Adverse Event Reporting Information and Prescribing Information for EYLEA® (aflibercept) can be accessed below and on the penultimate page via a link or QR code.

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

Formulary Guide

Interactive resource for completion of formulary templates

EYLEA 8 mg (aflibercept 114.3 mg/mL solution for intravitreal injection)[1]

- For the treatment of neovascular (wet) age-related macular degeneration in adults
- For the treatment of visual impairment due to diabetic macular oedema in adults
- For the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal retinal vein occlusion) in adults

Prescribing Information and adverse event reporting information for EYLEA® (aflibercept) 2 mg and 8 mg is available via the QR code on the right.

Either click here or scan the QR code for prescribing information and adverse event reporting information.

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

EYLEA 8 mg (aflibercept 8 mg) represents a line extension from the currently available EYLEA/aflibercept 2 mg dose.

This formulary guide is for local health systems that require a new full formulary application for aflibercept 8 mg.

Reporting adverse events and quality complaints

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc.

If you want to report an adverse event or quality complaint, reports can be directed to Tel.: 0118 2063500
Email: pvuk@bayer.com.
Further information is available on the "contact" tab at www.bayer.co.uk

This formulary guide has been developed and funded by Bayer plc as an information source to aid completion of hospital formulary templates.

How to use this document

- This document is an interactive resource to support users to complete hospital formulary templates.
- Users can navigate the document by using the hyperlinked sections shown at the top of each page, or by using the contents list below, to find the relevant sections.
- Text can be copied from each section, as required, to aid in the completion of hospital formulary templates.

Contents

AE, adverse event; AWMSG, All Wales Therapeutics and Toxicology Centre; DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neovascular age-related macular degeneration; NICE, National Institute for Health and Care Excellence; RVO, retinal vein occlusion; SMC, Scottish Medicines Consortium.

Please refer to the Summary of Product Characteristics as appropriate before prescribing aflibercept 8 mg. Aflibercept 8 mg represents a line extension from the currently available aflibercept 2 mg dose.

Details of aflibercept 8 mg

Aflibercept 8 mg overview[1]

Generic & brand name	Aflibercept 8 mg (EYLEA® 8mg)
Manufacturer	Bayer plc
Licensed indications	Aflibercept 8 mg is indicated for the treatment of adult patients with: • Neovascular (wet) age-related macular degeneration (**nAMD**) • Visual impairment due to diabetic macular oedema (**DMO**) • Macular oedema secondary to retinal vein occlusion (RVO; branch, central and hemiretinal RVO)
Drug action	• Aflibercept is a **vascular endothelial growth factor (VEGF) inhibitor** • Evidence supports a pathophysiological role for the overactivation of VEGF receptors (e.g. for VEGF-A and placental growth factor) in retinal diseases through neovascularisation and excessive vascular permeability
Route of administration, pharmaceutical form and strengths available	• Aflibercept 8 mg is to be **administered via intravitreal injection only**. It must only be administered by a qualified healthcare professional experienced in intravitreal injections. • The aflibercept 8 mg dose requires use of EYLEA 114.3 mg/mL. Each pre-filled syringe is for single use in one eye only.
Posology: nAMD and DMO	**The licensed posology with aflibercept 8 mg in nAMD and DMO is the same** • Aflibercept 8 mg treatment is **initiated with one injection per month for 3 consecutive doses** • Injection **intervals may then be extended up to every 4 months** based on the physician's judgement of visual and/or anatomic outcomes Subsequently, the treatment intervals **may be further extended up to 6 months**, such as with a treat-and-extend dosing regimen, while maintaining stable visual and/or anatomic outcomes • **For patients being switched to aflibercept 8 mg** from aflibercept 2 mg or other anti-VEGF treatments, treatment regimens can differ from that used for treatment -naïve patients. Treatment intervals should be determined based on visual and/or anatomic outcomes ◦ **In patients with stable visual and anatomic outcomes**, previous treatment intervals can be maintained or extended after the first aflibercept 8 mg injection, such as with a treat-and-extend dosing regimen ◦ **In patients with suboptimal visual and/or anatomic outcomes**, treatment with aflibercept 8 mg may begin with one injection per month for up to 3 consecutive doses followed by adjustment of injection intervals, such as with a treat-and-extend dosing regimen • If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly based on the physician's discretion. The interval between two injections should not be shorter than 1 month • If visual and/or anatomic outcomes indicate that the patient is not benefiting from continued treatment, aflibercept 8 mg should be discontinued. • Aflibercept at monthly doses of 8 mg has **not been studied for more than 3 consecutive doses in the PULSAR (nAMD) and PHOTON (DMO) studies. Available data support the administration of more than 3 consecutive monthly doses for certain patients, however, the data are currently limited.** • The frequency of monitoring visits should be based on the patient's status and at the physician's discretion
Posology: RVO	• Aflibercept 8 mg treatment is initiated with one injection per month for 3 consecutive doses • Injection intervals may then be extended based on the physician's judgement of visual and/or anatomic outcomes • For patients being switched to aflibercept 8 mg from aflibercept 2 mg or other anti-VEGF treatments, treatment regimens can differ from that used for treatment-naïve patients. Treatment intervals should be determined based on visual and/or anatomic outcomes ◦ In patients with stable visual and anatomic outcomes, previous treatment intervals can be maintained or extended after the first aflibercept 8 mg injection, such as with a treat-and-extend dosing regimen ◦ In patients with suboptimal visual and/or anatomic outcomes, treatment with aflibercept 8 mg may begin with one injection per month for up to 3 consecutive doses followed by adjustment of injection intervals, such as with a treat-and-extend dosing regimen • If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly based on the physician's discretion. The interval between two injections should not be shorter than 1 month • If visual and/or anatomic outcomes indicate that the patient is not benefiting from continued treatment, aflibercept 8 mg should be discontinued • The frequency of monitoring visits should be based on the patient's status and at the physician's discretion.
Further guidance for use	**Please refer to the aflibercept 8 mg Summary of Product Characteristics for United Kingdom for information regarding:** • Contraindications (section 4.3) • Special warnings and precautions for use (section 4.4) • Interactions with other medicinal products (section 4.5) • Fertility, pregnancy and lactation (section 4.6)

