1. Introduction

This protocol describes how patients prescribed medicines for Alzheimer's disease (donepezil, galantamine, rivastigmine, and memantine) can be managed safely in primary care, secondary care and across the interface. It sets out responsibilities for each party, to ensure that these medicines are initiated, prescribed and monitored appropriately, and with the BNF and NICE guidelines in mind.

This protocol does not cover the drug treatment of non-Alzheimer’s dementias. If the patient has mixed dementia that includes Alzheimer's disease, the latter is covered by this protocol.

Background

PRINCIPLES OF TREATMENT

Mild/ moderate Alzheimer's disease
Donepezil, galantamine and rivastigmine as monotherapies are recommended in NICE technology appraisal guidance as options for managing mild to moderate Alzheimer's disease under the “conditions of treatment” specified below. Treatment should normally be started with the drug with the lowest acquisition cost (taking into account required daily dose and the price per dose once shared care has started). However, an alternative acetylcholinesterase (AChE) inhibitor could be prescribed if it is considered appropriate when taking into account adverse event profile, expectations about adherence, medical comorbidity, possibility of drug interactions and dosing profiles.

Moderate/severe Alzheimer's disease / intolerance to treatment
Memantine monotherapy is recommended as an option for managing Alzheimer's disease for people with:

- moderate Alzheimer's disease who are intolerant of or have a contraindication to AChE inhibitors or
- severe Alzheimer's disease

Treatment should be under the “conditions of treatment” specified below.

Conditions of treatment

- For people who are not taking an AChE inhibitor or memantine, prescribers should only start treatment with these on the advice of a clinician who has the necessary knowledge and skills. This could include:
• secondary care medical specialists such as psychiatrists, geriatricians and neurologists
• other healthcare professionals (such as GPs, nurse consultants and advanced nurse practitioners), if they have specialist expertise in diagnosing and treating Alzheimer's disease.

- Once a decision has been made to start an AChE inhibitor or memantine, the first prescription may be made in primary care. (Some Memory Assessment Services (MAS) in Essex do not use this model of care, and the first prescription is provided by secondary care.)
- For people with an established diagnosis of Alzheimer's disease who are already taking an AChE inhibitor, primary care prescribers may start treatment with memantine without taking advice from a specialist clinician. Primary care prescribers with limited expertise are encouraged to seek guidance from secondary care colleagues before doing so.
- Ensure that local arrangements for prescribing, supply and treatment review follow the NICE guideline on medicines optimisation.
- Do not stop AChE inhibitors in people with Alzheimer's disease because of disease severity alone.

Established Alzheimer's disease
For people with an established diagnosis of Alzheimer's disease who are already taking an AChE inhibitor:

- consider memantine in addition to an AChE inhibitor if they have moderate disease
- offer memantine in addition to an AChE inhibitor if they have severe disease

In both cases this should be based on the individual and their needs. Memantine may not be required if someone is stable, and where it is not clinically indicated i.e. no behavioural challenges.

DIAGNOSIS AND PRESCRIBING

There are several different models of care in place across EPUT for the treatment of dementia. Refer to the local CCG and MAS for details of the model applicable in a particular geography.

The responsibilities of professionals involved will therefore vary depending on their place in the pathway, and the type of pathway in use in their locality.

In the two MAS models of care, a specialist both makes a diagnosis and provides initial treatment, and the GP is then invited to participate in shared care. In the acute models, a specialist makes a diagnosis, and the GP is tasked to prescribe.

Other models of care may be in use across Essex, including Specialist Dementia and Frailty Services (SDFS), but the principles remain broadly the same as the MAS, and the broad term MAS will be used in this document to include all such services.
The term Community Dementia Nurse (CDN) is used throughout this document, but it is recognised that some services do not have this exact role. Therefore where reference is made to CDN, this will mean CDN or equivalent.

