South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

Essential Shared Care Agreement
Drugs for Dementia

Please complete the following details:

Patient's name, address, date of birth
Consultant's contact details (p.3)
And send One copy to:

1. ***the patient's GP***
2. ***put one copy in care plan***
3. ***give one copy to the patient***

Patient's name:	
NHS Number:	
Patient's address:	
Patient's Date of Birth:	
As of this date: **Please add to repeat prescription**	
Medication prescribed: **Dose:**	

The aim of this shared care agreement is to provide information on the responsibilities of the General Practitioner and the Consultant while sharing the care of patients prescribed medicines covered by the shared care agreement.

Guidelines will only be written when it has been agreed that shared care is an appropriate option, and will include a statement of Specialist Unit /GP responsibilities. Shared Care Guidelines will ensure that all GPs have sufficient information to enable them to undertake responsibility for specialist therapies and other therapies which may affect/interact with specialist therapies.

It is not the intention to insist that GPs prescribe such a therapy and any doctor who does not wish to undertake the clinical and legal responsibility for a Shared Care Drug is not so obliged. (It should be noted that it is inappropriate to decline the invitation to shared care on the grounds of cost alone). Acceptance of the Shared Care Guidelines will be endorsed by the Medicines Management Teams of the CCGs.

The information contained in this guideline is issued on the understanding that it is the best available from the resources at our disposal at the time of issue.

For further information please refer to the relevant Summary of Product Characteristics and NICE guidance or contact your local Specialist or Drug Information Centre.

Further copies of this guideline may be obtained from:

- South Staffordshire & Shropshire Healthcare Foundation NHS Trust
- CCG Prescribing Advisers.

Produced: April 2016
Review date: April 2018
Replaces: E040

SHARED CARE GUIDELINES: Drugs for Dementia

Place in Therapy:

Licensed indications & key NICE guidance: Donepezil, galantamine and rivastigmine (AChE inhibitors) are licensed for the symptomatic treatment of mild to moderately severe Alzheimer's disease; rivastigmine is also licensed for symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Memantine is licensed for treatment of patients with moderate to severe Alzheimer's disease, and NICE guidance allows memantine as an option in moderate Alzheimer's disease in those who are either intolerant of or have a contraindication to AChE inhibitors or in severe Alzheimer's disease.

NICE CG 42 on Dementia makes specific recommendations on Alzheimer's disease, dementia with Lewy bodies (DLB), frontotemporal dementia, vascular dementia and mixed dementias, as well as recommendations that apply to all types of dementia. Dementia in Parkinson's disease shares a number of similarities with DLB. Although the evidence base for dementia in Parkinson's disease was not examined specifically in the context of this guideline, the recommendations for DLB may be useful when considering treatments for dementia in Parkinson's disease. Use of the drugs in dementia will be in line with NICE CG 42.

Only specialists in the care of dementia should initiate treatment. Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global, functional or behavioural symptoms.
See section 'supporting information' for further details.

Criteria for Transfer of Prescribing to Primary Care

- The patient must have been prescribed treatment for at least 2 months after reaching the maintenance dose, to have shown response to treatment and be on a stable dosage before the primary care clinician is asked to accept responsibility for prescribing. Ensure informed consent is obtained from all parties (patients (where capacity allows), carers and doctors).
- Ensure consenting parties have sufficient, accurate and timely information in an understandable form.

Specialist Services Responsibilities:

1. Undertake assessment to diagnose the dementia.
2. Counsel patients and carers about the implications of the diagnosis, likely effects of medication and treatment endpoints. Provide written information on the medication, e.g. leaflets from the Trust's Choice & Medication web-site http://www.choiceandmedication.org/south-staffs/
3. Initiate and stabilise treatment with donepezil, galantamine or rivastigmine, if clinically appropriate, and ensure compliance. Memantine is an option for people with moderate Alzheimer's Disease who are intolerant of or who have a contraindication to AChE inhibitors, or in severe Alzheimer's disease.
4. The least expensive drug and formulation (i.e. generic donepezil tablets (first-line) and generic riviastigmine capsules (second-line)) should normally be chosen, unless there are patient specific reasons not to (and in these cases, the rationale for the drug/formulation, choice must be communicated to the primary care clinician and documented in the patient's notes) .
5. Send a letter to the GP suggesting that the patient's condition now seems appropriate for a shared care approach, and that shared care is assumed to be formally agreed for this patient, unless the practice respond differently within 2 weeks, communicate the anticipated date of transfer of prescribing responsibility – ensure that the GP is provided with a copy of the shared care agreement.
6. Continue to prescribe until the date of transfer of prescribing responsibility.

