

Hull & East Riding Prescribing Committee

Prescribing Framework for Acetylcholinesterase Inhibitors and Memantine for the Treatment and Management of Dementia

We agree to treat this patient within this Prescribing Framework
Specialist Prescriber's Name
Specialist Prescriber's Signature
Professional register name and registration number
Consultant's name (if working under direction of Consultant)
Speciality/Department:
Primary care prescriber name:
Primary care prescriber Signature
Professional register name and registration number:
The proposed SCF refers to the following medication (tick as appropriate):
Donepezil Rivastigmine Galantamine Memantine
Please specify formulation if required (eg. tablet, oral solution): Service Humber CHCP HUTH NLAG RDASH
OPCMHT (Humber /RDASH only):

The front page of this form should be completed by the specialist and the form sent to the patient's general practice. If the primary care prescriber is unable to accept prescribing responsibility for the above patient the specialist prescriber should be informed within two weeks of receipt of this framework and specialist prescriber letter. In such cases the primary care prescriber are requested to update the specialist prescriber, by letter, of any relevant changes in the patient's medication / medical condition.

Prescribing framework for Treatment and management of dementia

Date approved by the APC: 10/2022

Version number: 2022.02

Full copy of framework can also be found at : <u>Humber Area Prescribing Committee</u> (northernlincolnshireapc.nhs.uk)

1. Background

There are three acetylcholinesterase inhibitors (AChEIs), licensed for the treatment of people with mild to moderate Alzheimer's Disease, namely Donepezil, Galantamine and Rivastigmine, and also a glutamine receptor antagonist Memantine, which is licensed for treating moderate to severe Alzheimer's disease.

NICE NG97 for Dementia (June 2018) states that the three acetylcholinesterase (AChE) inhibitors donepezil, galantamine and rivastigmine as monotherapies are recommended as options for managing mild to moderate Alzheimer's disease, and 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.

All of them under all of the conditions specified below:

- 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:
 - o secondary care medical specialists such as psychiatrists, geriatricians and neurologists
 - o 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.
- 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 (see recommendation 1.5.4) without taking advice from a specialist clinician.
- Ensure that local arrangements for prescribing, supply and treatment review follow the <u>NICE guideline</u> on medicines optimisation.
- Do not stop AChE inhibitors in people with Alzheimer's disease because of disease severity alone.

If prescribing an AChE inhibitor (donepezil, galantamine or rivastigmine), 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 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.

This recommendations is from <u>NICE technology appraisal guidance on donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease</u>.(NICE TA 217)

This framework aims to provide guidelines for the initiation of dementia drugs by specialists for the management of people with Alzheimer's disease, mixed dementia (Alzheimer's disease with concomitant vascular dementia), dementia associated with Parkinson's Disease and Lewy Body Dementia and subsequent management by GPs. It sets out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

NICE are currently working to appraise the clinical and cost effectiveness of aducanumab within its marketing authorisation for treating mild cognitive impairment (MCI) in early Alzheimer's disease but guidance has not yet been published.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL(91)127 "Responsibility for prescribing between hospitals and GPs.

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2. Indication

The Acetylcholinesterase inhibitors (AChEIs) are indicated in the treatment of patients with mild to moderate dementia in Alzheimer's Disease. Rivastigmine is also indicated for mild to moderate dementia in Parkinson's disease. They are additionally used in mixed Alzheimer's disease/vascular dementia (i.e. Alzheimer's Disease with concomitant vascular dementia associated with Parkinson's Disease or Lewy Body Dementia with non- cognitive symptoms causing significant distress or leading to behaviour that challenges).