2. Responsibilities

Secondary Care

All prescribers:

1. Confirm the diagnosis of dementia, including subtype where possible. Before prescribing, check for contraindications (including undertaking an ECG only where clinically appropriate), interactions with current medicines. Assess the likelihood of patient compliance/concordance. Counsel patients/carers as to the likely benefits and risks of treatment, including the consequence of poor compliance. This should be supported with written information, including leaflets about drug treatment. Printable information about dementia is available from the NHS website: https://www.nhs.uk/conditions/dementia/
   Printable leaflets about drug treatment are available from the Choice and Medication website: https://www.choiceandmedication.org/eput
2. Offer advice as to the limited effectiveness of treatment over time as the illness progresses.
3. Provide clear documentation of mental capacity assessments in patient notes.
4. Provide GP a detailed report with information relating to the initial memory clinic assessment, including baseline test results.
5. Provide generic prescriptions unless local formulary states specific brand name to be used.
6. Provide ongoing timely response to GP concerns relating to dementia disease or treatment.

Patient seen by MAS General Hospital / MAS Community by a consultant:

1. On initiation of medicine for Alzheimer’s disease, provide patient with information about treatment, and information on the Dementia Intensive Support team/service (DIST/DISS), Community Dementia Nurses (CDNs), and contact details of Consultant’s secretary.
2. Offer an initial trial period of treatment for 3 months, and assess response and tolerability during, and at the end of the trial period. The dose should be titrated according to response and tolerance.
3. Inform the GP of the patient’s tolerance to the medicine and its efficacy; this will include a discussion/feedback from the patient/carer at the time that the maintenance dose is achieved.
4. Once the patient has been adequately stabilised and continuation of treatment is clinically justifiable (usually after 3 months, but up to 6 months in some services where complexities and risks are managed and stabilised), write to GP requesting them to accept shared care prescribing responsibility for the relevant drug (using template in Appendix 1).
   At the same time as making this request:
- Prescribe for one further month to cover until the GP prescribing start date.
- Inform the patient to obtain further supplies from their GP.
- Send a clinic letter promptly so that the GP will be in receipt of the clinic letter within one week of the prescription being issued.

5. It is assumed that shared care is agreed unless the GP formally declines (in West Essex it should not be assumed that shared care has been agreed by the GP, and it should be confirmed, not assumed.) If declining shared care, GP will write to the specialist within 14 days of receiving shared care request.

**Patient seen in Acute hospital – flagged to DIST/DISS Team and seen by Dementia specialist:**

1. Discuss patient in MDT. Once patient is at home, DIST will contact / visit the patient.
2. Medicine options will be discussed with consultant. Medicines decision will be sent to GP via task on the electronic patient record.
3. The GP will initiate prescribing – see responsibilities below.
4. DIST/DISS team will support patient for 6 weeks.
5. Patient, other professional, carer or family may contact for further advice or support after this period.
6. GP is notified of discharge and referral made by DIST/DISS to CDN for regular review.

**Patient seen in Care Home, identified by CDN:**

1. Discuss patient in MDT.
2. Patient now follows acute pathway.

**All prescribers (and CDNs where appropriate):**

1. Deal with any behavioural difficulties experienced by the patient, including those arising from the use of the drug treatment for dementia that was offered, and any other adverse events reported by the GP relating to the treatment of this condition.
2. If patients do not attend for specialist reviews, contact carer and report to GP.
3. Evaluate adverse events noted by the GP or the patient.
4. Report any suspected adverse event from medicines prescribed for dementia, to the GP and, if appropriate, to the MHRA.
5. Undertake overall monitoring of disease status and drug therapy.
6. On discontinuing treatment, consider restarting/switching treatment if the patient experiences a dramatic deterioration of cognitive function or unacceptable side effects. Inform GP and patient/carer of rationale.

CDNs will support reviews in all scenarios, in some geographical areas. Some areas provide support via other agencies, e.g. Alzheimer’s Society, Dementia Review and Support team, DISS on a needs approach, 6 monthly Medication Monitoring. The specific support available will be detailed in the letter (Appendix 1).
**General Practitioner Responsibilities**

If further information is required contact 0300 1230808 (EPUT contact centre).