AE, adverse event; HTA, Health Technology Assessment.

nAMD clinical data: PULSAR trial

Overview and study design

PULSAR was a Phase III, multicentre, randomised, double-masked study in patients with treatment-naïve nAMD that evaluated the efficacy and safety profile of aflibercept 8 mg compared to that of aflibercept 2 mg[2]

- Patients were randomised 1:1:1 at baseline to the following groups, before receiving three initial monthly loading doses:[2]
  - Aflibercept 8 mg at 12-week treatment intervals (8q12)
  - Aflibercept 8 mg at 16-week treatment intervals (8q16)
  - Aflibercept 2 mg at 8-week treatment intervals (2q8)
- The study was 96 weeks in duration with an optional 60 week open-label extension until Week 156. In the extension study, 417 patients originally assigned to 8q12 and 8q16 continued on aflibercept 8 mg while maintaining their latest intervals. 208 patients originally assigned to 2q8 at the beginning of the study were switched to aflibercept 8 mg starting at 12-week intervals.[1,2]
- Dosing intervals for the aflibercept 8 mg groups could be shortened if pre-specified criteria were met. At week 52, patients in the aflibercept 8 mg groups were also eligible for treatment extension if pre-specified criteria were met. During the open-label extension study, treatment intervals could be shortened or extended in all groups based on pre-specified criteria.[1,2]

Patient population

Eligible patients were aged ≥50 years with treatment-naïve nAMD[3]

- *Please request reference for comprehensive list of key eligibility criteria*

Study endpoints

- The primary non-inferiority endpoint was the mean change in BCVA at Week 48[3]
- The key secondary endpoint was the proportion of patients without intraretinal fluid and subretinal fluid in the central subfield at Week 16[3]

Patient characteristics

- In the PULSAR trial, 1,009 patients with nAMD were included in the statistical analyses. Baseline characteristics were balanced between the groups[2]

Please refer to section 5.1 in the United Kingdom Summary of Product Characteristics for the baseline patient characteristics of this study

Results: efficacy through Week 96

Aflibercept 8 mg met its primary endpoint of non-inferiority in vision gains compared to aflibercept 2 mg at Week 48, which were stable and maintained through Week 96[3]

Key efficacy results

Characteristic	AFL 2q8	AFL 8q12	AFL 8q16
N (FAS)[2]	336	335	338
LS mean change in BCVA from baseline to Week 48, ETDRS letters (primary endpoint)[2]	7.0	6.1	5.9
LS mean change in BCVA from baseline to Week 96, ETDRS letters[2]	6.6	5.6	5.5
LS mean change in CST from baseline to Week 96, µm[2]	–147	–152	–149
Proportion of patients with absence of IRF and SRF in the central subfield at Week 16, % (key secondary endpoint)[2]	52	62	65
Mean number of injections administered from baseline to Week 96, n[2]	12.8	9.7	8.2

- 78% of patients randomised to aflibercept 8q16 (n=338) achieved a last assigned treatment interval of ≥16 weeks at Week 96[1]
  - 53% achieved a last assigned treatment interval of ≥20 weeks[1]
- 87% of patients randomised to aflibercept 8q12 (n=335) achieved a last assigned treatment interval of ≥12 weeks at Week 96[1]
  - 41% achieved a last assigned treatment interval of ≥20 weeks[1]

Results: efficacy through Week 156

Functional and anatomic improvements observed in the PULSAR trial up to Week 96 were largely maintained through Week 156 in the PULSAR extension study.[4]

Key efficacy results

Characteristic	AFL 8q12 continued on aflibercept 8 mg	AFL 8q16 continued on aflibercept 8 mg	AFL 2q8 switched to aflibercept 8 mg
N[1]	185	190	208
LS mean change in BCVA from baseline to Week 156, letters[1]	3.57	3.23	4.58
LS mean change in CRT from baseline to Week 156, µm[1]	-148.42	-147.54	-145.21

- 54% of patients randomised to the aflibercept 8q12 treatment arm (n=185) achieved a last assigned treatment interval of ≥16 weeks at Week 156[1]
  - 24% achieved a last assigned treatment interval of 24 weeks[1]
- 62% of patients randomised to the aflibercept 8q16 treatment arm (n=190) achieved a last assigned treatment interval of ≥16 weeks at Week 156[1]
  - 24% achieved a last assigned treatment interval of 24 weeks[1]
- 43% of patients who were switched from 2q8 to aflibercept 8 mg (n=208) achieved a last assigned treatment interval of ≥16 weeks at Week 156[1]
  - No 24 week data available for patients originally randomised to 2q8 due to study design/length of study[1]

2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; AFL, aflibercept; BCVA, best corrected visual acuity; CST, central subfield thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; HTA, Health Technology Assessment; IRF, intraretinal fluid; LS, least squares; nAMD, neovascular age-related macular degeneration; SRF, subretinal fluid.