Memantine is indicated in the treatment of moderate and severe stage Alzheimer's Disease. It is additionally used in mixed dementia (Alzheimer's disease with concomitant vascular dementia), Parkinson's disease dementia and Lewy Body Dementia, in the following circumstances;-

- a) Patients with moderate stage Alzheimer's Disease, or mixed dementia (Alzheimer's disease with concomitant vascular dementia) as an alternative AChEIs, in any of the following circumstances;-
 - Patients appropriate for drug treatment are unable to tolerate an ACHEI
 - When there are medical contraindications to the prescription of ACHEIs
 - There has been a loss of treatment effect from ACHEIs
- b) Patients with Alzheimer's Disease (AD), mixed dementia (Alzheimer's disease with concomitant vascular dementia), Parkinson's disease dementia or Lewy Body Dementia (DLB) with non-cognitive symptoms and behaviour that challenges causing significant distress or potential harm to the individual or others if a non-pharmacological approach is inappropriate or has been ineffective in patients where:
 - A non-pharmacological approach is inappropriate or has been ineffective and;-
 - Antipsychotic drugs are inappropriate or have been ineffective
 - ACHEIs are inappropriate or have been ineffective
- c) 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.

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3. Dose

	Dose	Renal Impairment	Hepatic impairment
Donepezil Tablet and orodispersible	5mg OD increasing to 10mg OD after one month Maintenance- 5 to 10mg OD	No adjustment	No adjustment. Caution on titration
Galantamine Tablet and oral solution	4mg BD for 4 weeks then 8mg BD for 4 weeks then 12mg BD Maintenance- 8 to12mg BD		Initiation: 4mg OM for at least one week. 4 mg twice daily for at least 4 weeks. Max:8mg bd Or for MR 8mg on alternate days for 1 week then 8mg daily for 4 weeks, max 16mg daily
Galantamine MR Capsule	8mg OD for 4 weeks then 16mg OD for 4 weeks then 24mg OD Maintenance- 16 to 24mg OD	Avoid if eGFR less than 9 mL/minute/1.73m2	
Rivastigmine Capsule and oral solution	1.5mg BD for 2 weeks then 3mg BD for 2 weeks then 4.5mg BD for 2 weeks then 6mg BD Maintenance- 3 to 6mg BD	No adjustment required, but closer	No adjustment required, but closer monitoring for side effects is advised
Rivastigmine Patch (for poor adherence)	4.6mg/24h for 4 weeks then 9.5mg/24hr for six months then 13.3mg/24 hr Maintenance- 9.5 to 13.3mg/24hr	monitoring for side effects is advised	
Memantine Tablets and oral Solution	5mg OD for 7 days then 10mg OD for 7 days then 15mg OD for 7 days then 20mg OD Maintenance- 20mg OD	eGFR30-49ml/ minute/1.73m2: if 10mg tolerated for 1 week, ok to increase to 20mg eGFR 5-29ml/minute /1.73m2: Max 10mg. eGFR below 5: Contraindicated	Mild to moderate impairment: No adjustment required Severe impairment: not recommended.

Donepezil: Doses above 10mg daily may be clinically appropriate in individual patients under specific circumstances, but would be 'off licence' and should only be undertaken under the direct supervision of a specialist team for the management of dementia, after a thorough consideration of the possible benefits and risks of such a course of action.

Rivastigmine: If treatment is interrupted for more than three days, it should be re-initiated either orally at 1.5 mg twice daily or at 4.6mg/24h and dose re-titrated.

Rivastigmine oral to transdermal switch: The first patch should be applied on the day following the last oral dose as follows:

Patients taking 3-6mg by mouth daily should initially switch to 4.6mg/24hour patch, and then titrate
as above.

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- o Patients taking 9mg daily by mouth should switch to 9.5mg/24hour patch if the oral dose is stable and well tolerated; if oral dose is not stable or well tolerated then patient should be switched to 4.6mg/24hour patch and titrate as above.
- Patients taking 12mg by mouth daily should switch to the 9.5mg/24hour patch.

