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PRESS RELEASE

NICE consults on revised first draft guidance on the use of drugs to treat Alzheimer's disease (including a review of existing guidance no. 19)

The National Institute for Health Clinical Excellence (NICE) is consulting on the revised draft of its review of donepezil, rivastigmine, galantamine and memantine for the treatment of Alzheimer's disease. The document has been published on the NICE website 2006 for a three week public consultation period which ends on 13 Feb 2006.

The Appraisal Committee is recommending that donepezil, galantamine and rivastigmine should be considered as options in the treatment of people with Alzheimer's disease of moderate severity only (that is, those with a mini mental state examination [MMSE] score of between 10 and 20 points).

Memantine is not recommended as a treatment option for people with moderately-severe to severe Alzheimer's disease except as part of clinical studies.

These recommendations are provisional and subject to consultation. The guidance which NICE issued on the use of donepezil, galantamine and rivastigmine for Alzheimer's disease in 2001 is still in force and will apply until updated guidance is issued. When published, the guidance will apply to newly diagnosed patients only. Patients currently using these drugs should continue to do so on the basis on which they were initiated.

The original and current NICE guidance on the use of donepezil, galantamine and rivastigmine for Alzheimer's disease issued in 2001 recommends the use of these drugs for all patients, with treatment stopping as soon as they no longer had an effect. NICE's review of this guidance initially concluded that there was not enough evidence to support the use of these drugs for all patients as recommended in the original guidance. However, responses received from stakeholders during consultation on this first draft suggested that the drugs may be more effective for certain groups of people. NICE therefore asked the pharmaceutical companies involved in the appraisal to look for evidence to support this, from the data in their clinical trials. The Appraisal Committee met on the 20 December 2005 to review this additional data. This new evidence, taken with data already seen by the Committee enabled the Committee to reach the conclusion that donepezil, galantamine and rivastigmine are both clinically and cost effective in patients with moderate Alzheimer's disease (approximately 40% of all patients).

Andrew Dillon, NICE Chief Executive and Executive Lead for this appraisal

said: "We are acutely aware of our responsibility to help people with Alzheimer's disease secure access to effective treatment. We needed to make the right decision, based on all the relevant evidence. By going the extra mile and asking the drug companies to delve deeper into their clinical trial data, we have been able to identify the right way to use these medicines. People with Alzheimer's will now receive these drugs when they can help them most. They and those who care for them will be able to feel more confident about gaining benefit from them and the NHS will know that its using its funds to best effect.

The advisory committee was not able recommend the use of memantine because there was insufficient evidence on its clinical benefit for patients with moderately-severe to severe Alzheimer's".

NICE is expecting to issue final guidance to the NHS in July 2006.

Ends

Further information: Sarita Tamber on 0207 067 5915 (0777 187 2561) or Lucy Betterton on 0207 067 5909.

Notes for editors

About NICE

1. On 1 April 2005 the National Institute for Clinical Excellence took on the functions of the Health Development Agency to form 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.

About this appraisal

3. The stakeholders involved in the appraisal are:

Consultee organisations (these organisations have a right of appeal)

Manufacturers/sponsors

- Eisai Ltd
- Lundbeck
- Novartis Pharmaceuticals Ltd
- Shire Pharmaceuticals Ltd

Patient/carer groups

- Age Concern England
- Alzheimer's Society
- Counsel and Care for the Elderly
- Dementia Care Trust
- Mental Health Foundation

Professional groups

- Association of British Neurologists
- British Geriatrics Society
- British Neuropsychiatry Association
- For Dementia
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal Pharmaceutical Society

Others

- Cheshire West PCT
- Department of Health
- Leeds West PCT
- Rugby PCT
- Welsh Assembly Government

Commentators (no right of appeal)

General

- British National Formulary
- National Collaborating Centre for Chronic Conditions
- NHS Purchasing and Supplies Agency
- NHS Quality Improvement Scotland

Research groups

- Alzheimer's Research Trust

- Dementia Research Group and Department of Old Age Psychiatry, Institute of Psychiatry
- Institute for Ageing and Health
- Research Institute for the Care of the Elderly

Associated Guidelines

- National Collaborating Centre for Mental Health – Guideline Development Group for Dementia
4. 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 (test 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.
 7. NICE is currently in the process of developing a clinical guideline on the management of dementia, including use of antipsychotic medication in older people. This will address the wider issue of care of patients with dementia (including Alzheimer’s disease). This guideline is expected to be published in November 2006. More details can be found from <http://www.nice.org.uk/page.aspx?o=63355>