This is a promotional material organised and funded by Bayer.
March 2026 | PP-EYL_8mg-GB-0884

nAMD clinical data: PULSAR trial

Results: safety profile through Week 96

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles[2]

- There were no cases of endophthalmitis, retinal vasculitis or occlusive retinitis[2]
- The most common adverse reactions (≥5%) reported in patients treated with aflibercept 8 mg were cataract, retinal haemorrhage, reduced visual acuity and vitreous floaters[2]

Ocular and non-ocular AEs (Week 96)[2]

Characteristic	AFL 2q8 (n=336)	All AFL 8 mg (n=673)
Ocular safety through Week 96, n (%)		
Patients with ≥1 ocular TEAE	181 (53.9)	345 (51.3)
Patients with IOI*	7 (2.1)	9 (1.3)
Non-ocular safety through Week 96, %		
APTC events†	3.3	1.8
Hypertension events†	8.0	8.2
Non-ocular serious TEAEs†	19.6	20.4
Deaths‡	3.6	2.5

Results: safety profile through Week 156

The overall safety profile in the extension phase was similar to that observed in the main phase.[1]

Ocular and non-ocular AEs (Week 156)[4§#]

Characteristic	AFL 2q8 → 8 mg (n=208)	AFL 8q12/8q16 (n=417)**
Ocular TEAEs, n (%)	130 (62.5)	251 (60.2)
Ocular SAEs, n (%)	7 (3.4)	21 (5.0)
Patients with IOI, n (%)	5 (2.4)	8 (1.9)
Non-ocular SAEs, n (%)	43 (20.7)	106 (25.4)
APTC events, n (%)	4 (1.9)	7 (1.7)
Deaths, n (%)	4 (1.9)	9 (2.2)

*Reported IOI terms: anterior chamber cell, chorioretinitis, iridocyclitis, iritis, uveitis, vitreal cells and vitritis; †TEAEs; ‡All events. §extension safety analysis set. #Cumulative events in the study eye from baseline through Week 156. **Patients who were randomised to the 8q12 or 8q16 groups at the beginning of the PULSAR study and continued treatment with aflibercept 8 mg through the PULSAR extension study.
2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; AFL, aflibercept; APTC, Anti-Platelet Trialists' Collaboration; DMO, diabetic macular oedema; HTA, Health Technology Assessment; IOI, intraocular inflammation; nAMD, neovascular age-related macular degeneration; SAE, serious adverse events; TEAE, treatment-emergent adverse events.

DMO clinical data: PHOTON trial

Overview and study design

PHOTON was Phase II/III, multicentre, randomised, double-masked study in treatment-naïve and previously treated patients with DMO that evaluated the efficacy and safety profile of aflibercept 8 mg compared to that of aflibercept 2 mg[5]

- Patients were randomised 2:1:1 at baseline to the following groups[1,5]
  - Aflibercept 8 mg at 12-week treatment intervals (8q12)
  - Aflibercept 8 mg at 16-week treatment intervals (8q16)
  - Aflibercept 2 mg at 8-week treatment intervals (2q8)
- Patients in the aflibercept 8 mg arms received three initial injections and those in the aflibercept 2 mg arm received five initial injections at 4-week intervals.[1,5]
- The study was 96 weeks in duration with an optional 60 week open-label extension until Week 156. In the extension study, 195 patients originally assigned to 8q12 and 8q16 continued on aflibercept 8 mg while maintaining their latest intervals. 70 patients originally assigned to 2q8 at the beginning of the study were switched to aflibercept 8 mg starting at 12-week intervals.[1,6]
- Dosing intervals for the aflibercept 8 mg groups could be shortened if pre-specified criteria were met. At week 52, patients in the aflibercept 8 mg groups were also eligible for treatment extension if pre-specified criteria were met. During the open-label extension study, treatment intervals could be shortened or extended in all groups based on pre-specified criteria.[1,6]

Patient population

Eligible patients were aged ≥18 years with type 1 or 2 diabetes[5]

- *Please request reference for comprehensive list of key eligibility criteria*

Study endpoints

- The primary non-inferiority endpoint was the mean change in BCVA at Week 48[6]
- The key secondary endpoint was the proportion of patients with ≥2-step improvement in Diabetic Retinopathy Severity Scale (DRSS) at Week 48[5]

Patient characteristics

- In the PHOTON study, 658 patients with treatment-naïve or previously treated DMO were included in the statistical analyses. Baseline characteristics were balanced between the groups[6]

Please refer to section 5.1 in the United Kingdom Summary of Product Characteristics for the baseline patient characteristics of this study

Results: efficacy through Week 96

- Aflibercept 8 mg demonstrated **non-inferior vision gains at 48 weeks (primary endpoint)** with both 12- and 16-week dosing regimens after only three initial monthly doses, compared with an aflibercept 2 mg 8-week dosing regimen after five initial monthly doses[5,6]
- Vision gains achieved from baseline to Week 48 **remained stable and were maintained to Week 96**[5,6]

Key efficacy results[5,6]

Characteristic	AFL 2q8	AFL 8q12	AFL 8q16
N (FAS)	167	328	163
LS mean change in BCVA from baseline to Week 48, ETDRS letters (primary endpoint)	8.7	8.1	7.2
LS mean change in BCVA from baseline to Week 96, ETDRS letters	7.7	8.2	6.6
LS mean change in CRT from baseline to Week 96, µm	–191	–194	–158
Mean number of injections administered from baseline to Week 96, n	13.8	9.5	7.8

- **88%** of patients randomised to the **aflibercept 8q16** treatment arm (n=163) achieved a last assigned **treatment interval of ≥16 weeks at Week 96**[1]
  - **47%** achieved a last assigned **treatment interval of ≥20 weeks**[1]
- **92%** of patients randomised to the **aflibercept 8q12 treatment** arm (n=328) achieved a last assigned **treatment interval of ≥12 weeks at Week 96**[1]
  - **43%** achieved a last assigned **treatment interval of ≥20 weeks**[1]

Results: efficacy through Week 156

At Week 156, patients in the 8q12/8q16[§] arm maintained visual and anatomic improvements achieved in the first 2 years. In the 2q8 → 8mg arm, visual and anatomic improvements achieved with fixed 2q8 dosing up to Week 96 were maintained with aflibercept 8 mg through to Week 156.[7]

