Therapeutics Advisory Group

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Norfolk and Waveney Integrated Care System

NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT

Shared care guidelines for the use of Donepezil, Galantamine, Rivastigmine and Memantine in the treatment of Dementia

Level 0 - Prescribe the drug and perform basic level of monitoring

Medication covered by this agreement	
Donepezil Galantamine Rivastigmine Memantine	
Indications for shared care	
Dementia and Alzheimers Disease as per NICE NG97. **Full details in main body of document**	
Specialist Prescribing and Monitoring Responsibilities (summary)	**GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities (summary)**
• Confirm diagnosis and clarify supervision • Notify the GP of the need to initiate therapy • Provide details of how the medication will be collected and any support required • Discuss benefits, side effects and prescribing guidelines of treatment with the patient and carer. • Ascertain willingness by the patient to take their medication and co-operation (within the bounds of their illness) • Recommend appropriate dose to initiate treatment. • Communicate any changes in treatment with the primary care prescriber as appropriate. • Monitor response to treatment and advise continuation for up to three months to the prescriber within 28 days of the initial prescription where appropriate • Memory Assessment and Treatment Service (MATS) will monitor cognition, behaviour and/or function • Continued assessment where appropriate • Supervise the withdrawal of treatment • Ensure clear back-up arrangements exist	• Prescribe at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). • Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation. • Consider specialist advice on any changes in treatment. • Monitor the patient's general health and wellbeing • Seek specialist advice if the patient experiences adverse reaction/interaction • In the event of deteriorating clinical condition assess and treat the underlying problem if physical. Refer back to the specialist if the deterioration relates to the progression of the condition being treated. • Report adverse events to the specialist and if appropriate to the MHRA. https://yellowcard.mhra.gov.uk/ • Keep the Mental Health team appraised of progress as appropriate.
Patient Information	
○ Report any adverse effects related to the specialist or GP. ○ The patient and carer should be prepared for any sudden deterioration that may occur if the drug is stopped and actions to take. ○ Share any concerns in relation to treatment with the specialist or GP. ○ Report to the specialist or GP if they do not have a clear understanding of their treatment. ○ Notify specialist services if the medication is no longer being taken.	
Specialist Contact Details	
Call the relevant Consultant Psychiatrist via the NSFT switchboard on (01603) 421421. NSFT Medicines information (MI) service: medinfo@nsft.nhs.uk	

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
- **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment

Dementia is a progressive, variable and largely irreversible condition that covers a wide range of symptoms. It is characterised by widespread impairment of mental function, including some or all of the following:

- memory loss
- communication difficulties and sensory impairment
- disorientation
- personality change
- difficulties with activities of daily living
- self-neglect
- behaviour that is out of character (for example, sleep disturbance or sexual disinhibition).

Approximately 815,000 people are living with dementia in the UK. The number of people living with dementia in the UK is expected to increase to 1,143,000 by 2025.

In June 2018 the National Institute for Health and Care Excellence (NICE) issued revised guidance NG97 on use in Dementia: assessment, management and support for people living with Dementia. This guidance recommended donepezil, galantamine and rivastigmine as monotherapy options for the treatment of mild to moderate Alzheimer's disease.

Memantine monotherapy is recommended as an option for people with moderate Alzheimer's disease who have a contra-indication or intolerance to donepezil, galantamine or rivastigmine OR who have severe Alzheimer's disease.

People with an established diagnosis of Alzheimer's disease who are already receiving treatment with one of donepezil, galantamine or rivastigmine may also be offered Memantine if they have severe disease, or Memantine may be offered if they have moderate disease.

