



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

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 <u>here</u> 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.



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- 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.

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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.



Details of aflibercept 8 mg

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

flibercept 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)
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 affibercept 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 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 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 mg² 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 nAMD³ ∘ 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 48³ The key secondary endpoint was the proportion of patients without intraretinal fluid and subretinal fluid in the central s 	ubfield at Week	16 ³			
Patient characteristics	 In the PULSAR trial, 1,009 patients with nAMD were included in the statistical analyses. Baseline characteristics were Please refer to section 5.1 in the United Kingdom Summary of Product Characteristics for the baseline patient ch 					
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 Key efficacy results Characteristic N (FAS)² LS mean change in BCVA from baseline to Week 48, ETDRS letters (primary endpoint)² LS mean change in BCVA from baseline to Week 96, ETDRS letters² LS mean change in CST from baseline to Week 96, μm² Proportion of patients with absence of IRF and SRF in the central subfield at Week 16, % (key secondary endpoint)² Mean number of injections administered from baseline to Week 96, n² 78% of patients randomised to aflibercept 8q16 (n=338) achieved a last assigned treatment interval of ≥16 weeks at V o 53% achieved a last assigned treatment interval of ≥20 weeks¹ 87% of patients randomised to aflibercept 8q12 (n=335) achieved a last assigned treatment interval of ≥12 weeks at V o 41% achieved a last assigned treatment interval of ≥20 weeks¹	AFL 2q8 336 7.0 6.6 -147 52 12.8 Veek 96 ¹		AFL 8q16 338 5.9 5.5 -149 65 8.2		
Results: efficacy through Week 156	Functional and anatomic improvements observed in the PULSAR trial up to Week 96 were largely maintained through Week Week efficacy results Characteristic N¹ LS mean change in BCVA from baseline to Week 156, letters¹ LS mean change in CRT from baseline to Week 156, μm¹ • 54% of patients randomised to the aflibercept 8q12 treatment arm (n=185) achieved a last assigned treatment interval • 24% achieved a last assigned treatment interval of 24 weeks¹ • 62% of patients randomised to the aflibercept 8q16 treatment arm (n=190) achieved a last assigned treatment interval • 24% achieved a last assigned treatment interval of 24 weeks¹ • 43% of patients who were switched from 2q8 to aflibercept 8 mg (n=208) achieved a last assigned treatment interval of 24 weeks¹	AFL 8q16 conton aflibercept 190 3.23 -147.54 I of ≥16 weeks a	inued AFL 20 8 mg aflibe at Week 1561			

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.

nAMD clinical data: PULSAR trial

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles²

- There were no cases of endophthalmitis, retinal vasculitis or occlusive retinitis²
- The most common adverse reactions (≥5%) reported in patients treated with aflibercept 8 mg were cataract, retinal haemorrhage, reduced visual acuity and vitreous floaters²

Ocular and non-ocular AEs (Week 96)²

Results: safety profile through Week 96

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

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)48#

Results: safety profile through Week 156

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)

2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; APTC, Anti-Platelet Trialists' Collaboration; DMO, diabetic macular oedema; HTA, Health Technology Assessment; IOI, intraocular inflammation; nAMD, neovascular agerelated macular degeneration; SAE, serious adverse events; TEAE, treatment-emergent adverse events.

^{*}Reported IOI terms: anterior chamber cell, chorioretinitis, iridocyclitis, iritis, uveitis, vitreal cells and vitritis; †TEAEs; ‡All 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.

