Adverse Event Reporting Information can be found below and on the penultimate page. 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

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.

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 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 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.

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.

Generic & brand name	Aflibercept 8 mg (EYLEA® 8mg)
Manufacturer	Bayer plc
Presentation/formulation details	Aflibercept (8 mg dose) 114.3 mg/mL solution for intravitreal injection in a vial. In Great Britain only: Aflibercept (8 mg dose) 114.3 mg/mL solution for intravitreal injection in pre-filled syringe.
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**)
Posology and administration[1,2]	● 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 administed 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 **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 three 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 ◦ 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 ◦ Treatment intervals should be shortened if visual and/or anatomic outcomes deteriorate, based on the physician's discretion, to **a minimum interval of 2 months in the maintenance phase** ● Aflibercept at monthly doses of 8 mg **has not been studied for more than three consecutive doses** ● The frequency of monitoring visits should be based on the patient's status and at the physician's discretion
Patient population	● Per 100,000 population the **UK** has an estimated: ◦ **62** treatment-naïve **nAMD** patients that are eligible for treatment[4,5] ◦ **10** treatment-naïve **DMO** patients that are eligible for treatment[4,6] **For a more detailed breakdown of UK population estimates please refer to the full formulary guide**
Economic modelling	**Aflibercept 8 mg is a high dose re-formulation of aflibercept 2 mg to which it is clinically equivalent in terms of efficacy**[7,8] Both aflibercept 8 mg and aflibercept 2 mg are available to the NHS at the **same confidential price per unit**[3] ● Aflibercept 8 mg may be given less frequently than aflibercept 2 mg and therefore may have a **lower per patient treatment cost**
NICE, SMC and AWMSG assessment of aflibercept 8 mg	● A NICE assessment of aflibercept 8 mg was considered unnecessary by NICE's topic selection committee, as a new formulation that is non-inferior to aflibercept 2 mg in terms of efficacy and with lower total costs does not warrant assessment[9,10] ● The SMC and the AWMSG have confirmed that **a submission is not required**, as aflibercept 8 mg is considered clinically equivalent to the 2 mg formulation in terms of efficacy
PULSAR and PHOTON: Clinical efficacy, treatment intervals and safety profile	● Results from the PULSAR (nAMD) and PHOTON (DMO) trials demonstrate **non-inferior vision gains from baseline to Week 48** with aflibercept 8 mg compared to aflibercept 2mg (primary endpoint), which remained stable and were maintained through Week 96[7,8,11,12] ● Of patients randomised to aflibercept **8 mg q16** at baseline, **78%** and **88%** of patients with **nAMD** and **DMO**, respectively, reached a **last assigned treatment interval** of **≥q16** at Week **96** with only **three loading doses**[7,8] ● The **safety** profile of **aflibercept 2 mg** and **aflibercept 8 mg** were **similar** in the PULSAR (nAMD) and PHOTON (DMO) trials[7,8,11,12] **For a more detailed summary of PULSAR and PHOTON please refer to the full formulary guide**
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:**[1,2] ● 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; AWMSG, All Wales Therapeutics and Toxicology Centre; DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; NICE, National Institute for Health and Care Excellence; q16, every 16 weeks; SMC, Scottish Medicines Consortium.

References

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AE, adverse event.

EYLEA prescribing information

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

AE, adverse event.

Contact details

For further information about EYLEA please contact Bayer Ophthalmology:

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

Telephone: 0118 2063000

AE, adverse event.