For people with non-Alzheimer's dementia NICE advises:

- 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 or rivastigmine are not tolerated
- Consider donepezil or rivastigmine for people with severe dementia with Lewy bodies
- Consider memantine for people with dementia with Lewy bodies if donepezil, galantamine or rivastigmine are not tolerated or are contra-indicated
- Only consider donepezil, galantamine or rivastigmine for people with vascular dementia if they have suspected co-morbid Alzheimer's disease, Parkinson's disease dementia or dementia with Lewy bodies
- Do not offer donepezil, galantamine, rivastigmine or memantine to people with fronto-temporal dementia or to people with cognitive impairment caused by multiple sclerosis

NG71 recommends the use of rivastigmine for people with mild to moderate Parkinson's disease dementia:

- Offer donepezil, galantamine or rivastigmine for people with mild to moderate Parkinson's disease dementia
- Consider donepezil, galantamine or rivastigmine for people with severe Parkinson's Disease dementia
- Consider memantine for people with Parkinson's disease dementia only if donepezil, galantamine or rivastigmine are not tolerated or contra-indicated.

Locally donepezil is the preferred first line option of the treatment choices described above where clinically indicated. Other treatment options may be used where donepezil is not tolerated or contra-indicated.

NICE also recommended that primary care prescribers should only start treatment with these medicines on the advice of a clinician with the necessary knowledge and skills and that once a decision has been made to start treatment, the first prescription may be made in primary care. Locally to ensure good patient care, this document provides information on the specialist support available to patients and primary care clinicians to support a shared care approach, though with prescribing initiated in primary care.

Indications NOT COVERED by this agreement

Currently the available treatments (donepezil, rivastigmine, galantamine or memantine) are licensed **ONLY** for dementia in Alzheimer's disease (all) and dementia in Parkinson's disease (rivastigmine only), however NICE advises use outside of licensed indication as described above.

Use of donepezil, galantamine, rivastigmine or memantine in people with fronto-temporal dementia or people with cognitive impairment caused by multiple sclerosis is **NOT COVERED** by this agreement.

Criteria for Patient Selection

- Initial referrals under these guidelines may come from either GPs or another hospital specialist.
- The referring doctor should screen the patient to exclude reversible causes of dementia **(see Initial screening requirements below).**
- NG97 advises that clinicians should consider minimising the use of medicines associated with increasing anticholinergic burden when assessing whether to refer a person with suspected dementia for diagnosis.

Recommended tests screening dementia:

- FBC, Serum B12 & folate, U&Es, glucose, LFTs, TFT Ca2+
- Consider gamma GT if possible, alcohol problems, ESR/CRP, VDRL/TPHA, syphilis EIA
- Where indicated - urinalysis for Glucose/infection
- Referral should be made to the specialist memory clinic

Links to Side Effects, Interactions and Cautions

	Side Effects		Interactions		Cautions	
	BNF	**SPC**	**BNF**	**SPC**	**BNF**	**SPC**
Donepezil	link	link	link	link	link	link
Galantamine	link	link	link	link	link	link
Rivastigmine	link	link	link	link	link	link
Memantine	link	link	link	link	link	link

Initiation of therapy and ongoing dose regimen

Specialist will notify GP of need to initiate under this agreement and related supervision period:

- **a.** 16 weeks/4 months stabilisation period for donepezil, galantamine or rivastigmine in Alzheimer's Disease
- **b.** 8 weeks for memantine in Alzheimer's Disease
- **c.** 8 weeks for rivastigmine for dementia in Parkinson's disease

A request to prescribe should provide details of how the medication will be collected and any support with medicines required, as well as contact details

Memory Assessment and Treatment Service (MATS) will monitor cognition, behaviour and/or function and advise the primary care prescriber on frequency of monitoring and what to do when the parameters change.

Duration of therapy / How the treatment will be reviewed and if appropriate, stopped

See table under **Monitoring responsibilities** and **Stopping treatment** below

Baseline assessment and ongoing monitoring – by Specialist

Parameter	Frequency of monitoring	Action
Cognition	At initiation of treatment, at 4 weeks and at 8 weeks, at 6 weeks (for use of rivastigmine for dementia in Parkinson's disease only); at 4 months (Alzheimer's disease), and as a baseline prior to medication being stopped.	Mini Mental State Examination or equivalent tool, informant review
Behaviour	At initiation of treatment, at 4 weeks and at 8 weeks, at 6 weeks (for use of rivastigmine for dementia in Parkinson's disease only); at 4 months (Alzheimer's disease), and as a baseline prior to medication being stopped.	Clinical Assessment, informant review
ADL Function	At initiation of treatment, at 4 weeks and at 8 weeks, at 6 weeks (for use of rivastigmine for dementia in Parkinson's disease only); at 4 months (Alzheimer's disease), and as a baseline prior to medication being stopped.	Clinical Assessment, informant review

GP / Community Team or other Primary Care monitoring responsibilities

None required. Monitor the patient's general health and wellbeing and liaise with the carer or care-worker as appropriate.

