South Central Priorities Committees
(Berkshire PCTs)

Policy Statement 146: **Donepezil, galantamine, rivastigmine and for the treatment of dementia associated with Parkinson's disease or Lewy Bodies**

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The South Central Priorities Committees have considered the evidence of clinical and cost-effectiveness of the acetylcholinesterase inhibitors (AChEIs) donepezil, galantamine and rivastigmine in patients with dementia associated with Parkinson's disease (PDD) or Lewy Body Dementia (LBD). In the majority of PDD or LBD patients, AChEIs produced only modest cognitive improvement, with limited evidence of cost-effectiveness. However there was evidence of significantly greater clinical benefit in patients with non-cognitive symptoms causing significant distress (e.g. visual hallucinations). This is in keeping with NICE-SCIE Clinical Practice Guideline 42. South Central Priorities Committees therefore RECOMMEND that the AChEIs donepezil, galantamine and rivastigmine should be available as an option to treat patients with dementia associated with Parkinson's disease or dementia with Lewy Bodies if they have non-cognitive symptoms causing significant distress to the individual (for example visual hallucinations), or leading to behaviour that challenges.
Other uses of the AChEIs donepezil, galantamine and rivastigmine in patients with PDD or LBD are LOW PRIORITY.

Parkinson's disease dementia (PDD) is diagnosed when dementia develops within the context of established Parkinson's disease – usually at least one year after the appearance of Parkinson's motor symptoms. This is an arbitrary definition, as when dementia occurs, it is usually after many years of Parkinson's disease.

Dementia with Lewy Bodies (LBD) is generally believed to be the second most common cause of degenerative dementia in the elderly, accounting for approximately 15% of dementia cases.

Some clinicians believe that PDD and LBD are part of the same spectrum of disease. Similar pathological changes (Lewy Bodies) are present in the brain, but in PDD these tend to be located in the basal ganglia, whereas in LBD they tend to be distributed through the cortex.

In both PDD and LBD there may be severe non-cognitive symptoms e.g. fluctuations in level of alertness and visual hallucinations.

Donepezil and Galantamine are not currently licensed for the treatment of patients with PDD or LBD. Rivastigmine is licensed for the treatment of patients with mild to moderately severe dementia associated with Parkinson's disease.

A review of the evidence for acetylcholinesterase inhibitors (AChEIs) in patients with PDD or LBD demonstrated cognitive benefits similar to those realised in patients with Alzheimer's disease i.e. improvements in cognition (2-3 points on ADAS-COG or 1-2 points on MMSE over up to 24 weeks). A Cochrane review found that AChEIs produce clinically meaningful improvement in approximately 15% of patients with PDD. Studies examining cost-effectiveness produced conflicting results. There was considerable uncertainty about estimates of cost-effectiveness produced by modelling.

Analyses of effectiveness of rivastigmine compared to placebo in patients with visual hallucinations demonstrated statistically significant greater cognitive and non-cognitive benefits compared to placebo in patients with PDD, and significant greater improvements in power of attention in patients with LBD.

NOTES:

1. *Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.*
2. *This policy will be reviewed in light of new evidence or guidance from NICE.*
3. *Berkshire Priorities Committee policy statements can be viewed at www.berkshire.nhs.uk/priorities*