7. Communicate to the GP re established regimen and when to refer back.
8. Communicate promptly with the GP when treatment is changed.
9. Monitor treatment at least once every 12 months (using cognitive, global, functional and behavioural assessment) as clinically appropriate, and communicate outcome to GP
10. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition (i.e. via normal referral protocol). Ensure that clear backup arrangements exist for GPs to obtain advice and support – the section on back-up advice (below) must be completed.
11. Review patient as stated overleaf cognitive, global, functional and behavioural assessment, communicating results to the GP.
12. Seek carer's views on the condition of the patient at baseline and at follow up.
13. Assess the point at which treatment is no longer beneficial. Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global, functional or behavioural symptoms. Arrange to monitor the clinical effects of gradual withdrawal of the medication.
14. Report adverse events to the MHRA on a Yellow Card form and to the GP

GP Responsibilities:

1. Reply to the request for shared care as soon as practicable by faxing back the signed agreement at Annex A
2. Prescribe donepezil, galantamine, riviastigmine or memantine at the dose recommended.
3. Adjust the dose as advised by the specialist.
4. Monitor treatment as stated overleaf.
5. Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
6. Refer back to specialist if the patient's condition significantly deteriorates, or if there are concerns over patient compliance.
7. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
8. Report adverse events to the MHRA on a Yellow Card Form, the Specialist, and the relevant CCG Medicines Management team.

Patient/carer's Role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with donepezil, galantamine, rivastigmine or memantine.
3. Inform specialist or GP of any other medication being taken, including over-the-counter products.
4. Report any adverse effects or warning symptoms to the specialist or GP whilst taking donepezil, galantamine, rivastigmine or memantine
   The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card form, available at pharmacies, GP surgeries or from the Yellow Card hotline (0808 100 3352 business hours), or by downloading the form at http://yellowcard.mhra.gov.uk/

Back-up advice on the above is available at all times:

South Staffordshire & Shropshire Healthcare Foundation NHS Trust – Contact Details

Contact	Speciality	Available	☎	Out of Hours
		Mon-Fri 8.30 – 5.00		

Supporting Information

Dosage and Administration
Donepezil: 5mg once daily in the evening, just before bed, increased if necessary after 1 month to 10mg once daily. An orodispersible tablet is available.
Galantamine: Standard release tablets: 4mg twice daily for 4 wekks, with the morning and evening meals; increase to 8mg twice daily for 4 weeks. An increase to 12mg twice a day may be considered following assessment including evaluation of clinical benefit and tolerability. If there is no increased response or tolerability is poor, reduce dose back to 8mg twice daily. Ensure adequate fluid intake. **Modified release tablet:** Initially 8mg once daily for 4 weeks each morning with food, increased to 16mg once daily for 4 weeks; maintenance 16-24mg once daily (reviewed as per standard tablets.
Rivastigmine: 1.5mg twice daily, with the morning and evening meals; increased in steps of 1.5mg twice daily at intervals of at least 2 weeks up to a maximum of 6mg twice daily. Retitration from 1.5mg twice daily should be undertaken if treatment is interrupted for more than several days. A transdermal patch is available.
Memantine: 5mg once daily, increased in steps of 5mg at weekly intervals, until reaching the recommended maintenance dose of 20mg once daily. An oral solution is available (NB solution should be dosed onto a spoon or into a glass of water).