DMO clinical data: PHOTON trial

Overview and study design	PHOTON was Phase II/III, multicentre, randomised, double-masked study in treatment 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 th • The study was 96 weeks in duration with an optional 60 week open-label extension and 8q16 continued on aflibercept 8 mg while maintaining their latest intervals. 70 paflibercept 8 mg starting at 12-week intervals. 1,6 • Dosing intervals for the aflibercept 8 mg groups could be shortened if pre-specified eligible for treatment extension if pre-specified criteria were met. During the open-lagroups based on pre-specified criteria. 1,6	e aflibercept 2 mg arm received until Week 156. In the extension patients originally assigned to 20 criteria were met. At week 52, p	d five initial injections on study, 195 patient q8 at the beginning o patients in the aflibe	s at 4-week into s originally ass of the study we	ervals. ^{1,5} signed to 8q12 ere switched to ups were also
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 48⁶ The key secondary endpoint was the proportion of patients with ≥2-step improvement 	ent in Diabetic Retinopathy Seve	erity Scale (DRSS) a	at Week 48 ⁵	
Patient characteristics	 In the PHOTON study, 658 patients with treatment-naïve or previously treated DMC between the groups⁶ Please refer to section 5.1 in the United Kingdom Summary of Product Character 		•		were balanced
Results: efficacy through Week 96	 doses, compared with an aflibercept 2 mg 8-week dosing regimen after five initial m Vision gains achieved from baseline to Week 48 remained stable and were maint Key efficacy results^{5,6} Characteristic N (FAS) LS mean change in BCVA from baseline to Week 48, ETDRS letters (primary endposed by the stable and were maint Key efficacy results^{5,6} LS mean change in BCVA from baseline to Week 96, ETDRS letters LS mean change in CRT from baseline to Week 96, μm 	ained to Week 96 ^{5,6}	AFL 2q8 167 8.7 7.7 –191	328 8.1 8.2 -194	AFL 8q16 163 7.2 6.6 -158
	 Mean number of injections administered from baseline to Week 96, n 88% of patients randomised to the aflibercept 8q16 treatment arm (n=163) achieve of 47% achieved a last assigned treatment interval of ≥20 weeks1 92% of patients randomised to the aflibercept 8q12 treatment arm (n=328) achieve of 43% achieved a last assigned treatment interval of ≥20 weeks1 	-			7.8
	At Week 156, patients in the 8q12/8q16§ arm maintained visual and anatomic improver improvements achieved with fixed 2q8 dosing up to Week 96 were maintained with affilied to the second secon	•	156. ⁷ AFL 8q16 conti	nued AFL 2d	
	LS mean change in BCVA from baseline to Week 156, letters	6.8	8.1		6.5
Results: efficacy through Week 156	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 20% achieved a last assigned treatment interval of 24 weeks¹ 82% of patients randomised to the aflibercept 8q16 treatment arm (n=49) achieved 43% achieved a last assigned treatment interval of 24 weeks¹ 50% of patients who were switched from 2q8 to aflibercept 8 mg (n=70) achieved a No 24 week data available for patients originally randomised to 2q8 due to study or stu	a last assigned treatment intervent last assigned treatment intervent	rval of ≥16 weeks a	at Week 156¹	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

Aflibercept 2 mg and aflibercept 8 mg showed similar safety profiles⁶

- There were no cases of ischemic optic neuropathy, retinal vasculitis, or occlusive retinitis⁶
- The most common ocular AEs (≥5%) reported in patients treated with aflibercept 8 mg were cataracts, conjunctival haemorrhage and vitreous floaters⁶

Ocular and non-ocular AEs (Week 96)6

Results:	safety	profile	through
Week 96			

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	

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**

Results: safety profile through Week 156

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.

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2q8, 2 mg every 8 weeks; 8q12, 8 mg every 12 weeks; 8q16, 8 mg every 12 weeks; 8q16, 8 mg every 16 weeks; AE, adverse event; 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.



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 population⁸ 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 year⁹
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 diabetes¹⁰ 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 baseline¹¹
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 care¹² 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 vision¹⁶ Delivering frequent injections is a burden to the NHS and causes capacity problems, which also affects patient care¹⁷ Treatments for which fewer injections are required to achieve the same outcomes for patients provide a benefit to both the patient and the NHS¹⁷

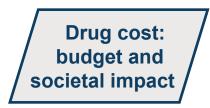
DMO, diabetic macular oedema; HTA, Health Technology Assessment; nAMD, neo-vascular age-related macular degeneration.



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^{1,2,6} 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 applied¹⁸
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
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 and DMO i.e. aflibercept 2 mg, ranibizumab, brolucizumab, faricimab¹² 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 ^{1,2,6}

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.



Drug cost: budget and societal impact

NHS list price	Aflibercept 8 mg (per vial or pre-filled syringe) has an NHS list price of £998
NHS confidential discounted price	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. In addition to the confidential discount on acquisition list price offered from launch of EYLEA 8 mg, a further discount has been applied ^{1,2,6,18}
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
	The estimates provided below focus on incident (treatment news) national and evalved protection with him from other anti-VEOEs to efficience at 0 and

- 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)^{21,22}

Estimated nAMD patient numbers eligible for treatment

	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

- 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)^{21,23}

	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

Estimated DMO patient numbers eligible for treatment

Environmental impact and • Reduction reduces

- 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^{2,6,24}
- In addition, reduced injection frequency will result in reduced use of clinical consumables and reduce the creation of medical waste²⁴

^{*} Assumption: the restrictions from NICE and SMC are different i.e. NICE has restrictions according to SCT 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.



