

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath),  
Crawley CCG and Horsham & Mid-Sussex CCG

<b>INFORMATION SHEET – Blue Traffic Light Classification</b>		
<b>Name of medicine</b>	Acetylcholinesterase inhibitors – Donepezil, Galantamine and Rivastigmine	
<b>Indication</b> (including whether for adults and/or children)	Mild to moderate dementia – including Alzheimer's Dementia, and Lewy Body Dementia and Parkinson's Disease Dementia	
<b>APC policy statement reference</b> (if applicable)	N/A	
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The information sheet is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface for medicines classified by Prescribing Clinical Network as **BLUE**

**BLUE** drugs are considered suitable for prescribing in primary care, following initiation and stabilisation by a specialist as ongoing monitoring can be undertaken in primary care without specialist support and WITHOUT the need for a formal shared care guideline.

For each drug classified as blue, the Surrey & North West Sussex Area Prescribing Committee (APC) will recommend the minimum supply and whether an information sheet is required or not. A minimum of one month supply of medication will be provided by the initiating consultant.

This information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications. A GP or Primary Care Prescriber must ensure they are familiar with the prescribing responsibilities. This information sheet is available on the internet <http://pad.res360.net/> forming part of the Prescribing Advisory Database (PAD) giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter.

## RESPONSIBILITIES and ROLES

<b>Consultant / Specialist responsibilities</b>
1. To assess the suitability of patient for treatment with an acetylcholinesterase inhibitor.
2. To discuss the aims, benefits and side effects of treatment with the patient and/or carer as well as their role
3. Carers' views on the patient's condition at baseline should be sought
4. Discuss implications of diagnosis and treatment with carers before treatment is initiated.
6. Explain to the patient and/or carer the treatment plan including the dosing schedule and request for transfer of care to GP. They will be provided with written information about the cholinesterase inhibitor and a contact number by the consultant/specialist.
7. Ensure all the necessary tests are undertaken (see under GPs responsibilities for initial tests required before referral).
8. Monitor and evaluate response to treatment, including adverse drug reactions, and to continue / discontinue treatment in line with agreed treatment plan. This may be undertaken by telephone consultation with the person or their carer, instigated by the person or their carer. A post-diagnostic appointment with a clinician (not consultant) will be made within 6 weeks.
9. Supply GP with summary of treatment plan and a copy of any information sheet available.
10. Advise GP if treatment is to discontinue at any point
11. To prescribe a minimum of three months treatment of the acetylcholinesterase inhibitor, until the patient is stabilised on the best tolerated dose
12. The dose will be titrated according to the Summary of Product Characteristics.
13. Define any characteristics of clinical response that can be reviewed by GP to assess response to drug
14. Discuss the ongoing supply arrangements with the patient and ensure they understand the plan for their subsequent treatment

15. Request the person or their carers to contact the consultant/specialist to discuss side effects. Patients prescribed galantamine should be warned of the signs of serious skin reactions and advised to stop taking galantamine immediately and seek medical advice should such symptoms occur
16. Accept referral back from the GP to the CMHTOP in a time appropriate manner (triaged to urgent, soon or routine depending on the circumstances). Examples of those to be referred back include those who develop intolerance to their dementia medication or if there are Behavioural and Psychological Symptoms of Dementia (BPSD) not manageable in primary care. The response could range from advice and guidance (e.g. possible side effects) to an urgent visit (immediate and significant risks).
17. Provide telephone support and advice to the GP when required.
18. Patients with ongoing need for support from the CMHTOP, e.g. those with emerging behavioural symptoms, will remain on the CMHTOP case load

<b>General Practitioner (GP) or Primary Care Prescriber responsibilities</b>
1. Initial referral to secondary care on suspicion of a dementia after carrying out the following tests: U&Es, LFTs, TFTs, HbA1c, lipid profile (non fasting), bone profile, FBC, B12 and folate, ESR
2. Subsequent prescribing including any dose titration as recommended by the consultant and/or manufacturer in the summary of product characteristics
3. Patient monitoring in Primary Care setting - Consider ability to manage ADL's, any emerging BPSD or carer strain, Blood pressure and Pulse
4. Patients prescribed galantamine should be warned of the signs of serious skin reactions and advised to stop taking galantamine immediately and seek medical advice should such symptoms occur
5. Monitor any side effects of medication and check for interactions with other drugs.
6. Liaise with the Specialist Team if any problems arise.

