

PRESS RELEASE

NICE issues final guidance on the use of ranibizumab and pegaptanib for the treatment of age-related macular degeneration (AMD)

NICE has today (27 August 2008) published its final guidance on the use of ranibizumab (Lucentis) and pegaptanib (Macugen) for the treatment of age-related macular degeneration (AMD). This means that the appeals against the final draft guidance on the use of these drugs have not been upheld. The guidance recommends ranibizumab as an option for the treatment of wet age-related macular degeneration if all of the following apply in the eye to be treated:

- Best possible visual acuity after correction with glasses or contact lenses is between 6/12 and 6/96.
- There is no permanent structural damage to the central fovea (the part of the eye that helps people to see things in sharp detail).
- The lesion size is no more than 12 times the size of the area inside the eye where the optic nerve connects to the retina.
- There are signs that the condition has been getting worse.
- The cost of ranibizumab beyond 14 injections is met by the manufacturer. The NHS should cover the drug cost of ranibizumab for the first 14 injections in each eye being treated. If people need more than 14 injections per eye, the manufacturer of ranibizumab has agreed to take over the drug cost from the NHS.
- Treatment should be stopped if a person's vision gets worse and there are changes inside the eye which show that treatment isn't working.

- Pegaptanib is not recommended for people with wet AMD. Healthcare professionals should not immediately stop prescribing pegaptanib for people who were already taking it when the guidance was issued. These people should be able to carry on taking pegaptanib until they and their healthcare professionals decide that it is the right time to stop treatment.

AMD is one of the leading causes of sight loss. AMD occurs in two forms, dry and wet (neovascular) AMD. Dry AMD is a form of extensive atrophy (wasting) of cells that progresses slowly, whereas the wet form can lead to rapid worsening of vision. There are about 26,000 new cases of wet AMD in the UK each year and the condition usually affects people who are over 50 years old, the risk increasing significantly with age. The condition also affects more women than men. The most commonly cited risk factor for AMD is cigarette smoking; the risk of developing AMD is more than 3 times greater for current and former smokers than for people who have never smoked.

Ranibizumab is given by injection into the eye and works by blocking a substance that causes new blood vessels to grow in the eye (known as vascular endothelial growth factor or VEGF), thereby stopping the bleeding at the back of the eye which causes the wet form of AMD.

Andrew Dillon, NICE Chief Executive, said: "Lucentis is an expensive drug, costing more than £10,000 for each eye treated. But that cost needs to be balanced against the likely cost savings. AMD results in reduced quality of life and increased risks of illness, particularly in relation to accidents – especially falls – and psychological ill-health. Studies have also demonstrated that patients with visual impairment tend to have longer hospitalisations, make greater use of health and community care services and are more likely to be admitted to nursing homes. It has been estimated that the costs related to sight impairment for patients treated with Lucentis are around £8000 cheaper than for patients who receive best supportive care over a 10 year period. Our guidance means that patients who are suitable for this treatment will have the same access to it, irrespective of where they live."

The guidance is available (from 00:01 on 27 August) on the NICE website at <http://www.nice.org.uk/TA155>

Ends

Notes to Editors

About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
2. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
3. As part of its interventional procedures (IP) work programme NICE has today also issued guidance on the implantation of miniature lens systems for advanced age-related macular degeneration this month.
 - The independent advisory committee acknowledges evidence shows this procedure can improve both vision and quality of life in the short-term; however, there currently is not enough long-term evidence on how well it works and how safe it is. Therefore the committee has recommended the procedure be used with special arrangements for clinical governance, consent and audit. This means that clinicians must ensure that the patient understands what is involved and agrees to the treatment, and the results of the procedure are recorded for further study. The committee also highlighted the importance of careful patient selection, including a detailed assessment to enable them to predict the patient's ability to process visual stimuli following the operation.
 - The IP programme makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. It does not make recommendations to the NHS about whether or not they should fund procedures. Decisions as to which procedures are available are taken at a local level are dependent on facilities and expertise available, as well as local governance arrangements.
 - The IP guidance on implantation of miniature lens systems for advanced age-related macular degeneration and further information can be found on the NICE website - <http://www.nice.org.uk/IPG272>.