References

- Bayer PLC. EYLEA (aflibercept) 8 mg summary of product characteristics for United Kingdom.
- 2. Korobelnik JF. Aflibercept 8 mg in Patients with Neovascular Age-Related Macular Degeneration: Phase 3 PULSAR Trial 96-Week Results. Presentation at the American Academy of Ophthalmology (AAO) Annual Congress; San Francisco, CA, USA, November 3–6, 2023.
- 3. Spitzer M. Intravitreal Aflibercept 8 mg Injection in Patients with Neovascular Age-Related Macular Degeneration: 48-Week Results from the Phase 3 PULSAR Trial. Presentation at the Association for Research in Vision and Ophthalmology (ARVO); New Orleans, LA, US, April 23–27, 2023.
- Wong TY. Presentation at the 22nd Angiogenesis, Exudation, and Degeneration 2025 Annual Meeting; 8 February 2025.
- 5. Do D. Aflibercept 8 mg for Diabetic Macular Edema: 48-Week Results From the Phase 2/3 PHOTON Trial. Presentation at the Association for Research in Vision and Ophthalmology (ARVO) 2023 meeting; Palo Alto, CA, USA, April 23–27, 2023.
- 6. Do DV. Aflibercept 8 mg for Diabetic Macular Edema: 96-Week Results From the Phase 2/3 PHOTON Trial. Presentation at the American Academy of Ophthalmology (AAO) Annual Congress; San Francisco, CA, USA, November 3–6, 2023.
- 7. Do D. Presentation at the American Academy of Ophthalmology (AAO) Annual Meeting, 18–21 October 2024.
- 8. National Institute for Health and Care Excellence. Age-related macular degeneration: diagnosis and management (NG82). Available at: https://www.nice.org.uk/guidance/ng82/evidence/full-guideline-pdf-170036251098. Accessed July 2025.
- **9.** Owen CG, Jarrar Z, Wormald R *et al*. The estimated prevalence and incidence of late stage age related macular degeneration in the UK. *Br J Ophthalmol*. 2012; 96 (5): 752–756.
- 10. Duphare C, Desai K, Gupta P et al. Diabetic macular edema. StatPearls [Internet]. StatPearls Publishing; Florida, US, 2023.
- 11. Jones CD, Greenwood RH, Misra A et al. Incidence and progression of diabetic retinopathy during 17 years of a population-based screening program in England. Diabetes Care. 2012; 35 (3): 592–596.
- 12. NHS England. Operational note: commissioning recommendations following the national procurement for medical retinal vascular medicines. National procurement for anti-VEGF and intravitreal corticosteroids. Available at: https://www.england.nhs.uk/long-read/operational-note-updated-commissioning-recommendations-for-medical-retinal-vascular-medicines-following-the-national-procurement-for-ranibizumab-biosimilars/.

 Accessed July 2025.
- 13. EURETINA Education Platform. 2022 clinical survey outcomes. Available at: https://eplatform.euretina.org/wp-content/uploads/2023/08/Final_2022-EURETINA-Survey-Supplement.pdf. Accessed July 2025.
- **14.** Royal College of Ophthalmologists. Commissioning guidance: Age related macular degeneration services: recommendations; May 2024. Available at: https://www.rcophth.ac.uk/wp-content/uploads/2021/08/AMD-Services-commendations.pdf. Accessed July 2025.
- 15. Whicher CA, O'Neill S and Holt RIG. Diabetes UK position statements. Diabetes in the UK: 2019. Diabet. Med. 2020; 37(2): 242–247.
- **16.** Monés J, Singh RP, Bandello F et al. Undertreatment of Neovascular Age-Related Macular Degeneration after 10 Years of Anti-Vascular Endothelial Growth Factor Therapy in the Real World: The Need for A Change of Mindset. Ophthalmologica 2020; 243 (1): 1–8.
- 17. Khachigian LM, Liew G, Teo KYC et al. Emerging therapeutic strategies for unmet need in neovascular age-related macular degeneration. J Transl Med 2023; 21 (1)
- **18.** Bayer. Data on File
- 19. National Institute for Health and Care Excellence. High-dose aflibercept for treating wet age-related macular degeneration TS ID 10590. Available at: https://www.nice.org.uk/guidance/topic-selection/gid-ta11133. Accessed July 2025.
- 20. National Institute for Health and Care Excellence. Aflibercept for untreated diabetic macular oedema. NICE guideline; TS ID 10621. Available at: https://www.nice.org.uk/guidance/topic-selection/gid-ta11134. Accessed July 2025.
- 21. Office of National Statistics. Estimates of the population for the UK, England, Wales, Scotland and Northern Ireland Office for National Statistics (ons.gov.uk) Mid-2021 dataset. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2021. Accessed July 2025.
- 22. Faricimab resource impact template for wet age-related macular degeneration. Available at: https://www.nice.org.uk/guidance/ta800/resources. Accessed July 2025.
- 23. Brolucizumab resource impact template for diabetic macular oedema. Available at: https://www.nice.org.uk/quidance/ta820/resources. Accessed July 2025.
- **24.** Power B, Brady R and Connell P. Analyzing the Carbon Footprint of an Intravitreal Injection. *J Ophthalmic Vis Res* 2021; 16 (3): 367–376.

HTA, Health Technology Assessment.



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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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