Key efficacy results[1]

Characteristic	AFL 8q12 continued on aflibercept 8 mg	AFL 8q16 continued on aflibercept 8 mg	AFL 2q8 switched to aflibercept 8 mg
N	103	49	70
LS mean change in BCVA from baseline to Week 156, letters	6.8	8.1	6.5
LS mean change in CRT from baseline to Week 156, µm	-190.3	-198.1	-197.4

- **62%** of patients randomised to the **aflibercept 8q12** treatment arm (n=103) achieved a last assigned **treatment interval of ≥16 weeks at Week 156**[1]
  - **20%** achieved a last assigned **treatment interval of 24 weeks**[1]
- **82%** of patients randomised to the aflibercept 8q16 treatment arm (n=49) achieved a last assigned **treatment interval of ≥16 weeks at Week 156**[1]
  - **43%** achieved a last assigned **treatment interval of 24 weeks**[1]
- **50%** of patients who were switched from 2q8 to aflibercept 8 mg (n=70) achieved a last assigned **treatment interval of ≥16 weeks at Week 156**[1]
  - No 24 week data available for patients originally randomised to 2q8 due to study design/length of study[1]

[§]Patients who were randomised to the 8q12 or 8q16 groups at the beginning of the PHOTON study and continued treatment with aflibercept 8 mg through the PHOTON extension study.
2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; AFL, aflibercept; BCVA, best corrected visual acuity; CRT, central retinal thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; HTA, Health Technology Assessment; LS, least squares; nAMD, neovascular age-related macular degeneration.

DMO clinical data: PHOTON trial

Results: safety profile through Week 96

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles[6]

- There were no cases of ischemic optic neuropathy, retinal vasculitis, or occlusive retinitis[6]
- The most common ocular AEs (≥5%) reported in patients treated with aflibercept 8 mg were cataracts, conjunctival haemorrhage and vitreous floaters[6]

Ocular and non-ocular AEs (Week 96)[6]

Characteristic	AFL 2q8 (n=167)	All AFL 8 mg (n=491)
Ocular safety through Week 96, %		
Patients with ≥1 ocular AE*	37.1	44.4
Patients with ≥1 IOI AE*	1.2	1.2
Patients with IOP ≥35 mmHg prior to or after injection†	1.2	0.4
Non-ocular safety through Week 96, %		
APTC events*	7.2	6.7
Hypertension events*	16.2	17.3
Non-ocular serious adverse events*	25.1	23.2
Deaths‡	5.4	4.7

Results: safety profile through Week 156

The overall safety profile in the extension phase was similar to that observed in the main phase.[1]

Ocular# and non-ocular AEs (Week 156)[7]**

Characteristic	AFL 2q8 → 8 mg (n=70)	AFL 8q12/8q16 (n=195)§
Ocular TEAEs, n (%)	37 (52.9)	108 (55.4)
Ocular SAEs, n (%)	3 (4.3)	4 (2.1)
Patients with IOI, n (%)	1 (1.4)	3 (1.5)
Non-ocular SAEs, n (%)	24 (34.3)	58 (29.7)
APTC events, n (%)	5 (7.1)	14 (7.2)
Deaths, n (%)	2 (2.9)	10 (5.1)

*Any ocular TEAE in the study eye; †IOP in the study eye; ‡All events. §Patients who were randomised to the 8q12 or 8q16 groups at the beginning of the PHOTON study and continued treatment with aflibercept 8 mg through the PHOTON extension study.
#Cumulative events in the study eye from baseline through Week 156.
**extension safety analysis set.
2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; AFL, aflibercept; APTC, anti-platelet trialist' collaboration; DMO, diabetic macular oedema; HTA, Health Technology Assessment; IOI, intraocular inflammation; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; SAE, serious adverse events; TEAE, treatment-emergent adverse events.

RVO clinical data: QUASAR trial

Overview and study design

QUASAR is a global randomised, double-masked, active-controlled Phase III study in treatment-naïve patients with macular oedema secondary to retinal vein occlusion (RVO) evaluating the efficacy and safety of aflibercept 8 mg used with extended dosing intervals compared to that of 2 mg aflibercept[1,8]

- Patients were randomised 1:1:1 at baseline to the following groups[1,8]
  - Aflibercept 8 mg at 8-week treatment intervals, after 3 initial injections at 4-week intervals (8q8/3)
  - Aflibercept 8 mg at 8-week treatment intervals, after 5 initial injections at 4-week intervals (8q8/5)
  - Aflibercept 2 mg at 4-week treatment intervals (2q4)
- Patients were treated for 60 weeks followed by a monitoring period through week 64.[1,8]
- Treatment intervals could be further adjusted based on treatment response.[1]
  - Dosing intervals for the aflibercept 8 mg groups could be shortened by 4 weeks if pre-specified criteria were met.
  - Treatment intervals could be extended at dosing visits from week 32 (f8q8/3 or 2q4)) or week 40 (8q8/5) if pre-specified criteria were met.

