The use of photodynamic therapy for age-related macular degeneration

Understanding NICE guidance – information for people with age-related macular degeneration, their families and carers, and the public
The use of photodynamic therapy for age-related macular degeneration
Understanding NICE guidance – information for people with age-related macular degeneration, their families and carers, and the public

Issue date: September 2003
Review date: September 2006

To order copies
Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0305. A version in Welsh and English is also available, reference number N0306. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0306. The NICE technology appraisal on which this information is based, Photodynamic therapy for age-related macular degeneration, is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0303.

NICE has produced an audio version of this leaflet on CD and cassette tape. Copies are available from NICE – phone 020 7067 5900 or send an email to nice@nice.nhs.uk.

National Institute for Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Web: www.nice.org.uk

ISBN: 1-84257-381-0

Published by the National Institute for Clinical Excellence
September 2003
Typeset by Icon Design, Eton
Printed by Abba Litho Sales Limited, London

© National Institute for Clinical Excellence, September 2003. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is permitted without the express written permission of the Institute.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is NICE guidance?</td>
<td>4</td>
</tr>
<tr>
<td>What is age-related macular degeneration?</td>
<td>5</td>
</tr>
<tr>
<td>What is photodynamic therapy?</td>
<td>8</td>
</tr>
<tr>
<td>What has NICE recommended on photodynamic therapy?</td>
<td>9</td>
</tr>
<tr>
<td>What should I do next?</td>
<td>12</td>
</tr>
<tr>
<td>Will NICE review its guidance?</td>
<td>13</td>
</tr>
<tr>
<td>Further information</td>
<td>13</td>
</tr>
</tbody>
</table>
What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of photodynamic therapy for age-related macular degeneration. NICE was asked to provide
guidance that will help the NHS in England and Wales decide when photodynamic therapy should be used.

**What is age-related macular degeneration?**

In the eyeball, the retina is an area that lies at the inside back surface. It contains the specialised cells that are needed for sight. The central part of the retina is called the macula.

In macular degeneration, the cells that make up the macula have become damaged and have stopped working properly. If you have macular degeneration, the central part of your vision is blurred. When macular degeneration happens in older adults, it’s known as ‘age-related macular degeneration’, which is shortened to ARMD.
Macular degeneration almost never causes someone to go completely blind. This is because the condition affects only the central area of sight, not the vision around the sides (known as peripheral vision).

There are two main types of ARMD – ‘wet’ and ‘dry’. The treatment that NICE has looked at, photodynamic therapy, is not suitable for the dry type, so the NICE guidance doesn’t cover people with dry ARMD. (Most people with macular degeneration have the dry form.)

**Wet ARMD**

With wet ARMD, new blood vessels start to grow into the area under the retina. The medical term for this is choroidal neovascularisation (CNV for short). The blood vessels are fragile and can easily bleed and leak fluid into the area under the retina. This, in turn, causes scarring and permanent damage to the area. Because of these changes, the macula cannot work properly.
When an eye specialist is investigating a person’s macular degeneration, he or she may use a technique called fluorescein angiography. This involves using a dye to show the leakage from new blood vessels. CNV is classified as ‘classic’ or ‘occult’ depending on the results of this test. The differences between classic and occult CNV are quite complicated and won’t be described here. In general, a person with classic CNV tends to lose their sight more quickly than a person with occult CNV. Some people have both classic and occult CNV in the same eye.

Another medical term that can be used to describe the damaged area is ‘subfoveal’. The fovea is the central part of the macula. In healthy eyes, it is the area that gives the clearest sight (that is, it lets a person see fine detail). If the new blood vessels grow under the area of the fovea, the person is said to have ‘subfoveal CNV’.
What is photodynamic therapy?

Photodynamic therapy (PDT for short) aims to destroy the blood vessels in the area under the retina without causing further damage to the retina itself. It cannot restore sight but may help to slow the loss of vision.

PDT involves putting a light-sensitive substance into the blood system. After a short wait to let the substance reach the blood vessels in the eye, a low-power laser is directed onto the area of damage in the eye. The energy from the laser activates the light-sensitive substance. Once activated, the light-sensitive substance can damage the new blood vessels in the area and make them close up.
What has NICE recommended on photodynamic therapy?

During the appraisal, NICE’s Appraisal Committee read and heard evidence from:

- good-quality studies of photodynamic therapy
- doctors with specialist knowledge of ARMD and its treatment
- individuals with specialist knowledge of the issues affecting people with wet ARMD
- organisations representing the views of people who will be affected by the guidance (because they have, or care for someone with, the condition or because they work in the NHS and are involved in providing care for people with the condition)
• the manufacturer of the light-activating substance.

The evidence is summarised in the full guidance (see end for details). More information about the studies is provided in the assessment report for this appraisal (see end for details).

NICE has made the following recommendations about the use of photodynamic therapy (PDT) to treat age-related macular degeneration (ARMD) within the NHS in England and Wales.

NICE recommends PDT for people with wet ARMD who have a confirmed diagnosis of classic subfoveal CNV, with no sign of occult CNV. People 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.
PDT treatment should be carried out by doctors who specialise in treating disorders of the retina and who have experience in using PDT.

PDT is not recommended for people who have wet ARMD with mostly classic subfoveal CNV (that is, at least half is classic but there is also some occult CNV). The exception is where the person is treated as part of a clinical study designed to provide useful information on the effectiveness of the treatment.

NICE has not made any recommendations about PDT for people who have ARMD with occult CNV. This is because, when the appraisal process started, the light-sensitive substance was not licensed to be marketed or prescribed for occult CNV in the UK. (This is because its 'marketing authorisation', which is normally needed before a medicine can be marketed or prescribed, did not cover patients with occult CNV. The process of giving a medicine its marketing authorisation is not
related to the NICE appraisal process and it is not carried out by NICE. Further information on this is available from the Medicines and Healthcare products Regulatory Agency (MHRA) – the website address and phone number for this organisation are included at the end of this leaflet.)

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. This may be judged by the effects of PDT on the results of fluorescein angiography and the rate of loss of vision.

What should I do next?

If you or someone you care for has age-related macular degeneration, you should discuss this guidance with your doctor or eye specialist.
Will NICE review its guidance?

Yes. The guidance will be reviewed in September 2006.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on photodynamic therapy for age-related macular degeneration that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0303.

If you have access to the Internet, you can find more information about macular degeneration on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 4647.
Information on the work of the Medicines and Healthcare products Regulatory Agency can be found on its website at www.mca.gov.uk. The phone number for enquiries is 020 7273 0000.

NICE has produced an audio version of this leaflet on CD and cassette tape. Copies are available from NICE – phone 020 7067 5900 or send an email to nice@nice.nhs.uk.