NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINES

Aflibercept Use in Wet Age-Related Macular Degeneration

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

Version Number:	5
Does this version include changes to clinical advice:	No
Date Approved:	31st May 2024
Date of Next Review:	31st May 2027
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Approval Group:	Ophthalmology Clinical Governance Group

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Protocol for Aflibercept use in wet age-related macular degeneration

1.Medicine name: Aflibercept 40mg/ml, solution for intravitreal injection (Eylea®)

2. Indication:
Aflibercept is licensed for the treatment of all subtypes of wet (neovascular) age-related macular degeneration (wAMD).

3. Prescriber details:
The treatment will be prescribed only by consultants with a special interest in medical retinal disease.

4. Criteria for patient selection:

Patients must fulfill **all** of the following criteria in the eye to be treated:

Patients presenting with recent visual loss with best corrected visual acuity (BCVA) better than or equal to 24 ETDRS letters (6/96 Snellen equivalent) and evidence of wAMD. If the BCVA falls out with this parameter, patients can still receive treatment at the discretion of the prescribing consultant.

No permanent scarring of the fovea resulting in a BCVA of less than or equal to 24 ETDRS letters.

The area affected by AMD is no larger than 12 times the size of the area inside the eye where the optic nerve connects to the retina.

A diagnosis of choroidal neovascularisation (CNV) will be confirmed by fundus fluorescein angiography (FFA), except in cases of allergy that preclude this, and optical coherence tomography (OCT). If polypoidal choroidal vasculopathy (PCV) is suspected then indocyanine green (ICG) angiography will be carried out and the patient will be considered for alternative treatment.

Treatment must be undertaken without delay and preferably within two weeks of initial development of symptoms or detection of a treatable lesion.

5. Contra-indications:

Hypersensitivity to the active substance or to any of the excipients.

Patients with active or suspected ocular or periocular infections.

Patients with active severe intraocular inflammation

Pregnancy

6. Administration details:

Year 1

The treatment can be given by a doctor or a trained practitioner. It should be noted that administration of the treatment by a trained practitioner is off-label but has been approved by the NHSGGC Governance Committee.

Aflibercept 2mg is administered by intravitreal injection under aseptic conditions. Aflibercept is initiated with a loading dose of one injection per month for three consecutive months. The patients will then be assessed one month following the loading dose. If the patient has responded to treatment then they will receive another injection one month following this, and at two monthly intervals for three further injections. A total of seven injections will be administered in the first year and a further assessment will be carried out at month 12.

If a patient has not responded to the initial loading dose then the decision to manage the patient differently may be made. Alternative management regimes may include more frequent injections with Aflibercept, more frequent monitoring, a PRN protocol, or switching to an alternative drug or treatment (e.g. Lucentis, macular laser or photodynamic therapy).

Patients will be given a phone number to contact if symptoms of concern occur between injections. An urgent assessment will then be arranged for the patient.

Injection schedule: Month 1,2,3,5,7,9,11
Follow up assessment schedule: Month 4,12

Subsequent years
From Year 2 onwards the management of the patient will be at the discretion of the prescribing consultant. Management regimes may include less/more frequent injections or less/more frequent monitoring.

7. Monitoring response to treatment:
Response to treatment will be assessed by measuring BCVA with ETDRS letter score, OCT examination and dilated fundus examination by a doctor trained in medical retina disease.

8. Stopping treatment:

Treatment will be stopped if:
-BCVA in the treated eye falls below 15 ETDRS letters on two consecutive visits.

-evidence of deterioration of lesion morphology despite optimum treatment e.g. progressive increase in lesion or worsening of OCT indicators.

-hypersensitivity or contra-indication to Aflibercept

9. Side-effects/cautions:
Most adverse events reported were transient, mild to moderate, and were attributed by the investigators to the injection procedure, rather than to the study drug. Serious adverse events related to the injection procedure occurred in less than 1% of intravitreal injections and included endophthalmitis and retinal detachment, and iatrogenic trauma.

Adherence to national guidance on intravitreal injections is required i.e. fully informed consent and injections being carried out in theatre or a dedicated clean room with adequate sterile technique by an ophthalmologist trained in intravitreal injections.

Systemic adverse events potentially related to systemic VEGF inhibition were not significantly greater in treatment groups compared to sham injection and PDT in the studies analysed by SMC.

Please refer to Summary of Product Characteristics (SPC) for Eylea available at www.medicines.org.uk for full details of side-effects and cautions for use.

10. Monitoring – treatment safety:
Patients will be given instruction and information on how to contact the eye department if symptoms of concern occur i.e. visual loss or eye pain or increased redness of the eye. The same procedures adopted for intraocular surgery e.g. cataract surgery will be adopted.

11. Written by: Dr Mike Gavin and Dr David Gilmour, Consultant Ophthalmologists and Alison Campbell, Clinical Pharmacist

12. Review date: May 2027