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 8mg (aflibercept 114.3 mg/mL solution for intravitreal injection)[1,2]

- 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

Prescribing Information and adverse event reporting information for EYLEA® (aflibercept) 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 8mg (aflibercept 8 mg) represents a line extension from the currently available EYLEA/aflibercept 2 mg dose.

As aflibercept 8 mg offers clinically equivalent efficacy (this terminology is used in this document to describe the results of primary endpoints powered for non-inferiority) and a similar safety profile to aflibercept 2 mg at the same unit cost to the NHS,[1,2,3] most local health systems will only require an update to their existing aflibercept 2 mg formulary listing rather than a full formulary application.

An expanded document developed to support formulary updates is also available.

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 https://yellowcard.mhra.gov.uk 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.

This is a promotional material organised and funded by Bayer.
Prescribing information for EYLEA® (aflibercept) is available on the first & penultimate pages via QR code and link.
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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; SMC, Scottish Medicines Consortium.

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Details of aflibercept 8 mg

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.

Aflibercept 8 mg overview[1,2]

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**)
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**. In Great Britain the injection must only be administered by a **qualified healthcare professional** experienced in administering intravitreal injections. In Northern Ireland, the injection must only be administered by a **qualified physician** experienced in administering intravitreal injections. • The aflibercept 8 mg dose requires use of the EYLEA 114.3 mg/mL vial or (in Great Britain only) PFS with OcuClick dosing system. Each vial or 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 5 months**, such as with a treat-and-extend dosing regimen, while maintaining stable visual and/or anatomic outcomes • If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly based on the physician's discretion. The shortest interval between two injections is 2 months in the maintenance phase • Aflibercept at monthly doses of 8 mg has **not been studied for more than 3 consecutive doses** • 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 GB Summary of Product Characteristics or NI Summary of Product Characteristics as appropriate 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[4]

- Patients were randomised 1:1:1 at baseline to the following groups, before receiving three initial monthly loading doses:[4]
  - 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 open-label extension until Week 156[4]
- Dosing intervals for the aflibercept 8 mg groups could be shortened or extended if pre-specified criteria were met[4]

Patient population

Eligible patients were aged ≥50 years with treatment-naïve nAMD[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[5]
- The key secondary endpoint was the proportion of patients without intraretinal fluid and subretinal fluid in the central subfield at Week 16[5]

Patient characteristics

- In the PULSAR trial, 1,009 patients with nAMD were included in the statistical analyses. Baseline characteristics were balanced between the groups[4]

Please refer to section 5.1 in the GB Summary of Product Characteristics or NI Summary of Product Characteristics as appropriate for the baseline patient characteristics of this study

Results: efficacy

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[5]

Key efficacy results

Characteristic	AFL 2q8	AFL 8q12	AFL 8q16
N (FAS)[4]	336	335	338
LS mean change in BCVA from baseline to Week 48, ETDRS letters (primary endpoint)[4]	7.0	6.1	5.9
LS mean change in BCVA from baseline to Week 96, ETDRS letters[4]	6.6	5.6	5.5
LS mean change in CST from baseline to Week 96, µm[4]	–147	–152	–149
Proportion of patients with absence of IRF and SRF in the central subfield at Week 16, % (key secondary endpoint)[4]	52	62	65
Mean number of injections administered from baseline to Week 96, n[4]	12.8	9.7	8.2

- 78% of patients randomised to aflibercept 8q16 (n=292) achieved a last assigned treatment interval of ≥16 weeks at Week 96[4]
  - 53% achieved a last assigned treatment interval of ≥20 weeks[4]
- 87% of patients randomised to aflibercept 8q12 (n=291) achieved a last assigned treatment interval of ≥12 weeks at Week 96[4]
  - 41% achieved a last assigned treatment interval of ≥20 weeks[4]

Results: safety profile

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles[4]

- There were no cases of endophthalmitis, retinal vasculitis or occlusive retinitis[4]
- The most common adverse reactions (≥5%) reported in patients treated with aflibercept 8 mg were cataract, retinal haemorrhage, reduced visual acuity and vitreous floaters[4]

Ocular and non-ocular AEs (Week 96)[4]

Characteristic	AFL 2q8 (n=336)	All AFL 8 mg (n=673)
Ocular safety through Week 96, n (%)		
Patients with ≥1 TEAE	181 (53.9)	345 (51.3)
Patients with ≥1 IOI AE*	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

*Reported IOI terms: anterior chamber cell, chorioretinitis, iridocyclitis, iritis, uveitis, vitreal cells and vitritis; †TEAEs; ‡All events.
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; 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; IOI, intraocular inflammation; IRF, intraretinal fluid; LS, least squares; nAMD, neovascular age-related macular degeneration; SRF, subretinal fluid; TEAE, treatment-emergent adverse events.

