Treatment intervals 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. In clinics that are unable to adjust treatment intervals at every visit owing to clinic capacity constraints, consider fixing treatment intervals for blocks of three or more injections.

§The consensus pathways were developed before the EYLEA 8 mg posology was updated to allow for extensions up to 24 weeks. 24-week extensions were not part of the consensus discussion and therefore not included in the final pathway. Please refer to the EYLEA 8 mg Summary of Product Characteristics for full licensed posology.

CST, central subfield thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; IVI, intravitreal injection; OCT, optical coherence tomography; Q8, every 8 weeks; VA, visual acuity; T&E, treat-and-extend; VEGF, vascular endothelial growth factor.

Expert Recommendations for Managing Visual Impairment due to DMO with EYLEA 8 mg[9]

Patient Selection & Initiation

- **Treatment-Naïve Patients:**
  Consider for all treatment-naïve patients with visual impairment due to DMO who would otherwise be eligible for aflibercept 2 mg
- **Patients receiving prior anti-VEGF treatment may be switched to:**
  EYLEA 8 mg if:
  - Complete control of disease activity is not achieved (suboptimal response)
  - Disease control is achieved but the injection interval is not suitable for the patient
  - Lack of response to current anti-VEGF treatment

  Allow ≥6 months of therapy with the alternative treatment before evaluating whether the response has been suboptimal

  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 at intervals ≤Q8
  - Consider switching initially to matched intervals for patients with stable disease receiving treatment with an alternative anti-VEGF at intervals ≥Q8

Loading & Administration

- Prioritise the loading phase of three consecutive injections, 1 month apart, to maximise the opportunity for long-term vision gains
- Where possible, the OcuClick® pre-filled syringe should be used to administer EYLEA 8 mg. The OcuClick may provide several practical benefits compared with a vial, including precise dose delivery, facilitation of slower drug delivery, reduced chances of infection, and consequently, a lower potential risk of endophthalmitis. It also simplifies the priming procedure compared to the EYLEA 2 mg pre-filled syringe
- Perform OCT at least at the first and third loading visits to inform subsequent treatment decision-making. If possible, OCT of both eyes at every anti-VEGF clinic visit is ideally recommended
- VA assessment should be mandatory at baseline.
- At all subsequent visits where an interval decision is required, OCT and VA assessments should be performed
- Clinicians should consider FFA or widefield OCT-A upon anti-VEGF treatment initiation to assess level of retinal ischaemia

Maintenance Phase

- **After three monthly loading doses**
  - Use an 8-week treatment interval if disease stability has not yet been achieved

  If the eyes are dry:
  - Consider accelerated T&E, extending to Q12 or Q16
  - If on the accelerated T&E pathway, clinicians may choose to monitor every 4-6 weeks between the third and fourth injection
- **Once stability is achieved:**
  - Adopt a T&E approach, adjusting intervals by 2–4 weeks up to Q20*, based on CST and VA
  - In patients with a suboptimal response to a previous anti-VEGF, adjust intervals by 2 weeks
- **Fixed dosing is suggested where T&E is not possible due to capacity issues, although there is a small probability of decreased vision (e.g., Q8 to Q16):**
  - For those who do not have a dry retina after loading, Q16 intervals should only be considered if monitoring is conducted between injections
  - Consider Q8 for eyes displaying fluid (although there are limited data on fixed Q8 for Eylea 8 mg)

Monitoring

The frequency with which patients require a full retinal examination and grading of retinopathy in both eyes depends on the severity of retinopathy at baseline. In general, examination and grading should be conducted every 3–6 months, although patients with mild NPDR who are receiving ongoing anti-VEGF treatment can be managed with examination and grading conducted at least every 12 months

- **OCT monitoring**
  - Both eyes should undergo OCT monitoring at every visit to allow changes in the fellow eye to be detected as early as possible
- **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

Managing Suboptimal Response

- Fluid can be tolerated in eyes with DMO more readily than in eyes with nAMD,[13,14] as such, Q8 can continue if VA does not deteriorate by more than 5 letters from the best recorded VA
- If worsening VA and increased CST at Q8 intervals, consider adjunct treatment with macular laser or switching to a steroid or an alternative anti-VEGF therapy
  - Intravitreal steroids may also be considered after 2 years if it is thought they could help reduce the injection burden beyond anti-VEGF monotherapy
- Ensure any visual loss is due to disease activity before changing intervals or switching therapy

Bilateral Treatment Considerations

- Where appropriate, treat both eyes on the same visit using precautions such as different drug batches
- If using different anti-VEGF agents, switch both eyes to aflibercept 8 mg for consistency
- When aligning treatment intervals:
  - For small differences, use the lowest common interval
  - For larger differences, schedule the longer-interval eye at every second visit
- There are currently limited data on the safety of bilateral treatment with aflibercept 8 mg or with concomitant use of other anti-VEGF agents, the consensus opinion is that bilateral same-day injection of aflibercept 8 mg can be undertaken with certain precautions†

Discontinuing Treatment & Long-Term Planning

- When considering extending patients to Q20 or discontinuing treatment, assess the patient's retinopathy using FFA or wide-field OCT-A
- Patients with no disease activity or controlled activity after 3 consecutive injections at Q16 or Q20 may discontinue treatment, with regular follow-up
  - The patient's next clinical review and full retinopathy grading should be after an interval no longer than the previous injection interval
- Inform clinicians managing the patient's diabetes that any changes to their diabetes treatment should be followed by an eye clinic visit within 4–8 weeks to monitor for rubeosis or neovascularisation
- For non-responders to all anti-VEGF therapy, consider vitrectomy if there is evidence of vitreomacular traction or an epiretinal membrane is present

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CST, central subfield thickness; DMO, diabetic macular oedema; FFA, Fundus Fluorescein Angiography; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; NPDR, non-proliferative diabetic retinopathy; OCT, optical coherence tomography; OCT-A, optical coherence tomography angiography; Q8, every 8 weeks; Q12, every 12 weeks; Q16, every 16 weeks; Q20, every 20 weeks; T&E, treat-and-extend; VA, visual acuity; VEGF, vascular endothelial growth factor.

References: 1. Korobelnik JF, et al. *Eye (Lond).* 2024;38(17):3218-3221; 2. Kubin AM, et al. *J Patient Rep Outcomes.* 2024;8(1):89; 3. Ruiz-Moreno JM, et al. *Ophthalmol Ther.* 2024;13(7):1937-1953; 4. Khachigian LM, et al. *J Transl Med.* 2023;21:133; 5. Udaondo P, et al. *Ophthalmol Ther.* 2022;11(2):489–502; 6. Gale RP, et al. *Eye (Lond).* 2019;33(Suppl 1):1–21; 7. Gale R, et al. *Eye (Lond).* 2017;31(Suppl 1):S1–S20; 8. Gale R, et al. Aflibercept 8 mg treat-and-extend pathway for the treatment of neovascular age-related macular degeneration: Guidance from a UK expert panel; 9. Bailey C, et al. Aflibercept 8 mg treat-and-extend pathway for the treatment of visual impairment due to diabetic macular oedema: Guidance from a UK expert panel; 10. Eylea (8 mg) Summary of Product Characteristics (SmPC); 11. Yu S, et al. *Eye (Lond).* 2025;39:154–61; 12. Schmidt-Erfurth U, et al. *Eye (Lond).* 2023;37(6):1160-1169; 13. Brown DM, et al. *Lancet.* 2024;403(10432):1153-1163; 14. Lanzetta P, et al. *Lancet.* 2024;403(10432):1141-1152.