4. Duration of treatment

Donepezil	Galantamine	Rivastigmine	Memantine
Treatment should be continued while it is considered to be having a worthwhile effect on cognitive, global, functional or behavioural symptoms, or where it is clinically judged that the withdrawal of treatment would not be in the patient's best interests (for example due to the risk of an adverse clinical outcome, such as triggering behaviour that challenges).			Examples of appropriate treatment end points include the development of significant side effects, the development of a significant physical illness, marked deterioration in the patients cognitive state or level of
In circumstances where there is a loss of treatment effect, after several months or years of treatment, the following options should be considered by the specialist team on an individual patient basis when clinically appropriate;-			functioning etc. Treatment should not be stopped on the basis of a score on the MMSE, or other approved diagnostic tools;
 Increasing t dose 	he dose to the BNF	maximum recommended	rather it should be a clinical decision, taking into account the
2. Considering	prescribing an alterr	native ACHEI	patient's mental, cognitive and behavioural state, physical health,
Considering memantine	the appropriatene	ess of the addition of	and prognosis

Sudden withdrawal of treatment should be avoided if possible, as this can precipitate a withdrawal reaction which can lead to an increased level of confusion

The specialist team should provide the GP with clear directions about treatment end points, together with the offer of support and advice when necessary.

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5. Contraindications and cautions

Donepezil	Galantamine	Rivastigmine	Memantine
Acetylcholinesterase inhibitors can cause unwanted dose-related cholinergic effects and should be started at a low dose and the dose increased according to response and tolerability.			Caution is recommended in patients with epilepsy, former history of convulsions or patients with predisposing factors for epilepsy
 Donepezil may exacerbate or induce extrapyramidal symptoms Neuroleptic malignant syndrome (NMS) has been reported to occur very rarely in association with Donepezil, particularly in patients also receiving concomitant antipsychotics. 	(such as Quinidine, Paroxetine or Fluoxetine) or CYP3A4 (such as Ketoconazole or Ritonavir): may lead to an increase in cholinergic adverse effects. In these circumstances a reduction of the		Concomitant use of N-methyl-D-aspartate (NMDA)-antagonists such as amantadine, ketamine or dextromethorphan should be avoided. These compounds act at the same receptor system as memantine, and therefore adverse reactions (mainly central nervous system (CNS)-related) may be more frequent or more pronounced (see also section 4.5).
 Asthma or Chronic Obstructive Pulmonary Disease(COPD) Susceptibility to peptic ulcers History of falls/syncope Sick sinus syndrome or cardiac conduction disorders, including bradycardia Electrolyte disturbances Urinary retention or bladder outflow obstruction Gastro-intestinal obstruction 			In most clinical trials, patients with recent myocardial infarction, uncompensated congestive heart failure (NYHA III-IV), or uncontrolled hypertension were excluded. As a consequence, only limited data are available and patients with these conditions should be closely supervised.
Known hypersensitivity to active ingredient, or any other component of the product			
Pregnancy & Breastfeeding			

Hepatic impairment or Renal impairment

(Patients with clinically significant renal or hepatic impairment might experience more adverse reactions) See dosing table (4) for specific instructions with each medication.

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Absolute contraindication to acetylcholinesterase inhibitors:

- Second or third-degree heart block in an unpaced patient- DO NOT prescribe AChEIs
- QT prolongation Avoid prescribing AChEIs and seek advice
- Bradycardia of < 50 bpm DO NOT prescribe AChEIs

Use of acetylcholinesterase inhibitors with caution:

AChEIs are potentially contraindicated in the following groups. Seek specialist advice and prescribe cautiously, if used, with ongoing monitoring:

- Left Bundle Branch block
- Patients on concomitant rate limiting drugs such as those listed below may be prescribed acetylcholinesterase inhibitors cautiously if pulse is between 50-60 bpm and asymptomatic
 - o beta-blockers
 - o amiodarone
 - o digoxin
 - o non-dihydropyridine calcium-channel blockers (e.g. diltiazem, verapamil).
- If rate limiting calcium channel blockers or beta-blockers are being used to treat hypertension, alternative anti-hypertensive agents might be considered to facilitate the introduction of acetylcholinesterase inhibitors