Patient population

Eligible patients were aged ≥18 years with treatment-naïve macular oedema involving the foveal center secondary to RVO[9]

- *Please request reference for comprehensive list of key eligibility criteria*

Study endpoints

- The primary non-inferiority endpoint was the mean change in BCVA from baseline at Week 36[9]
- The key secondary endpoint was the number of active injections from baseline to Week 36[9]

Patient characteristics

- In the QUASAR study, 892 patients with treatment-naïve macular oedema secondary to RVO were included in the statistical analyses. Baseline characteristics were balanced between the groups[1]

Please refer to section 5.1 in the United Kingdom Summary of Product Characteristics for the baseline patient characteristics of this study

Results: efficacy through Week 64

- Aflibercept 8 mg demonstrated **non-inferior vision gains at 36 weeks (primary endpoint)** with 8-week dosing regimens after only three initial monthly doses, compared with an aflibercept 2 mg 4-week dosing regimen[1]
- Vision gains achieved from baseline to Week 36 **remained stable and were maintained to Week 64**[1]
- Aflibercept 8 mg demonstrated **superiority in terms of the number of active injections from baseline to 64 weeks**, compared with an aflibercept 2 mg 4-week dosing regimen[1]

Key efficacy results[1]

Characteristic	AFL 8q8/3	AFL 2q4
N (FAS)	293	301
LS mean change in BVCA from baseline to Week 36, ETDRS letters (primary endpoint)	17.4	17.5
LS mean change in BVCA from baseline to Week 64, ETDRS letters	17.8	17.3
LS mean number of injections administered from baseline to week 36	6.1	8.8
LS mean number of injections administered from baseline to week 64	8.5	11.7

- **96%** of patients randomised to the **aflibercept 8q8/3 treatment arm** (n=293) achieved a last assigned **treatment interval of ≥8 weeks at Week 64**[1]
  - **86%** achieved a last assigned **treatment interval of ≥12 weeks**
  - **64%** achieved a last assigned **treatment interval of ≥16 weeks**
  - **41%** achieved a last assigned **treatment interval of ≥20 weeks**

Results: safety profile through Week 36

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles

- There were no cases of occlusive retinal vasculitis

Ocular and non-ocular AEs (Week 36)[10]

Characteristic	AFL 8q8/3	AFL 2q4
Ocular safety though week 36, %		
Patients with ocular TEAEs	39.9	32.6
Patients with IOI	0.7	1.3
Ocular safety though week 36, %		
APTC events	0	1.7
Non-ocular serious adverse events	7.5	8.6
Deaths	0.7	0.7

2q4, aflibercept 2 mg at 4-week treatment intervals; 8q8/3, 8 mg every 8 weeks after 3 initial injections at 4-week intervals; 8q8/5, 8 mg every 8 weeks after 5 initial injections at 4-week intervals; AE, adverse event; APTC, anti-platelet trialist' collaboration; BCVA, best corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; IOI, intraocular inflammation; LS, least squares; RVO, retinal vein occlusion.

Burden of disease

nAMD	• nAMD is a **common cause of acute and significant visual loss**, and its prevalence in the UK is expected to increase with the ageing population[11] • In a meta-analysis of population data in the UK (2007–2009), the prevalence of nAMD among people aged ≥50 years was estimated to be **2.4%**[12] • In the UK, approximately **40,000 people develop nAMD each year**[12]
DMO	• Nearly **1 in 3** people with diabetes have some evidence of DMO, and its prevalence is expected to rise with the increasing prevalence of diabetes[13] • In the UK the diabetic screening programme showed the 1-year cumulative incidence of maculopathy in type 2 diabetes mellitus was **5.2%** in those with non-proliferative diabetic retinopathy at baseline[14]
RVO	• RVO is a common cause of visual loss in the UK, and retinal vein occlusions are the second commonest cause of reduced vision due to retinal vascular disease.[15] • The incidence and prevalence of RVO increases with age[16] and BRVO occurs approximately 2–6 times as frequently as CRVO.[15] • There is no prevalence or incidence data available for the UK,[15] but one study has estimated the prevalence of RVO to be 0.7% in persons aged ≥55 years.[17]
UK NHS	• Eyecare is the **highest volume outpatient speciality** within the NHS and the medicines used for medical retinal vascular conditions account for some of the highest cost and volume treatments used within secondary care[18] • Lack of capacity is a major problem in the NHS because **clinics struggle to deliver the number of injections** that are required for individuals[19,20] • Due to increasing life expectancy, increasing prevalence of obesity and diabetes, and an ageing population, the NHS expects that **demand for medical retinal vascular treatments will continue to increase** in the future as more patients with eye disease are diagnosed and treated[18,21]
Unmet need	• Intravitreal injections are onerous for patients and the healthcare system. **Ocular injections can be a source of fear, stress and anxiety** and have negative effects on adherence and vision[22] • **Delivering frequent injections is a burden to the NHS** and causes capacity problems, which also affects patient care[23] • Treatments for which **fewer injections are required** to achieve the same outcomes for patients provide a benefit to both the patient and the NHS[23]

BRVO, Branch Retinal Vein Occlusion; CRVO, Central Retinal Vein Occlusion; DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neo-vascular age-related macular degeneration; RVO, retinal vein occlusion.

Cost-effectiveness / Health Technology Assessment

Overview	• In the PULSAR, PHOTON and QUASAR clinical trials, **aflibercept 8 mg was found to be clinically equivalent to aflibercept 2 mg in terms of efficacy**; aflibercept 8 mg also demonstrated a safety profile consistent with EYLEA 2 mg, with no new safety signals reported in PULSAR, PHOTON and QUASAR[1,2,6] • **EYLEA 8 mg is as clinically effective as EYLEA 2 mg** in terms of efficacy, and costs less per patient due to less frequent injections. It is therefore **more cost-effective than EYLEA 2 mg**[1,2,6] • In addition to the confidential discount on acquisition list price offered from launch of EYLEA 8 mg, a further discount has been applied[24]
NICE	• Aflibercept 8 mg is a high dose re-formulation of aflibercept 2 mg to which it is clinically equivalent in terms of efficacy. **Aflibercept 8 mg may be given less frequently** than aflibercept 2 mg and therefore may have a **lower per patient treatment cost** • As such, an **assessment of aflibercept 8 mg was considered unnecessary** by NICE's topic selection committee, i.e. a new formulation that is non-inferior to aflibercept 2 mg in terms of efficacy with at least equal cost-effectiveness does not warrant assessment • The statement from NICE confirming that an **assessment of aflibercept 8 mg is not needed** in nAMD is available here and for DMO is available here[25,26]
SMC and AWMSG	• Both the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG), after reviewing the efficacy and confidential pricing, have confirmed that **a submission is not required for aflibercept 8mg**. • Funding for aflibercept 8 mg is therefore **covered under the original 2 mg recommendation**
Existing management and place in therapy	• Aflibercept 8 mg is anticipated to provide a treatment option alongside other anti-VEGF medications licensed for **intravitreal use in nAMD, DMO and RVO** i.e. aflibercept 2 mg, ranibizumab, brolucizumab, faricimab[18] • **Use of aflibercept 8 mg should be considered locally** and included in local protocols to align with national policies • **Aflibercept 8 mg should be considered in nAMD, DMO and RVO**; given that aflibercept 8 mg may be injected less frequently than aflibercept 2 mg, aflibercept 8 mg may have benefits for clinic capacity and patient treatment cost [1,2,6]

DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neovascular age-related macular degeneration; NICE, National Institute for Health and Care Excellence; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

Drug cost: budget and societal impact

NHS list price

- Aflibercept 8 mg has an NHS list price of £998 per vial or pre-filled syringe (PFS).

NHS confidential discounted price

- Effective 1st December 2025, the confidential price of EYLEA 8 mg will be discounted by 35% from the original NHS confidential price. This is an additional 10% compared to the price which has been effective from Q1 2025.
- The 2 mg dose pricing has remained unchanged.
- Please note that EYLEA 2 mg and 8 mg vials will be phased out over the coming months, but EYLEA 8 mg and 2 mg PFS format will remain available.
- **Summary**
  - A 35% discount for EYLEA 8 mg is effective from 1st December 2025.
  - EYLEA 8 mg is as clinically effective as EYLEA 2 mg and has been shown to require fewer injections per patient.
  - EYLEA 8 mg and 2 mg PFS format will remain available

Budget impact

- As **fewer injections and/or hospital visits are anticipated per patient for aflibercept 8 mg compared to the current standard of care** (aflibercept 2 mg), the introduction of aflibercept 8 mg may be **expected to reduce annual service costs**. Each injection not needed will save the NHS the cost of that injection in addition to saving an administration visit
- The potential savings to the NHS are dependent on current treatment practices – if you require more information aligned to your current practice, ***please contact a Bayer representative***

Estimated nAMD patient numbers eligible for treatment

- The estimates provided below focus on incident (treatment-naïve) patients and exclude potential switching from other anti-VEGFs to aflibercept 8 mg
- Numbers have been provided by nation and per 100,000 population (final row)

Number of patients eligible for treatment (nAMD)[27,28]

	UK	Great Britain	England and Wales	England	Wales	Scotland	NI
All persons	67,026,292	65,121,729	59,641,829	56,536,419	3,105,410	5,479,900	1,904,563
Number of people ≥50 years, mid 2021	25,707,465	25,004,164	22,778,476	21,473,353	1,305,123	2,225,688	703,301
Incidence of nAMD people ≥50, %	0.19%	0.19%	0.19%	0.19%	0.19%	0.19%	0.19%
Number with nAMD	48,844	47,508	43,279	40,799	2,480	4,229	1,336
Proportion who are eligible for treatment	85%	85%	85%	85%	85%	85%*	85%
Number	41,518	40,382	36,787	34,679	2,108	3,594	1,136
Number (per 100,000 population)	***62***	***62***	***62***	***61***	***68***	***66***	***60***

Estimated DMO patient numbers eligible for treatment

- The estimates provided below focus on incident (treatment-naïve) patients and exclude potential switching from other anti-VEGFs to aflibercept 8 mg
- Numbers have been provided by nation and per 100,000 population (final row)

Number of patients eligible for treatment (DMO)[27,29]

	UK	Great Britain	England and Wales	England	Wales	Scotland	NI
All persons	67,026,292	65,121,729	59,641,829	56,536,419	3,105,410	5,479,900	1,904,563
Adult population at mid-2021	52,441,872	50,993,029	46,593,763	44,140,325	2,453,438	4,399,266	1,448,843
Prevalence of diabetes	7.42%	7.42%	7.42%	7.42%	7.42%	7.42%	7.42%
Number	3,891,187	3,783,683	3,457,257	3,275,212	182,045	326,426	107,504
Prevalence of visual impairment due to DMO	2.77%	2.77%	2.77%	2.77%	2.77%	2.77%	2.77%
Number	107,786	104,808	95,766	90,723	5,043	9,042	2,978
Proportion with CRT ≥400 µm	26%	26%	26%	26%	26%	26%	26%
Number	28,024	27,250	24,899	23,588	1,311	2,351	774
Proportion of prevalent population with CRT <400 µm who change to ≥400 µm each year	8.5%	8.5%	8.5%	8.5%	8.5%	8.5%*	8.5%
Number	6,780	6,592	6,024	5,707	317	569	187
Number (per 100,000 population)	***10***	***10***	***10***	***10***	***10***	***10***	***10***

* Assumption: the restrictions from NICE and SMC are different i.e. NICE has restrictions according to CRT whereas the SMC has restrictions according to starting vision. For simplicity, it has been assumed that in practice a comparable number of patients will be eligible and the restrictions from NICE have been applied to Scotland to provide an estimate of eligible patients; differences might exist due to rounding. #UK population figures calculated as England + Wales + Scotland + Northern Ireland; †Great Britain population calculated as England + Wales + Scotland.
AE, adverse event; BRVO, branch retinal vein occlusion; CRT, central retinal thickness; CRVO, central retinal vein occlusion; DMO, diabetic macular oedema; HTA, Health Technology Assessment; NI, Northern Ireland; nAMD, neovascular age-related macular degeneration; NICE, National Institute for Health and Care Excellence; RVO, retinal vein occlusion; SMC, Scottish Medicines Consortium; VEGF, vascular endothelial growth factor.