1. Provide a full drug/medical history (as recorded on the GP electronic patient record) to the Memory Assessment Service.
2. Whenever possible, prior to referral to the Memory Assessment Service, perform an initial blood screen to rule out possible causes for cognitive impairment (FBC, ESR, U&E, LFT, GGT, calcium profile, blood glucose, TFT, B12 and red cell folate).
3. Whenever possible perform an initial dementia assessment using one of the tools used in practice (6CIT, Mini-COG, GPCOG, Mini-ACE (MACE), and MMSE).
4. Once the patient has been adequately stabilised and continuation of treatment is clinically justifiable (usually after 3 months), the GP will be asked to accept shared care prescribing responsibility for the relevant drug. It is assumed that shared care is agreed unless the GP formally declines. If declining shared care, GP will write to specialist within 14 days of receiving shared care request.
5. Generic prescriptions should be generated unless local formulary states specific brand name to be used.
6. Where the acute treatment model is used, initiate prescription following advice from DIST/DISS/CDN or equivalent via task on the electronic patient record for patients in the community. If a GP is tasked to prescribe, the associated baseline tests and any required clinical screening (including the results of an ECG only if clinically appropriate) will be communicated by the specialist team to the GP prior to, or at the same time as the task request.
7. Monitor the patients overall health and wellbeing during the normal consultation process.
8. Check for possible drug interactions when newly prescribing or stopping concurrent medicines.
9. Report any suspected adverse event to the specialist clinician and, if appropriate, to the MHRA.
10. Deal with any concomitant illness, with specialist clinic support if appropriate.
11. On discontinuation of treatment, refer to the specialist clinician if the patient is observed to experience a dramatic deterioration in cognitive function, or if needing advice.

**3. Prescribing information**

Refer to BNF\(^2\), and Summary of Product Characteristics SPC for each drug, available at [www.medicines.org.uk](http://www.medicines.org.uk)

Where a dose adjustment is advised in the BNF or SPC due to hepatic or renal impairment, or other reason, prescribers with limited expertise should seek guidance from secondary care colleagues on choice of dose, frequency of monitoring, and any action required in response to that monitoring. The Maudsley Guidelines\(^3\) provide recommendations on the use of anti-dementia medicines in renal impairment, and these are summarised for each drug below.

**Donepezil**
Indication: Mild to moderate dementia in Alzheimer’s disease

Dose: Adult. Initially 5 mg (orally) once daily at bedtime. This dose should be continued for at least one month. Following a clinical assessment after one month, the dose may be increased if necessary to 10 mg once daily.

Cautions: Asthma; chronic obstructive pulmonary disease; sick sinus syndrome; supraventricular conduction abnormalities (including bradycardia, right bundle branch block/complete bundle branch block LBBB or RBBB); susceptibility to peptic ulcers.

Side-effects

Common or very common
Aggression; agitation; appetite decreased; common cold; diarrhoea; dizziness; fatigue; gastrointestinal disorders; hallucination; headache; injury; muscle cramps; nausea; pain; skin reactions; sleep disorders; syncope; urinary incontinence; vomiting

Uncommon
Bradycardia; gastrointestinal haemorrhage; hypersalivation; seizure

Rare or very rare
Cardiac conduction disorders; extrapyramidal symptoms; hepatic disorders; neuroleptic malignant syndrome; rhabdomyolysis

Hepatic impairment: Manufacturer advises caution (risk of increased exposure in mild to moderate impairment; no information available in severe impairment).

Renal impairment: Dose as in normal renal function for GFR <10-50ml/min. Clearance unaffected by renal impairment.

Interactions: Avoid concomitant administration with other cholinesterase inhibitors. May interfere with the activity of anticholinergic medication. May interact with drugs which significantly reduce the heart rate e.g. Digoxin, Beta Blockers, certain calcium-channel blocking agents and amiodarone. Some enzyme inhibitors such as Ketoconazole, Quinidine, Itaconazole, Erythromycin and Fluoxetine could inhibit the metabolism of these medicines, resulting in increased drug levels. Enzyme inducers such as Rifampicin, Phenytoin, Carbamazepine and alcohol may reduce the levels of these drugs. May exaggerate the effects of succinylcholine type muscle relaxants during anaesthesia.

Rivastigmine

Indication: Mild to moderate dementia in Alzheimer’s disease
Dose: Orally, adult. Initially 1.5 mg twice daily, increased in steps of 1.5 mg twice daily, dose to be increased at intervals of at least 2 weeks according to response and tolerance; usual dose 3–6 mg twice daily (max. per dose 6 mg twice daily), if treatment interrupted for more than several days, retitrate from 1.5 mg twice daily.