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6. Adverse effects

Donepezil	Galantamine	Rivastigmine	Memantine
Very common and Com	mon adverse effects		
	Headaches &	Dizziness	
Nausea, Diarrhoea, Vomiting, Anorexia & Weight Loss		jht Loss	
Fatigue, Syncope, Fall	s. hallucinations		
o Common cold o Agitation o Aggression o Abnormal dreams or nightmares o Insomnia o Abdominal disturbances o Rash, pruritus o Muscle cramps o Urinary incontinence o Pain	 Decreased appetite Depression Tremor Somnolence or Lethargy Bradycardia Hypertension Abdominal pain Dyspepsia Hyperhidrosis Muscle spasms Asthenia Malaise Skin reactions 	 Anxiety Sweating Heartburn Stomach pain Feeling agitated Feeling tired or weak Generally feeling unwell Trembling or feeling confused 	 Drug hypersensitivity Somnolence, Balance disorders, Hypertension, Dyspnoea, Constipation, Elevated liver function test. Headache
Uncommon adverse effects			
Seizures, Brady	cardia, Sinus bradycardia		
 Gastrointestinal haemorrhage Gastric/duodenal ulcers Hypersalivation 	 Hypersensitivity Dehydration Paraesthesia Dysgeusia Hypersomnia Blurred vision Tinnitus Supraventricular extrasystoles Atrioventricular block first degree Palpitations Hypotension Flushing Retching Muscular weakness 	 Depression Difficulty in sleeping Fainting or accidentally falling Changes in how well your liver is working 	 Fungal infections Confusion Hallucinations Abnormal gait Cardiac failure Venous thrombosis / thromboembolism Vomiting Fatigue
Rare and very Rare adv	verse effects		
 Extrapyramidal symptoms Sino-atrial block Atrioventricular block Liver dysfunction including hepatitis Rhabdomyolysis NMS (neuroleptic malignant syndrome) 	○Hepatitis○Severe cutaneous adverse reactions (SCARs)	○Chest pain○Rash, itching○Fits (seizures)○ Ulcers in your stomach or intestine	○Pancreatitis○Psychotic reactions○Hepatitis○Seizures

Specific information should be sought from the current BNF (electronically www.bnf.org/bnf/) or Data Sheet (electronically www.medicines.org.uk)

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The manufacturer of galantamine recommends that patients are warned of the signs of serious skin reactions and should be advised to stop taking galantamine immediately and seek medical advice if symptoms occur

7. Interactions

Refer to BNF Online to check for potential interactions with the medication/s of choice.

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.bnf.org.uk).

8. Monitoring

a. Drug Monitoring for Acetylcholinesterase Inhibitors

There is no requirement or need to monitor any additional biochemical or other markers during treatment with any of the drugs for dementia. Routine pulse checks should be carried out for patients taking acetylcholinesterase inhibitors at **baseline and during initiation** in accordance with the Rowland algorithm (Page10)

- 1. Pulse under 50 bpm
 - Withhold treatment with cholinesterase inhibitor
 - $_{\odot}$ Review to identify any underlying cause/consider withdrawal of co-prescribed β –blockers and reassessment
 - o If cause found unrelated to drug, or if pacemaker fitted, consider initiation (Patients fitted with cardiac pacemakers do not need pulse checks as pacemakers safeguard from developing bradycardia)
- 2. Pulse between 50 and 60 bpm and asymptomatic
 - Start/continue treatment
 - o Review pulse and symptoms after one week
 - o If patient remains asymptomatic
 - o continue drug
 - check pulse one week after each dose increase
- 3. Pulse 50-60 bpm and **symptomatic** (e.g. syncope or 'funny turns')
 - Withhold or stop treatment with cholinesterase inhibitor
 - \circ Review to identify any underlying cause/consider withdrawal of co-prescribed β –blockers and reassessment
 - o If cause found unrelated to drug, or if pacemaker fitted, consider retrial of medication, with monitoring of pulse
- 4. Pulse over 60bpm
 - Start/continue treatment
 - o Routine pulse checks at baseline, after each dose increase during titration

Routine baseline ECG is only recommended prior to initiating treatment with acetylcholinesterase inhibitors in patients with:

- Unexplained syncope
- Bradycardia
- Patients taking concomitant cardiac rate-limiting medication e.g. beta-blockers, amiodarone

Cardiac monitoring for patients established on acetylcholinesterase inhibitors

- After initiation the pulse rate and symptoms should be monitored at 1 month.
- After any upwards titration of dose the pulse rate and symptoms should be reviewed after a further month
- Any abnormal pulse rate or cardiac symptoms should be managed under the "Rowland algorithm" (Page 11)

