NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Ranibizumab use in Wet Age Related Macular Degeneration (AMD)

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.

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Approval Group:	Medicines Utilisation Subcommittee of ADTC

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 Ranibizumab use in wet age-related macular degeneration (AMD)

1. Medicine name: Ranibizumab 10mg/ml, solution for intravitreal injection (Lucentis)

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

3. Prescriber details:
The treatment will be prescribed only by consultants with a special interest in 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) between 6/12 and 6/96 and evidence of neovascular (wet) AMD in the eye considered for treatment.

There should be no permanent damage to the central fovea.

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 optical coherence tomography (OCT). Fundus fluorescein angiography (FFA) will be carried out when classification of the lesion is not possible, or when it is not possible to assess level of activity. Indocyanine green angiography (ICGA) will be carried out in cases of suspected polypoidal choroidal vasculopathy. Angiography will not be carried out in cases of allergy.

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:

Ranibizumab 0.5mg is administered by intravitreal injection under aseptic conditions. Ranibizumab is initiated with a loading dose of one injection per month for three consecutive months. This will be followed by a maintenance phase in which patients will be monitored monthly for any change in visual function, and any change on OCT or clinical examination. On rare occasions patients will require repeat FFA. The decision to re-treat is based on a combination of factors which include subjective and objective visual function, OCT appearance and clinical examination. If the CNV lesion is deemed to be active further ranibizumab will be administered at intervals of no less than one month.

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. The treatment can be given by an ophthalmologist 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

Pre-administration: Topical proxymethacaine or oxybuprocaine and povidine iodine 5% are instilled to the eye to be treated immediately before injection

7. Monitoring response to treatment:

Patients will be required to be monitored to assess the effect of the treatment and identify adverse events. This will involve measuring visual function using the Early Treatment of Diabetic Retinopathy Study (ETDRS) letter score acuity, OCT and clinical assessment. This assessment will be carried out one month after the loading dose of three injections, and monthly following this.

8. Stopping treatment:

Treatment will be stopped if:
-BCVA in the treated eye persistently falls below 6/60 during treatment.

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

-hypersensitivity or contra-indication to ranibizumab.

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.
Systemic adverse events potentially related to systemic VEGF inhibition were not significantly greater in treatment groups compared to sham injection and Photo Dynamic Therapy (PDT) in the studies analysed by SMC. Please refer to Summary of Product Characteristics (SPC) for Lucentis 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 & Dr David Gilmour, Consultant Ophthalmologists and Douglas Malcolmson, Lead Clinical Pharmacist