NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Ranibizumab use in Visual Impairment associated with Diabetic Macular Oedema

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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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 Visual Impairment associated with Diabetic Macular Oedema

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

2. Indication:

The treatment of visual impairment due to macular oedema secondary to diabetes mellitus (diabetic retinopathy)

3. Prescriber details:

The treatment will be prescribed only by consultants with a special interest in retinal disease. Administration by intravitreal injection will be by a suitably trained medical practitioner, an advanced nurse practitioner (Band 7) or a trained nurse injector (Band 6/7).

4. Criteria for patient selection:

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

Best Corrected Visual Acuity (BCVA) $\leq$ 75 (ETDRS letter score) and a mean central retinal subfield thickness measured using OCT of 250 micrometres or greater.

Patient awareness of subjective visual impairment is not an absolute requirement but treatment in such cases should be supervised by a Consultant Ophthalmologist with a specialist interest in the treatment of diabetic eye disease.

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

Evidence of significant macular ischaemia* (either clinically, on OCT angiography if available, or on flourescein angiography) which in the clinicians view would preclude an adequate response to treatment.

6. Administration details:
Ranibizumab 0.5mg is administered by intravitreal injection under aseptic conditions. Treatment is given monthly and continued until maximum visual acuity is achieved i.e. the patient's visual acuity is stable for three consecutive monthly assessments performed while on ranibizumab treatment. If there is no improvement in visual acuity over the course of the first three injections, a further three injections should be considered. More than six injections (if there is no visual improvement nor anatomical response) is not recommended.

Pre and post administration: Topical proxymethacaine or oxybuprocaine are instilled to the eye to be treated immediately before injection. Topical providone iodine drops (MINIMS) are then added to the conjunctival sac for at least 3 minutes before injection and additional skin preparation of the eyelids and surrounding area is carried out using the same or an equivalent preparation.

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 acuity, OCT and clinical assessment. This will be required at monthly intervals when ranibizumab is being administered and thereafter at the clinician's discretion – usually at intervals of three months once stability has been achieved.

8. Stopping treatment:
Treatment will be stopped if:

- BCVA and OCT features are stable for three consecutive clinical assessments performed while on ranibizumab treatment.

- BCVA> 75 ETDRS letters OR mean central retinal subfield thickness is less than 250 micrometres.

    - If there is no improvement in visual acuity over the course of a **maximum** of six injections. (Or earlier if there is no anatomical response demonstrated after the first three injections)

- Evidence of deterioration of lesion morphology despite optimum treatment e.g. progressive increase in central retinal subfield thickness or no (partial) response or worsening of visual acuity.

- Evidence of significant macular ischaemia – see above*

- 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.
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 the groups detailed above who have been adequately 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 ranibizumab 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, Consultant Ophthalmologist. NHS Greater Glasgow and Clyde

12. Review date: 13/03/2026