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- Asymptomatic patients with pulse rate above 60 bpm should be rechecked at 6 months.
- Patients with satisfactory pulse who are asymptomatic should be monitored annually e.g. as part of the General Practice dementia Quality Outcomes Framework (QOF) check.
- If the patient becomes unwell or develops symptoms they would need a full assessment including a check of their pulse and blood pressure

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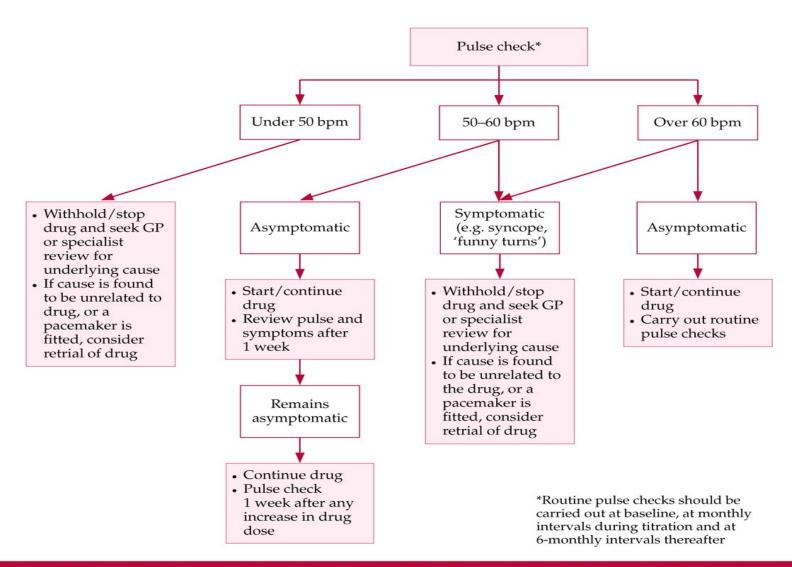


Fig. 1 Suggested guidelines for managing cardiovascular risk prior to and during treatment with acetylcholinesterase inhibitors in Alzheimer's disease. bpm, heartbeats per minute; the 'drug' means the chosen AChE inhibitor.

Courtesy of Rowland et al

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b. Disease Monitoring for All Anti-dementia Medications

Routine compliance and side effects should be monitored by patients, carers, members of the specialist team (when appropriate) and the prescriber.

This may be provided by either the primary care team or specialist team, depending on individual patient and carer needs.

When assessing the severity of Alzheimer's disease and the need for treatment, healthcare professionals should not rely solely on cognition scores in circumstances in which it would be inappropriate to do so. These include:

- if the cognition score is not, or is not by itself, a clinically appropriate tool for assessing the severity of that patient's dementia because of the patient's learning difficulties or other disabilities (for example, sensory impairments), linguistic or other communication difficulties or level of education or
- o if it is not possible to apply the tool in a language in which the patient is sufficiently fluent for it to be appropriate for assessing the severity of dementia or
- o if there are other similar reasons why using a cognition score, or the score alone, would be inappropriate for assessing the severity of dementia.

In such cases healthcare professionals should determine the need for initiation or continuation of treatment by using clinical judgement, taking into account information provided by the patient and carers and after conducting a Mental State Examination (including appropriate assessment of cognition).

The management of patients with dementia should involve partnership working to provide psycho-social and pharmacological interventions as outlined in the locally developed stepped care model for patients with dementia, based on the recommendations of the national Dementia Strategy.

9. Information to patient

The prescriber initiating treatment will be responsible for informing the patient and their carer about likely benefits and risks (including possible side effects) from the treatment prior to starting the drug. In situations where the patient is unable to give informed consent due to a lack of mental capacity, the patient's 'best interests' should be determined as outlined in the Capacity Act, by liaising with the patients relatives and carers, as well as other professionals involved in their care, prior to starting any possible treatment.

