

## Policy Statement

### **Ranibizumab (Lucentis®) for the treatment of choroidal neovascularisation (adults)**

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Intravitreal Ranibizumab (IVR) is now licensed to treat patients for visual impairment due to choroidal neovascularization (CNV) associated with causes **other than** neovascular age-related macular degeneration (nAMD) or secondary to pathologic myopia (PM). NICE are not assessing Lucentis for this new indication.

Intravitreal Ranibizumab (IVR) is commissioned by NHS Wiltshire CCG for the treatment of the following conditions that haven't been assessed by NICE in accordance with the criteria detailed below.

#### **Choroidal neovascularisation**

Patients with choroidal neovascularisation (CNV) from causes other than AMD such as:

- Central serous retinopathy
- Inflammatory Uveitis and Chorio-retinal conditions
- Choroidal rupture or Angioid streaks (if the patient has associated myopia, follow NICE TA)
- Hereditary Macular Dystrophies (like Sorsby's Dystrophy)
- Idiopathic CNV

Can be offered a treatment with ranibizumab intravitreal injections when they fulfil **ALL** the following criteria:

- 1) Diagnosis of active CNV has been confirmed. This will normally require fluorescein angiography unless the patient has clinical contraindications.
- 2) Best corrected visual acuity (BCVA) is 6/96 (24 ETDRS letters) or better in the eye to be treated.
- 3) There is no significant permanent structural damage to the fovea, defined as longstanding fibrosis or atrophy or significant disciform scar, that would prevent functional benefit from treatment,
- 4) There is evidence of recent disease progression, defined as newly identified sight threatening CNV **OR** new haemorrhage and/or sub retinal fluid **OR** documented recent visual decline **OR** increase in size of CNV between visits.

Dr Rachel Hobson, Formulary Pharmacist, NHS Wiltshire CCG. Adapted with permission January 2017 from: NHS Swindon CCG policy: Bevacizumab for the treatment of retinal vein occlusion, diabetic macular oedema, neovascular glaucoma and choroidal neovascularisation. (September 2011)

- 5) The Ophthalmic surgeons should follow The Royal College of Ophthalmologists Guidelines for Intravitreal Injections Procedure 2009<sup>1</sup>. It is expected that most of these cases will need 2-3 doses of the treatment, however up to maximum of 6 per eye may be used.

### **Discontinuing Treatment**

Treatment will be permanently discontinued if the following criteria indicating deterioration despite treatment are met:

- 1) The best-corrected visual acuity (BCVA) in the eye being treated deteriorates to less than 6/96 after three or more injections. **OR**
- 2) There is a reduction in BCVA in the treated eye to less than 15 letters (3logMAR lines)(absolute) on 2 consecutive visits in the treated eye attributable to CNV. **OR**
- 3) BCVA falls by 30 letters or more, compared with baseline or best recorded level since baseline **OR**
- 4) There is evidence of deterioration in the morphology of the CNV lesion despite optimum treatment, assessed over 3 consecutive visits. Relevant evidence includes change in lesion size, new haemorrhages or exudates **OR**
- 5) A hypersensitivity reaction to ranibizumab is established or suspected.

### **Further Requirements**

1. All patients treated within these policies must be included in prospective six monthly departmental clinical audit of all criteria specified in this policy. The audit will include criteria reflecting anticipated benefits including reduction in laser treatments required per patient), adverse events (ocular and systemic) and expenditure.

3. A maximum of 50 doses of ranibizumab a year will be commissioned per acute provider. If a provider wishes to use more than the agreed amount for these indications, prior approval must be sought from the CCG.

### **Background to the treatment.**

Ranibizumab is a monoclonal antibody that recognises and blocks vascular endothelial growth factor (VEGF). VEGF stimulates the growth of new blood vessels. When new blood vessels grow within the eye (in response to damage), the growth tends to be abnormal and leak fluid causing the layers of the retina to separate.

The MINERVA study<sup>2</sup>, showed that ranibizumab treatment resulted in a significant gain of visual acuity by approximately 10 letters at two months; this gain was maintained to month 12 of the one-year study<sup>3</sup>. Ranibizumab has therefore proven to be effective for the treatment of CNV, regardless of the underlying etiology<sup>3</sup>.

## Background to the condition

CNV is an ocular condition caused by the growth of abnormal blood vessels below the retina, which cause disruption to vision<sup>4</sup>. The condition can occur rapidly, and is a major cause of vision loss, causing symptoms including visual distortion, color disturbances, partial loss of vision or a blindspot within the visual field<sup>5</sup>. CNV is most commonly associated with neovascular ("wet") age-related macular degeneration and pathologic myopia, but it can also occur with many other conditions including uveitis, central serous chorioretinopathy, angioid streaks, trauma, retinal or macular dystrophies, and with no apparent cause (idiopathic CNV)<sup>6</sup>

## References:

- 1.) The Royal College of Ophthalmologists. Guidelines for Intravitreal Injections Procedure 2009 [https://www.rcophth.ac.uk/wp-content/uploads/2015/01/2009-SCI-012\\_Guidelines\\_for\\_Intravitreal\\_Injections\\_Procedure\\_1.pdf](https://www.rcophth.ac.uk/wp-content/uploads/2015/01/2009-SCI-012_Guidelines_for_Intravitreal_Injections_Procedure_1.pdf)
- 2.) ClinicalTrials.gov. Identifier NCT01840410. Available at: <https://clinicaltrials.gov/ct2/show/study/NCT01840410> (link is external).
- 3.) Lai, T et al. Efficacy and safety of ranibizumab 0.5 mg in adult patients with visual impairment due to choroidal neovascularization associated with rare diseases: 12 month results of the MINERVA study. European Society of Retina Specialists (EURETINA) 2016. <http://euretina.org/copenhagen2016/programme/free-papers-details.asp?id=4443&day=0>
- 4.) American Academy of Ophthalmology. What Are Choroidal Neovascular Membranes? Available at: <http://www.aao.org/eye-health/diseases/choroidal-neovascular-membranes>.
- 5.) American Academy of Ophthalmology. Choroidal Neovascular Membranes Symptoms. Available at: <http://www.aao.org/eye-health/diseases/choroidal-neovascular-membranes-symptoms>
- 6.) Cohen S et al. Etiology of choroidal neovascularization in young patients. Ophthalmology 1996; 103: 1241-1244.