Dose: By transdermal application using patches, adult. Apply 4.6 mg/24 hours daily for at least 4 weeks, increased if tolerated to 9.5 mg/24 hours daily for a further 6 months, then increased if necessary to 13.3 mg/24 hours daily, increase to 13.3 mg/24 hours patch if well tolerated and cognitive deterioration or functional decline
demonstrated; use caution in patients with body-weight less than 50 kg, if treatment interrupted for more than 3 days, retitrate from 4.6 mg/24 hours patch.

Dose equivalence and conversion:

When switching from oral to transdermal therapy, patients taking 3–6 mg by mouth daily should initially switch to 4.6 mg/24 hours patch, then titrate as above. Patients taking 9 mg by mouth daily should switch to 9.5 mg/24 hours patch if oral dose stable and well tolerated; if oral dose not stable or well tolerated patients should switch to 4.6 mg/24 hours patch, then titrate as above. Patients taking 12 mg by mouth daily should switch to 9.5 mg/24 hours patch. The first patch should be applied on the day following the last oral dose.

Cautions: Bladder outflow obstruction; conduction abnormalities; duodenal ulcers; gastric ulcers; history of asthma; history of chronic obstructive pulmonary disease; history of seizures; risk of fatal overdose with patch administration errors; sick sinus syndrome; susceptibility to ulcers.

Side-effects (general):

*Common or very common*
- Anxiety; appetite decreased; arrhythmias; asthenia; dehydration; depression; diarrhoea; dizziness; drowsiness; fall; gastrointestinal discomfort; headache; hyperhidrosis; hypersalivation; hypertension; movement disorders; nausea; skin reactions; syncope; tremor; urinary incontinence; urinary tract infection; vomiting; weight decreased

*Uncommon*
- Aggression; atrioventricular block

*Rare or very rare*
- Pancreatitis; seizure

*Frequency not known*
- Hepatitis

Specific side-effects:

*Common or very common*
- with oral use: Confusion; gait abnormal; hallucinations; malaise; parkinsonism; sleep disorders

*Uncommon*
- with oral use: Hypotension
- with transdermal use: Gastric ulcer

*Rare or very rare*
- with oral use: Angina pectoris; gastrointestinal disorders; gastrointestinal haemorrhage

*Frequency not known*
- with transdermal use: Hallucination; nightmare

Further information: Dose should be started low and increased according to response if tolerated.

Treatment should be interrupted if dehydration resulting from prolonged vomiting or diarrhoea occurs and withheld until resolution—retitrate dose if necessary.

Transdermal administration is less likely to cause side-effects.
Hepatic impairment: Manufacturer advises caution (risk of increased exposure; no information available in severe impairment). Dose adjustments - Manufacturer advises cautious dose titration according to individual tolerability.

Renal impairment: Titrate according to individual tolerability. For GFR<50ml/min start at a low dose and gradually increase.

Monitoring requirements: Monitor body-weight. Particular caution should be exercised in titrating patients with body weight below 50 kg above the recommended effective transdermal patch dose of 9.5 mg/24hr. They may experience more adverse reactions and may be more likely to discontinue due to adverse reactions. Carefully titrate and monitor these patients for adverse reactions (e.g. excessive nausea or vomiting) and consider reducing the maintenance dose to the 4.6 mg/24hr transdermal patch, or a well-tolerated oral dose of the oral formulation, if such adverse reactions develop.

Directions for administration with transdermal use: Apply patches to clean, dry, non-hairy, non-irritated skin on back, upper arm, or chest, removing after 24 hours and sitting a replacement patch on a different area (avoid using the same area for 14 days).

Patient and carer advice: For Exelon® patches: Advise patients and carers of patch administration instructions, particularly to remove the previous day's patch before applying the new patch—consult product literature.

Interactions: Avoid concomitant administration with other cholinesterase inhibitors. May interfere with the activity of anticholinergic medication. May interact with drugs which significantly reduce the heart rate e.g. Digoxin, Beta Blockers, certain calcium-channel blocking agents and amiodarone. Some enzyme inhibitors such as Ketoconazole, Quinidine, Itraconazole, Erythromycin and Fluoxetine could inhibit the metabolism of these medicines, resulting in increased drug levels. Enzyme inducers such as Rifampicin, Phenytoin, Carbamazepine and alcohol may reduce the levels of these drugs. May exaggerate the effects of succinylcholine type muscle relaxants during anaesthesia.

