

PRESS RELEASE -

NICE guidance sets recommendations on photodynamic therapy for age-related macular degeneration

The National Institute for Clinical Excellence (NICE) has issued guidance on the use of photodynamic therapy (PDT) for age-related macular degeneration (ARMD) within the NHS in England and Wales.

The Department of Health and the National Assembly for Wales asked NICE to look at PDT for ARMD because genuine uncertainty as to its long-term value for patients, combined with how best it should be used had resulted in 'post code prescribing'.

The NICE guidance makes it clear to the NHS and patients, no matter where they live in England and Wales, if and where this treatment can add value so that those patients who can benefit from the treatment will now be able to do so.

- NICE has recommended the use of PDT for a group of people with one type of "wet" ARMD. (people with wet ARMD who have a confirmed diagnosis of classic subfoveal CNV, with no sign of occult CNV. Individual's should also have at least 6/60 vision – this means that they can see (with glasses if they usually wear them) the same line of test letters 6 metres away that a person with normal vision can see when 60 metres away). The evidence showed that for people within this group, PDT had a reasonable chance of halting or slowing down the progression of the disease.
- For a second group of people (with a different type of wet ARMD), the evidence as to whether these patients were likely to derive any benefit from PDT, proved inconclusive. The independent advisory committee that advises NICE recommended that these people should access treatment through clinical studies which will help to provide evidence as to the outcome and effectiveness of such

treatment. Those receiving treatment would then be helping to provide good quality evidence about the benefits of PDT for this second group. The Department of Health has agreed to fund a nationwide clinical study and NICE will take results from the study into account when reviewing its guidance on PDT in 2006.

- Everyone with ARMD who started a course of PDT on the NHS before the NICE guidance was issued should have the option of continuing the course until their clinical condition indicates that it is appropriate to stop
- NICE has not issued any guidance in relation to a group of patients with a third type of wet ARMD because, at the time the evidence was assembled, PDT was not licensed for use in this group. Similarly, NICE has not issued any guidance in relation to the more common “dry” form of ARMD because PDT is not licensed for people with dry ARMD.

Anne-Toni Rodgers, Corporate Affairs Director and Executive Lead said , "This has been a particularly challenging appraisal, which has taken longer than anyone involved would have wished, but it is right when faced with challenging issues that we allow time for the proper consideration of evidence and consultation. The outcome is a good one, both for those with macular degeneration and the NHS. Within the types of macular degeneration we were able to issue guidance on - all patients who might benefit from this treatment will now be able to access it."

Miss Rodgers added: “The process NICE follows is genuinely consultative and involves bringing all of the evidence together and engaging with professionals and patients. Today’s guidance provides clear advice to the NHS and patients, no matter where they live in England and Wales, on where this treatment can add value. Once fully implemented it means that people with age-related macular degeneration should no longer be denied treatment on the basis of where they live.”

Professor David Barnett, Chair of the NICE Appraisal Committee said, "We have been faced with an extremely challenging and complex task with this appraisal. On average, NICE technology appraisals take around 12 months to complete. Some appraisals take longer when they need to be extended to allow additional evidence to be gathered or if the evidence has to be re examined after an appeal.

We recognise the importance of this decision to those with age-related macular degeneration and their families and carers. We believe that it was important that it was better to make the decision on the best available evidence rather than making potentially the wrong decision without full evaluation of all the facts.”

Professor Alan Bird, Professor of Ophthalmology at the Institute of Ophthalmology, University College, London says: “Contrary to media reports, age-related macular degeneration almost *never* causes total blindness, although it has a serious impact on vision, independence and quality of life. We welcome and support today’s guidance as it provides health professionals with clear guidance on where and when this treatment can add value. Accessing PDT for those who may be able to benefit from this treatment should now be that much easier as a result of the NICE guidance. The approval ends a period of uncertainty and will simplify the management of a disorder that accounts for 50% of disability in the UK. “

Ends

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Notes to Editors

1. A Question and Answer Document accompanies this release which explains why and how NICE developed its recommendations. It also answers some common questions.

About NICE

2. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.
3. NICE produces guidance in three areas of health:
 - the use of new and existing medicines and treatments within the NHS in England and Wales – technology appraisals.
 - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use – interventional procedures.
 - NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).
4. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.

About technology appraisals

5. Media briefings giving further details of the guidance are available on the NICE website at www.nice.org.uk
6. Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:
 - medicines (for example, drugs)
 - medical devices (for example, hearing aids or inhalers)
 - diagnostic techniques (tests used to identify diseases)
 - surgical procedures (for example, repairing hernias)
 - health promotion activities (for example, patient education models for diabetes).
5. Our technology appraisal recommendations are prepared by an independent Committee, who include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The Committee considers the evidence on the clinical and cost effectiveness of the technology – this includes hearing the views of, and evidence from, clinical health professionals, experts and patients.
6. NHS organisations in England and Wales have to make the resources and facilities available to enable NICE guidance to be implemented. In January 2002 the Government announced a legal obligation for the NHS to provide funding for treatments and drugs recommended by NICE as a part of its technology appraisals work programme.