<b>Patient / Carer role</b>
1. Informing the specialist team, primary care prescriber or other healthcare professional if he or she has further questions or wants more information about the treatment
2. Tell the consultant / specialist or GP or Primary Care Prescriber of any other medication being taken, including over-the-counter products.
3. Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, primary care prescriber or other healthcare professional involved in their care
4. Supported to know how to report any adverse effects to the specialist team, primary care prescriber or other healthcare professional involved in their care, and how adverse effects can be managed
5. To be available for monitoring as required
6. Attend follow-up appointments with the consultant / specialist / GP. Non-attendance of appointments may result in treatment being stopped
7. Patients prescribed galantamine should be warned of the signs of serious skin reactions and advised to stop taking galantamine immediately and seek medical advice should such symptoms occur

## Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at [www.bnf.org](http://www.bnf.org), and Summary of Product Characteristics (SPC), available at [www.medicines.org.uk](http://www.medicines.org.uk) for detailed product and prescribing information and specific guidance.

### Background to disease and use of medicine for the given indication

Dementia is a progressive degenerative neurological syndrome affecting around 5% of those aged over 65 years, rising to 20% in the over-80s. This age-related disorder is characterised by cognitive decline, impaired memory and thinking, and a gradual loss of skills needed to carry out activities of daily living. Often, other mental functions may also be affected, including changes in mood, personality and social behaviour. The various types of dementia are classified according to the different disease processes affecting the brain. The most common cause of dementia is Alzheimer's disease (AD), accounting for around 60% of all cases. Vascular dementia and dementia with Lewy bodies (DLB) are responsible for most other cases. Alzheimer's disease and vascular dementia may co-exist and are often difficult to separate clinically. Dementia is also encountered in about 30– 70% of patients with Parkinson's disease. (Maudsley Prescribing Guidelines in Psychiatry, 13<sup>th</sup> Edition)

### Indication

NICE guidance states the following:

- The three acetylcholinesterase (AChE) inhibitors donepezil, galantamine and rivastigmine as monotherapies are recommended as options for managing mild to moderate Alzheimer's disease.
- Offer donepezil or rivastigmine to people with mild to moderate dementia with Lewy bodies

- Only consider galantamine for people with mild to moderate dementia with Lewy bodies if donepezil and rivastigmine are not tolerated.
- Consider donepezil or rivastigmine for people with severe dementia with Lewy bodies.
- Only consider AChE inhibitors or memantine for people with vascular dementia if they have suspected comorbid Alzheimer's disease, Parkinson's disease dementia or dementia with Lewy bodies.
- Offer a cholinesterase inhibitor for people with mild or moderate Parkinson's disease dementia.
- Consider a cholinesterase inhibitor for people with severe Parkinson's disease dementia.

The manufacturer's licensed indications are:

- Donepezil – for the symptomatic treatment of mild to moderately severe Alzheimer's dementia.
- Galantamine – for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type.
- Rivastigmine – Patch - Symptomatic treatment of mild to moderately severe Alzheimer's dementia
- Rivastigmine – Oral preparations - Symptomatic treatment of mild to moderately severe Alzheimer's dementia, and symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease.

### **Dosage and Administration**

Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

### **Expected outcome**

Treatment of symptoms of dementia or an improvement in cognitive function

### **Monitoring**

No specific monitoring required

**Cautions, contraindications** - Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Adverse effects** - Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Drug interactions** - Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

### **Glossary**

**AChE** – Acetylcholinesterase

**AD** – Alzheimer's Disease

**ADLs** – Activities of Daily Living

**B12** – Vitamin B12

**BPSD** – Behavioural and Psychological Symptoms of Dementia

**CMHTOP** – Community Mental Health Team for Older People

**DLB** – Dementia with Lewy Bodies

**ESR** – Erythrocyte Sedimentation Rate

**FBC** – Full Blood Count

**HbA1c** – A measure of glycated haemoglobin

**LFTs** – Liver Function Tests

**TFTs** – Thyroid Function Tests

**U&Es** – Urea and Electrolytes

**Reference** - Dementia: assessment, management and support for people living with dementia and their carers, NICE guideline (NG97) Published date: June 2018