**Galantamine**

Indication: Mild to moderately severe dementia in Alzheimer's disease

By mouth

Dose: Adult. *Immediate-release medicines* (orally). Initially 4 mg twice daily for 4 weeks, increased to 8 mg twice daily for at least 4 weeks; maintenance 8–12 mg twice daily. Preferably taken with morning and evening meals.

Dose: Adult. *Modified-release capsules* (orally). Initially 8 mg once daily for 4 weeks, increased to 16 mg once daily for at least 4 weeks; maintenance 16–24 mg daily. An increase to the maintenance dose of 24mg/day should be considered on an individual basis depending on response to drug and tolerability. In individual patients not showing an increased response or not tolerating 24mg/day, a dose reduction to 16mg/day should be considered.

Galantamine XL capsules should be administered once-daily in the morning,
preferably with food. Prescribe brand as per local formulary agreement.

Cautions: Avoid in gastro-intestinal obstruction; avoid in urinary outflow obstruction; avoid whilst recovering from bladder surgery; avoid whilst recovering from gastro-intestinal surgery; cardiac disease; chronic obstructive pulmonary disease; congestive heart failure; electrolyte disturbances; history of seizures; history of severe asthma; pulmonary infection; sick sinus syndrome; supraventricular conduction abnormalities; susceptibility to peptic ulcers; unstable angina

Side-effects:
*Common or very common*
Appetite decreased; arrhythmias; asthenia; depression; diarrhoea; dizziness; drowsiness; fall; gastrointestinal discomfort; hallucinations; headache; hypertension; malaise; muscle spasms; nausea; skin reactions; syncope; tremor; vomiting; weight decreased
*Uncommon*
Atrioventricular block; dehydration; flushing; hyperhidrosis; hypersomnia; hypotension; muscle weakness; palpitations; paraesthesia; seizure; taste altered; tinnitus; vision blurred
*Rare or very rare*
Hepatitis; severe cutaneous adverse reactions (SCARs)

Further information: Manufacturer advises increasing dose according to response and tolerability. Serious skin reactions (including Stevens-Johnson syndrome and acute generalized exanthematous pustulosis) have been reported—manufacturer advises discontinue at the first appearance of skin rash.

Hepatic impairment: Manufacturer advises caution in moderate impairment (risk of increased plasma concentrations); avoid in severe impairment (no information available). Dose adjustments - Manufacturer advises for immediate-release preparations in moderate impairment, initially 4 mg once daily (preferably in the morning) for at least 7 days, then 4 mg twice daily for at least 4 weeks; maximum 8 mg twice daily. Manufacturer advises for modified-release preparations in moderate impairment, initially 8 mg on alternate days (preferably in the morning) for 7 days, then 8 mg once daily for 4 weeks; maximum 16 mg daily.

Renal impairment: Dose as in normal renal function for GFR 10-50ml/min. Manufacturer contraindicates use in GFR <10ml/min. Plasma levels may be increased in patients with moderate and severe renal impairment.

Patient and carer advice: Manufacturer recommends that patients are warned of the signs of serious skin reactions; they should be advised to stop taking galantamine immediately and seek medical advice if symptoms occur.

Interactions: Avoid concomitant administration with other cholinesterase inhibitors. May interfere with the activity of anticholinergic medication. May interact with drugs which significantly reduce the heart rate e.g. Digoxin, Beta Blockers, certain calcium-channel blocking agents and amiodarone. Some enzyme inhibitors such as Ketoconazole, Quinidine, Itraconazole, Erythromycin and Fluoxetine could inhibit the metabolism of these medicines, resulting in increased drug levels. Enzyme inducers such as Rifampicin, Phenytoin, Carbamazepine and alcohol may reduce the levels of these drugs. May exaggerate the effects of succinylcholine type muscle relaxants during anaesthesia.
**Memantine**

Indication: Moderate to severe dementia in Alzheimer's disease.  
Dose: Adult. Initially 5 mg once daily. This initial dose should be continued for 1 week in order to reduce the risk of undesirable effects, then increased in steps of 5 mg every week; usual maintenance 20 mg daily; maximum 20 mg per day.