Consultant / Specialist prescribing responsibilities

2. Confirm diagnosis and clarify who is providing supervision.
3. Notify the GP of the need to initiate therapy under the shared care agreement and the related supervision period:
   - **a.** 16 weeks/4 months stabilisation period for donepezil, galantamine or rivastigmine in Alzheimer's Disease
   - **b.** 8 weeks for memantine in Alzheimer's Disease
   - **c.** 8 weeks for rivastigmine for dementia in Parkinson's disease

   A request to prescribe should provide details of how the medication will be collected and any support with medicines required with contact details
4. Discuss benefits, side effects and prescribing guidelines of treatment with the patient and carer. The patient and carer should be prepared for any sudden deterioration that may occur when the drug is stopped and actions to take.

5. Ascertain willingness by the patient to take their medication and co-operation (within the bounds of their illness) with the assessment of their illness before asking the primary care prescriber to initiate. Assurance of compliance may need to come from either the carer or care worker.
6. Assess donepezil, galantamine, rivastigmine or memantine dosage for treatment of alzheimer's disease and recommend appropriate dose to primary care prescriber to initiate treatment.
7. Communicate any changes in treatment with the primary care prescriber as appropriate.
8. Monitor response to treatment and advise continuation for up to three months to the primary care prescriber within 28 days of the initial prescription **only** where there has been an improvement or no deterioration in score, **or** where there is evidence of global improvement on behavioural and/or functional assessment. Assessment of compliance should also be made at this stage.
9. Memory Assessment and Treatment Service (MATS) will monitor cognition, behaviour and/or function and advise the primary care prescriber on frequency of monitoring and what to do when the parameters change.
10. Continued assessment must be offered where the client and or their family have specific needs.
11. If necessary, supervise the withdrawal of treatment and provide supporting advice to the patient and carer.
12. Ensure clear back-up arrangements exist for the primary care prescriber, including direct telephone helpline for advice and support.

Report adverse events to the MHRA - www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm as appropriate.

GP prescribing responsibilities

1. Prescribe donepezil, galantamine, rivastigmine or memantine at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation.
2. Consider specialist advice on any changes in treatment.
3. Monitor the patient's general health and wellbeing and liaise with the carer or care-worker as appropriate.
4. Seek specialist advice if the patient experiences adverse reaction/interaction or (for donepezil, galantamine or rivastigmine in alzheimer's disease).
5. In the event of deteriorating clinical condition assess and treat the underlying problem if physical. Refer back to the specialist if the deterioration relates to the progression of the condition being treated.
6. Report adverse events to the specialist and if appropriate to the MHRA. https://yellowcard.mhra.gov.uk/
7. Keep the mental health team appraised of progress as appropriate. Contact specialist staff if there are any concerns or consider that the medication should be stopped.

Stopping treatment / Specialist referral / follow-up

- Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global, functional and/or behavioural symptoms.
- Patients who continue treatment should be reviewed regularly using cognitive, global, functional and/or behavioural assessment
- Treatment should only be stopped as part of a shared decision-making process, if there are signs of significant deterioration or the person is approaching end of life

○ Treatment should be reviewed by a specialist team before discharge to GP care. Most patients will be discharged from specialist care after 16 weeks and may need re-referral is there are treatment concerns. Carers' views on the patient's condition at follow-up should be sought.
Further information and supporting documents
NG97 - Dementia: assessment, management and support for people living with dementia and their carers – June 2018

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