Drug cost: budget and societal impact

Estimated RVO patient numbers eligible for treatment

- The estimates provided below focus on incident (treatment-naïve) patients and exclude potential switching from other anti-VEGFs to aflibercept 8 mg
- Numbers have been provided by nation and per 100,000 population (final row)

Number of patients eligible for treatment (DMO)[27,30,31]

	UK[#]	Great Britain[†]	England and Wales	England	Wales	Scotland	NI
All persons							
Number of people aged ≥40 years, mid 2021	34,170,578	33,223,797	30,310,726	28,645,796	1,664,930	2,913,071	946,781
Branch RVO (BRVO)							
Incidence of branch RVO in people ≥40 years, %	0.12	0.12	0.12	0.12	0.12	0.12	0.12
Number with BRVO	41,005	39,869	36,373	34,375	1,998	3,496	1,136
Proportion with macular oedema (%)	85	85	85	85	85	85	85
Proportion with visual impairment due to macular oedema (i.e., eligible for treatment), %	50	50	50	50	50	50	50
Number	17,427	16,944	15,458	14,609	849	1,486	483
Central RVO (CRVO)							
Incidence of central RVO in people ≥40 years, %	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Number with CRVO	11,390	11,075	10,104	9,549	555	971	316
Proportion with macular oedema (%)	75	75	75	75	75	75	75
Proportion with visual impairment due to macular oedema (i.e., eligible for treatment), %	100	100	100	100	100	100	100
Number	8,543	8,306	7,578	7,161	416	728	237
BRVO and CRVO							
Number	25,970	25,250	23,036	21,771	1,265	2,214	720
Number (per 100,000 population)	76	76	76	76	76	76	76

Source: UK census population data 2021 age 40+
BRVO, Branch Retinal Vein Occlusion; CRVO, Central Retinal Vein Occlusion; RVO, retinal vein occlusion.
[#]UK population figures calculated as England + Wales + Scotland + Northern Ireland; [†]Great Britain population calculated as England + Wales + Scotland.

Net zero target for NHS emissions must be achieved by 2045[32]

Environmental impact and sustainability

- Compared with aflibercept 2 mg, aflibercept 8 mg is anticipated to have a positive impact regarding environmental impact and sustainability
  - Reduced dosing frequency when compared with aflibercept 2 mg means that fewer clinic visits will be required for patients. This means fewer car journeys and reduced use of public transport is required[2,6,33]
- In addition, reduced injection frequency will result in reduced use of clinical consumables and reduce the creation of medical waste[33]

Sustainability across ophthalmology

Ophthalmology services experienced ~8.9 million patient attendances in England between 2023–2024, making it one of the busiest outpatient specialities in the UK[34–36]

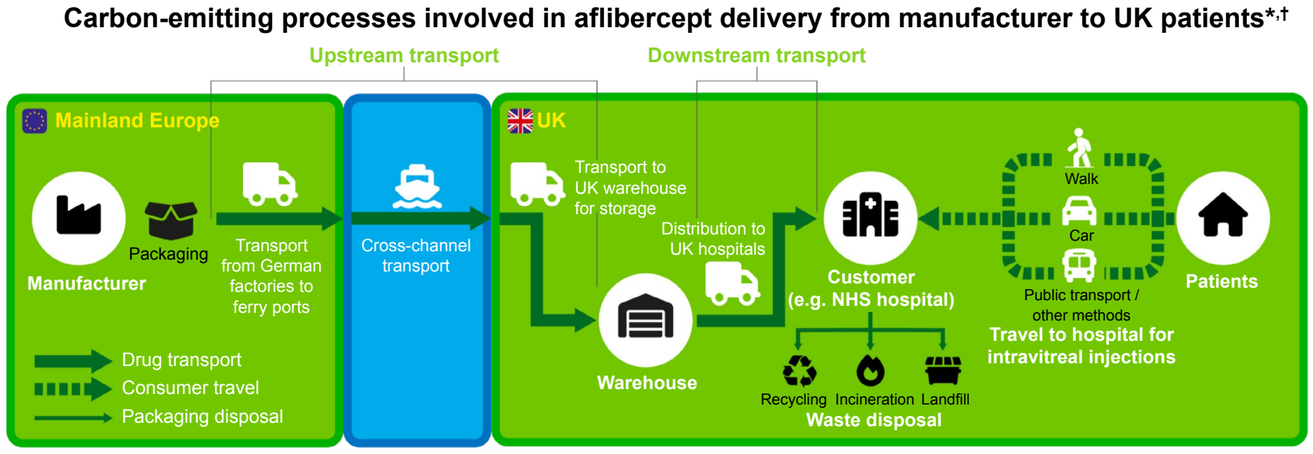
- With a growing aging population, the number of nAMD cases in the UK is expected to further rise[37]
- Therefore, sustainability, a key focus within the NHS[33,38] is important across ophthalmology

Study overview

Sustainability of 8 mg aflibercept: Insights from Bowley et al. 2025[39]

- Aflibercept 8 mg may allow patients with nAMD to receive less frequent injections after the initial monthly loading doses while providing similar clinical outcomes vs. aflibercept 2 mg[40]
- The packet size of aflibercept 8 mg PFS is smaller than that of aflibercept 2 mg PFS[39*]
- Hypothesis: aflibercept 8 mg PFS was anticipated to be associated with a reduced environmental impact compared with aflibercept 2 mg PFS[39*]
- **The potential difference in the carbon emissions between aflibercept 8 mg PFS and aflibercept 2 mg PFS for manufacturer to UK patients was evaluated[39*]**

Carbon-emitting processes involved in aflibercept delivery from manufacturer to UK patients*,†