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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[6]

- Patients were randomised 1:2:1 at baseline to the following groups[6]
  - 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 monthly loading doses and those in the aflibercept 2 mg arms received five monthly loading doses[6]
- The study was 96 weeks in duration with an optional open-label extension until Week 156[7]
- Dosing intervals for the aflibercept 8 mg groups could be shortened or extended if pre-specified criteria were met[7]

Patient population

Eligible patients were aged ≥18 years with type 1 or 2 diabetes[6]

- *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[7]
- The key secondary endpoint was the proportion of patients with ≥2-step improvement in Diabetic Retinopathy Severity Scale (DRSS) at Week 48[6]

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[7]

Please refer to section 5.1 in the GB Summary of Product Characteristics or NI Summary of Product Characteristics as appropriate for the baseline patient characteristics of this study

Results: efficacy

- 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[6,7]
- Vision gains achieved from baseline to Week 48 **remained stable and were maintained to Week 96**[6,7]

Key efficacy results[6,7]

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=139) achieved a last assigned **treatment interval of ≥16 weeks at Week 96**[7]
  - **47%** achieved a last assigned **treatment interval of ≥20 weeks**[7]
- **92%** of patients randomised to the **aflibercept 8q12 treatment** arm (n=256) achieved a last assigned **treatment interval of ≥12 weeks at Week 96**[7]
  - **43%** achieved a last assigned **treatment interval of ≥20 weeks**[7]

Results: safety profile

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles[7]

- There were no cases of ischemic optic neuropathy, retinal vasculitis, or occlusive retinitis[7]
- The most common ocular AEs (≥5%) reported in patients treated with aflibercept 8 mg were cataracts, conjunctival haemorrhage and vitreous floaters[7]

Ocular and non-ocular AEs (Week 96)[7]

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

*Any ocular TEAE in the study eye; †IOP in the study eye; ‡All events.
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; 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; IOI, intraocular inflammation; LS, least squares; nAMD, neovascular age-related macular degeneration

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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[8] • 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%**[9] • In the UK, approximately **40,000 people develop nAMD each year**[9]
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[10] • 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[11]
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[12] • Lack of capacity is a major problem in the NHS because **clinics struggle to deliver the number of injections** that are required for individuals[13,14] • 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[12,15]
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[16] • **Delivering frequent injections is a burden to the NHS** and causes capacity problems, which also affects patient care[17] • Treatments for which **fewer injections are required** to achieve the same outcomes for patients provide a benefit to both the patient and the NHS[17]

DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neo-vascular age-related macular degeneration.

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Cost-effectiveness / Health Technology Assessment

Overview	• In the PULSAR and PHOTON 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 **similar safety profile** to aflibercept 2 mg[1,2,4,7] • **Aflibercept 8 mg is as clinically effective as aflibercept 2 mg**, and on average costs less per patient, due to less frequent injection. It is therefore **more cost-effective than aflibercept 2 mg**[1,2,4,7]
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 lower total costs 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[18,19]
SMC and AWMSG	• Both the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) have confirmed that as aflibercept 8 mg is clinically equivalent to aflibercept 2 mg in terms of efficacy and available at the same confidential price, **a submission is not required** • 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 and DMO** i.e. aflibercept 2 mg, ranibizumab, brolucizumab, faricimab[12] • **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 and DMO**; 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[1,2,4,7]

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

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Drug cost: budget and societal impact

NHS list price

- Aflibercept 8 mg (per vial) has an NHS list price of £998
- Aflibercept 8mg is available to the NHS at the same confidential price per units as aflibercept 2 mg. As aflibercept 8 mg is as clinically effective as aflibercept 2 mg in terms of efficacy, and on average costs less per patient due to less frequent injections, it is therefore more cost-effective than aflibercept 2 mg[1–4,7]

NHS confidential discounted price

- Aflibercept 8 mg (per vial) is **available to the NHS at the same confidential discounted price as aflibercept 2 mg**[3]

Budget impact

- Both aflibercept 8 mg and aflibercept 2 mg are available to the NHS at the same confidential price per unit[3]
- 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)[20,21]

	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)[20,22]

	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***

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[4,7,23]
- In addition, reduced injection frequency will result in reduced use of clinical consumables and reduce the creation of medical waste[23]

* 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.
AE, adverse event; CRT, central retinal thickness; 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; SMC, Scottish Medicines Consortium; VEGF, vascular endothelial growth factor.

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HTA, Health Technology Assessment.

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EYLEA prescribing information & adverse event reporting

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Reporting adverse events and quality complaints

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk 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

For further information about EYLEA please contact Bayer Ophthalmology:

Bayer plc,
400 South Oak Way,
Reading,
RG2 6AD.

Telephone: 0118 2063000

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