Cautions: Epilepsy; history of convulsions; risk factors for epilepsy

Side-effects:

*Common or very common*
- Balance impaired; constipation; dizziness; drowsiness; dyspnoea; headache; hypersensitivity; hypertension

*Uncommon*
- Confusion; embolism and thrombosis; fatigue; fungal infection; hallucination; heart failure; vomiting

*Rare or very rare*
- Seizure

*Frequency not known*
- Hepatitis; pancreatitis; psychotic disorder

Hepatic impairment: Manufacturer advises avoid in severe impairment—no information available.

Renal impairment: Avoid if GFR less than 5 mL/min. Dose adjustments:  
Reduce dose to 10 mg daily if GFR 30–49 mL/min, if well tolerated after at least 7 days dose can be increased in steps to 20 mg daily. Reduce dose to 10 mg daily if GFR 5–29 mL/min.

Directions for administration: For oral solution, manufacturer advises solution should be dosed onto a spoon or into a glass of water. For soluble tablets, manufacturer advises drink resulting solution immediately when dissolved in water.

Interactions: concomitant use of N-methyl-D-aspartate (NMDA)-antagonists such as amantadine, ketamine or dextromethorphan (very common in OTC dry cough remedies) should be avoided. The effects of L-dopa, dopaminergic agonists, and anticholinergics may be enhanced by concomitant treatment with memantine

**References**

APPENDIX 1 - TEMPLATE LETTER TO REQUEST SHARED CARE

Date [Insert date letter typed here]

Dear Dr [insert Doctors name here]

Patient name: [insert Patients name here]

Date of birth: [insert date of birth]

NHS Number: [insert NHS Number]

Diagnosis: [insert diagnosis here]

As per the agreed EPUT Shared Care Protocol for the prescribing and monitoring of medicines for Alzheimer’s Disease, this patient is now suitable for prescribing to move to primary care.

A copy of the approved shared care protocol for these medicines can be found on the EPUT website https://eput.nhs.uk/our-services/pharmacy/formulary-prescribing-guidelines-mental-health/ , and a paper copy is attached.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care.

I confirm that I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted, the need for any monitoring, how monitoring will be arranged, and the roles of the consultant / community dementia nurse, GP and the patient in shared care. I confirm the patient has understood and consented to this shared care arrangement at this time.

Treatment with [insert drug name/ brand, drug formulation] was started on [insert date started], the patient is currently on a dose of [insert dose].

Tolerance: [insert details].

Side effects experienced: [insert details].

[Insert additional information regarding prescribing plan here: review, planned dosage changes etc.]

Recent monitoring:

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I have prescribed for this patient for a further month. I will send a clinic letter so the GP practice will be in receipt of the clinic letter within ONE week of the prescription being issued.

Your agreement to shared care will be assumed unless I receive a formal letter from you declining shared care within 14 days of receiving this request. Please undertake prescribing and monitoring from [insert date] (NB: date must not be less than one month from the date of
Please undertake the following:
- monitor the patients overall health and wellbeing during the normal consultation process;
- check for possible drug interactions when newly prescribing or stopping concurrent medication;
- report any suspected adverse event to the specialist clinician and, if appropriate, to the MHRA;
- deal with any concomitant illness, with specialist clinic support if appropriate;
- on discontinuation of treatment, refer to the specialist clinician if the patient is observed to experience a dramatic deterioration in cognitive function.

Review

A review of this medicine will be supported by [insert details of review plan including timescales, e.g. Community Dementia Nurse / Medication Monitoring service, state the frequency of review e.g. 6-monthly/annual]

and will include a discussion with the patient (and their families and carers as appropriate) as to whether the medicines should be continued.

Re-referral

[Insert details of how to re-refer back to Memory Assessment Service if needed]:

[Insert details if patient can self-refer back to the Memory Assessment Service within 6 months of discharge to GP]:

If you are unwilling or unable to accept this shared care agreement, please reply within 14 days of receiving this request stating the reason why you are unable to provide this service.

Yours sincerely

[Name], [Job title], [Contact number], [Care coordinator & contact no.]
[Community team & contact no.]

PAPER COPY OF THE EPUT PROTOCOL “Shared Care Protocol for the prescribing and monitoring of medicines for Alzheimer’s Disease” TO BE PRINTED AS ENCLOSURE.