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10. Responsibilities of clinicians involved in shared care

Stage of Treatment

Specialist Service

General Practitioner

Initiation

- Selection of suitable patients
- To develop and co-ordinate the implementation of a comprehensive care plan for the patient and their carer
- Once the Specialist Service has given a patient a diagnosis of Dementia, initiated treatment or a change in treatment has been implemented due to deterioration or additional symptoms, and the patient has been stable on the medication/s for 2-3months, their care will be transferred back to primary care for ongoing management and review (under the shared care protocol).
- Undertake monitoring as outlined in section 8a and 8b
- Undertake and interpret routine baseline ECG prior to initiation **only** in patients with:
 - Unexplained syncope
 - Bradycardia
 - Patients taking concomitant cardiac rate-limiting medication e.g. beta-blockers, amiodarone
- Provide verbal and written treatment information to patient and their carer
- To provide appropriate monitoring of the patient for treatment and side effects during the initiation phase, in liaison with the patient's GP
- Ensure clear advice is provided to the General Practitioner regarding potential treatment end points
- Maintenance
- Provide advice and guidance to GP's: ongoing advice and guidance may be required to support the patient and their significant others appropriately, and/or that as the patient's condition progresses additional assessment and/or interventions may be required to support the patients with increasing risks to self or others.
- Any subsequent advice, guidance, or requests for reassessment / engagement of the services to support this cohort above will be directed to the Specialist Service managing the patient.
- OP CMHT is only available for patients started by memory clinic (Memory Assessment Service) – patients started by HUTH or CHCP must be discussed with relevant service who started the therapy.

Older Persons CMHTs

 This process should not require a full 're-referral' to occur, however it is essential that the primary care practitioner has undertaken all necessary steps to resolve any reversable issues and/or undertake any activities which

- Liaise and seek advice from the specialist team, when appropriate
- Monitoring of pulse prior to or at the point of referral
- Take over prescribing of medication after the patient is on a stable dose, and provide ongoing clinical care

- Seek advice from specialist if necessary
- Carry out routine pulse check and cardiac review 6 months after initiation and then annually
- GP can consider
 the use of
 memantine as an
 adjunct if they feel
 clinically
 appropriate;
 seeking advice
 from the specialist
 if required

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may be of benefit to the patient once the request is processed by OP CMHT.

- o Examples:
 - primary care practitioner will need to have held consultation with patient prior to A&G /re-assessment request and undertaken any necessary primary care based assessments (Bio-psycho-social); this should ideally include repeat blood screens and/or any additional investigations which may be required to rule out other pathologies / relevant to the request
 - i.e. if concern relates to potential cardiac issues an ECG may be of benefit,
 - if query is regarding memantine prescription or titration up to date, eGFR may be helpful.
- CMHT/sector doctor will then review the request and either:
 - a) provide the necessary advice (A&G only) and/or
 - B) undertake comprehensive MH assessment and agree new plan of care

Discontinuation

- Advising the GP when medication should be discontinued
- Provide any necessary supervision, support or advice during the discontinuation phase
- To initiate alternative treatment, should this be clinically appropriate
- treatment end points previously outlined; seeking advice from specialist if required
- Co-operate with the specialist during discontinuation

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Contact Details:

Humber Teaching NHS Foundation Trust: contact as advised in clinic letter.

East House Bridlington	01262 458220
Rosedale Community Unit Hedon	01482 344400
MEMORY CLINIC, COLTMAN STREET, HULL HU3 2SG	01482 336617
Hull Integrated Team for Older People HICTOP	01482 335795
Crisis and Intervention Team for Older People (CITOP)	01482 344567
Goole OPCMHT	01405 608288
Haltemprice and Beverley OPCMHT	01482 344222

Hull University Hospitals NHS Trust:

During office hours: Neurology secretaries 01482 675592

Out of hours: Contact on-call Physician for Neurology via Switchboard: 01482 875875

ICC:

If urgent by telephoning 01482 450078 or via ERS.

Advice will be via telephone or following further assessment of patient.

APPROVAL PROCESS

Written by:	Alberto Ortiz-Moya (Principal Pharmacist MH Services HTFT)
Consultation process:	HTFT DTG, HUTH Neurology, Older People MH Services, ICC
Approved by:	HTFT DTG, HERPC
Ratified by:	Humber Area Prescribing Committee
Review date:	10/2025

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