NHS
Pan Mersey
Area Prescribing Committee

RANIBIZUMAB intravitreal injection (Lucentis®) for choroidal neovascularisation (non-NICE indications)

The Pan Mersey Area Prescribing Committee recommends the prescribing of RANIBIZUMAB intravitreal injection (Lucentis®), by ophthalmologists only, for the treatment of visual impairment secondary to choroidal neovascularisation (CNV) in conditions not covered by NICE technology appraisals.

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Ranibizumab may be considered an option in the management of patients with visual impairment secondary to CNV. There is limited experience of using ranibizumab for this indication in children and adolescents aged 12-18 years. It is unlicensed for children under the age of 12.

The most common cause of CNV is wet age-related macular degeneration (wAMD), but any condition which involves the retinal pigment epithelium (RPE) and damages the Bruch's membrane can be complicated by CNV. Such conditions include, but are not limited to, pathological myopia (PM), angioid streaks (AS), inflammatory or infectious conditions (histoplasmosis, sarcoidosis, multifocal choroiditis (MFC), punctuate inner choroidopathy (PIC), central serous chorioretinopathy (CSCR)), choroidal tumours, trauma and idiopathic or hereditary causes.

The use of ranibizumab to treat visual impairment due to CNV secondary to wAMD and PM is covered by NICE technology appraisals. This statement covers the use of ranibizumab for CNV secondary to other causes, which were not considered by NICE because the ranibizumab licence only covered CNV associated with PM at that time. The licence was extended in November 2016 to the treatment of visual impairment CNV due to any cause.

Intravitreal bevacizumab (an unlicensed product) has been used in some centres to treat indications covered by this licence extension. Prescribers should give due consideration to MHRA guidance, stating that where a UK licensed product exists it should be used in preference to unlicensed specials, when prescribing for this indication.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

APC board date: 27 Sep 2017 | Last updated: 25 Sep 2019
This recommendation has been designated suitable for inclusion on the Pan Mersey APC static list and will only be reviewed if significant new evidence becomes available.
APC administration provided by Midlands and Lancashire Commissioning Support Unit

Prescribing policy statement
Version: 2.1
STATIC

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Effectiveness[1]

Ranibizumab is an anti-vascular endothelial growth factor (VEGF) agent, which blocks the angiogenic role of VEGF, implicated in the pathogenesis of CNV. In the 12-month MINERVA study (n=178), ranibizumab was shown to achieve a clinically and statistically significant improvement in the best corrected visual acuity from baseline to month two compared to placebo (difference for LS mean, 9.94 (95% CI 6.97-12.91, p <0.001). The observed benefits were maintained at 6 and 12 months in an open-label extension phase.

Safety[1,2]

Adverse reactions of treatment are mostly limited to the eye. Those most commonly reported in the clinical trials include vitritis, vitreous detachment, retinal haemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival haemorrhage, eye irritation, sensation of a foreign body in the eye, increased production of tears, blepharitis, dry eye, ocular hyperaemia, itching of the eye and increased intraocular pressure. Nasopharyngitis, arthralgia and headaches are also commonly reported. Ranibizumab is contra-indicated in patients with active or suspected ocular or periocular infections or with active severe intraocular inflammation.

Cost[3]

Ranibizumab solution for injection pre-filled syringe: £551 (NHS list price). A commercial in confidence patient access scheme (PAS) is in place for this agent.

It is anticipated that these patients will already be known to ophthalmology services, so implementation of this policy is unlikely to significantly change tariff activity. The incidence and prevalence of these conditions are not fully known, so exact patient numbers are not clear. Intelligence collected from local ophthalmology units suggest patient numbers will be <50/year for the Pan Mersey area.

In trials, the average number of injections per patient was 5.8. Therefore, assuming 50 patients per annum receiving 6 injections, the annual drug acquisition cost of implementing this policy is £165,300 (approximately £9,500 per 100,000 population). This does not include the PAS discount.

Patient factors[1,2]

No dose adjustments are required in patients with hepatic or renal impairment or in the elderly population. There is limited experience of use in the paediatric population.

Caution should be exercised when treating patients with a prior history of stroke or transient ischaemic attack, as non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors.

Prescribing information

The recommended dose of ranibizumab is 0.5mg given as a single intravitreal injection. The treatment regimen for patients with CNV should be determined on an individual basis based on disease activity. Some patients may only require a single injection in the first 12 months; other patients may require more frequent administration, including up to monthly injections. Ongoing frequency of treatment is determined by the specialist based on disease activity.

Implementation notes

Monitoring for disease activity may include clinical examination, optical coherence tomography (OCT) or fluorescein angiography (FA). While many patients may only need one or two injections during the first year, some patients may need more frequent treatment. Therefore, monitoring is recommended monthly for the first two months and at least every three months thereafter during the first year. After the first year, the frequency of monitoring should be determined by the treating physician. The interval between two doses should not be shorter than one month.

References

1. Lai TYY, Staurenghi G, Lanzetta P, et al. Efficacy and safety of ranibizumab for the treatment of choroidal neovascularization due to uncommon cause: twelve-month results of the MINERVA study. Retina 2018 Aug; 38(8): 1464-1477.
2. Novartis Pharmaceuticals UK Ltd. Summary of Product Characteristics: Lucentis 10mg/ml solution for injection in pre-filled syringe, 26 July 2018. Accessed 12 July 2019.
3. NHS Business Services Authority. dm+d browser. Accessed 26 July 2019.