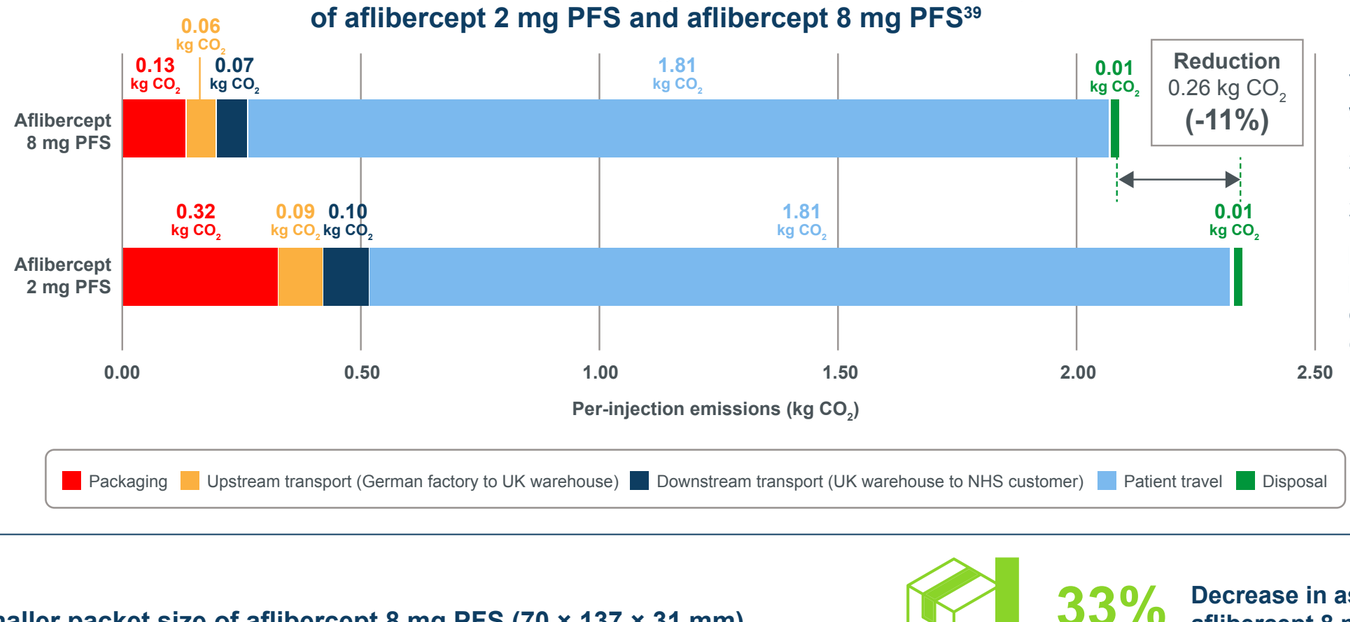
Taken from Bowley N et al. 2025. © The Author(s) 2025. Published by Springer Nature under CC BY 4.0.

The key areas of focus were:

- Packaging creation
- Patient travel
- Waste disposal
- Upstream and downstream transport of aflibercept

Carbon footprint per injection

Carbon emissions between factory gate and UK patients per injection of aflibercept 2 mg PFS and aflibercept 8 mg PFS[39]



The overall carbon footprint per injection was calculated to be:

2.1 kg CO_2 for aflibercept 8 mg PFS vs.

2.3 kg CO_2 for aflibercept 2 mg PFS.

Each aflibercept 8 mg PFS injection is estimated to have reduced carbon emissions of 11% (0.26 kg CO_2) compared with aflibercept 2 mg PFS.[39]

Impact of packet size on transport emissions

Smaller packet size of aflibercept 8 mg PFS (70 × 137 × 31 mm) vs. aflibercept 2 mg PFS (94 × 135 × 31 mm) enables ~67% more units to fit on a single pallet[39]

33% **Decrease in associated transport emissions with aflibercept 8 mg vs aflibercept 2 mg[39]**

66% **Reduction in plastic polypropylene with aflibercept 8 mg vs aflibercept 2 mg[39]**

Per population modelling

Per-population modelling applied to the entire eligible UK nAMD population over initial 2 years of using aflibercept 8 mg PFS vs. aflibercept 2 mg PFS suggested:[39]

~277,000–736,000 kg CO_2

reduction between factory gate and UK patients (equivalent to ~22%–47% reduction in emissions)[39]

- The greatest factor affecting the reduction in carbon footprint over a **sustained treatment period** was a decrease in **patient travel** and therefore emissions with aflibercept 8 mg PFS vs. aflibercept 2 mg PFS[39]
- The reduction in patient travel was made possible by the **improved durability** associated with aflibercept 8 mg PFS and the consequent **reduction in hospital visits**, compared with aflibercept 2 mg[39#†]

Due to the many assumptions and estimations that were necessary, these results should be interpreted with caution, and a long-term prospective study is needed to reinforce these findings.

*Aflibercept PFS was chosen as the focus of the study vs. aflibercept vial for IVT injection, as the PFS is used by the majority of healthcare providers in the UK.[39]

#It was assumed that one injection equated to one hospital visit.[39]

†Estimated numbers of injections are estimates for PFS specifically, even if extrapolated from studies where vials were used.[39]

nAMD, neovascular age-related macular degeneration; NHS, National Health Service; PFS, pre-filled syringe

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HTA, Health Technology Assessment.

EYLEA prescribing information & adverse event reporting

Prescribing Information and adverse event reporting information for EYLEA® (aflibercept) 2 mg and 8 mg is available via the QR code on the right.

Either click here or scan the QR code for prescribing information and adverse event reporting information.

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

Reporting adverse events and quality complaints

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc.

If you want to report an adverse event or quality complaint, reports can be directed to Tel.: 0118 2063500 Email: pvuk@bayer.com.

Further information is available on the "contact" tab at www.bayer.co.uk

AE, adverse event; DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neovascular age-related macular degeneration.

Contact details

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