Monitoring:
Specialist team: Monitor for effectiveness at least once every 12 months (using cognitive, global, functional and behavioural assessment) as clinically appropriate.
GP: As cholinesterase inhibitors have been associated with weight loss, weight should be monitored on a regular basis. Patients at increased risk for developing ulcers, e.g. those with a history of ulcer disease or those receiving medicines which will increase risk of bleeding e.g. non-steroidal anti-inflammatory drugs(NSAIDs), aspirin, anticoagulants, selective serotonin reuptake inhibitors (SSRIs), should be monitored for symptoms of peptic ulcer disease or gastrointestinal bleeding, or prophylactic prescribing of a gastro-protectant considered. Contact the specialist team between specialist's yearly reviews if there are any concerns which may need earlier attention.

Cautions:
All three **AChE inhibitors** are cautioned in: cardiovascular disease, severe asthma, obstructive pulmonary disease or active pulmonary infections, people at increased risk of developing peptic ulcer They may exacerbate/induce extrapyramidal symptoms. Caution is recommended when selecting neuromuscular blocking agents with anaesthesia.
Memantine is cautioned in those with a history of convulsions. Patients with recent myocardial infarction, uncontrolled hypertension or uncompensated congestive heart failure should be closely monitored, as should those who have drastic diet changes e.g. from a carnivore to a vegetarian diet, or a massive ingestion of alkalising gastric buffers.

Contra-indications: All four drugs are contra-indicated where there is hypersensitivity to the active substance or any of the excipients. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take donepezil or Galantamine; those with rare hereditary problems of fructose intolerance should not take memantine oral solution (contains sorbitol).
Galantamine: contraindicated in people with severe hepatic or severe renal impairment, or in those who have both significant renal and hepatic dysfunction.
Donepezil: contraindicated in patients with a known hypersensitivity to piperidine derivatives.
Rivastigmine: contraindicated in patients with a known hypersensitivity to carbamate derivatives or in those with severe liver impairment.

Side Effects (see individual SPCs for full list):
Donepezil: nausea, vomiting, anorexia, diarrhoea, fatigue, insomnia, headache, dizziness, syncope, hallucinations, agitation, aggression, muscle cramps, urinary incontinence, rash, pruritus, **less commonly** gastric and duodenal ulcers, gastro-intestinal haemorrhage, bradycardia, seizures; **rarely** sino-atrial block, AV block, hepatitis, extrapyramidal symptoms, potential for bladder outflow obstruction.
Galantamine: nausea, vomiting, diarrhoea, abdominal pain, dyspepsia, syncope, rhinitis, sleep disturbances, dizziness, confusion, depression, headache, fatigue, anorexia, tremor, fever, weight loss, **less commonly** arrhythmias, palpitation, myocardial infarction, cerebrovascular disease,

paraesthesia, tinnitus and leg cramps; **rarely** bradycardia, seizures, hallucinations, agitation, aggression, dehydration, hypokalaemia and rash; **very rarely** gastro-intestinal bleeding, dysphagia, hypotension, exacerbation of Parkinson's Disease and sweating.
Rivastigmine: nausea, vomiting, diarrhoea, dyspepsia, anorexia, abdominal pain, dizziness, headache, drowsiness, tremor, asthenia, malaise, agitation, confusion, sweating, weight loss; **less commonly** gastric or duodenal ulceration, bradycardia, syncope, depression, insomnia; **rarely** angina pectoris, seizures; **very rarely** gastro-intestinal haemorrhage, pancreatitis, cardiac arrhythmias, hypertension, hallucinations, extrapyramidal symptoms (including worsening of Parkinson's Disease), rash.
Memantine: constipation, hypertension, dyspnoea, headache, dizziness, drowsiness; **less commonly** vomiting, thrombosis, heart failure, confusion, fatigue, hallucinations and abnormal gait **very rarely** seizures, pancreatitis, psychosis, depression and suicidal ideation also reported

South Staffordshire and Shropshire Healthcare NHS
NHS Foundation Trust
A Keele University Teaching Trust

Shared Care Agreement - Drugs for Dementia

Name of Prescriber:

Specialist Area:

Telephone Number:

Fax Number:……

Signature: Date:

Patient's Name:

Address:

Drug and dose:

Name of GP:

Signature: Date:

Practice Address