NHS
Pan Mersey
Area Prescribing Committee

SHARED CARE FRAMEWORK

The Pan Mersey Area Prescribing Committee recommends the prescribing of ATOMOXETINE for ADHD in accordance with NICE NG87.

SHARED CARE

1. Background	**NHS Halton CCG** for the treatment of adults only **NHS Knowsley CCG** for the treatment of adults only **NHS St Helens CCG** for the treatment of adults only **NHS Warrington CCG** for the treatment of adults only **NHS Wirral CCG** for the treatment of adults only This shared care framework aims to provide clarity on the responsibilities of all professionals involved in commissioning and prescribing across primary, secondary and tertiary care. Good organisation of care across the interface between primary and secondary/tertiary care is crucial in ensuring that patients receive high quality care – and in making the best use of clinical time and NHS resources in all care. Attention deficit hyperactivity disorder (ADHD) is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness The National Institute for Health and Clinical Excellence (NICE) issued a clinical guideline, Attention Deficit Hyperactivity Disorder: diagnosis and management (NG87) in 2018. This document advises that treatment for ADHD should only be initiated by a healthcare professional with expertise in ADHD and should be based on a comprehensive assessment and diagnosis. Continued prescribing and monitoring of drug therapy may be performed by the primary care clinicians, under shared care arrangements. NICE NG87 states: Offer atomoxetine to children aged 5 years and over and young people if they cannot tolerate methylphenidate or lisdexamfetamine or their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses. Symptoms of ADHD can persist into adulthood in about two thirds of all patients. For patients transitioning into adulthood, specialists should ensure appropriate arrangements are made for referral into adult services. In such circumstances a new shared care agreement will need to be made between the primary care clinician and the new specialist provider. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist or psychiatrist.

	Atomoxetine is an inhibitor of the pre-synaptic noradrenaline transporter. It is not a psychostimulant and is not an amphetamine derivative.
2. Licensed indications	Atomoxetine is indicated for the treatment ADHD in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.
3. Locally agreed off-label use	Children aged 5-6 years.
4. Initiation and ongoing dose regime	Careful dose titration is necessary at the start of treatment and should always be carried out under the supervision of the specialist. Transfer of monitoring and prescribing to primary care is normally after 3 months if the request to prescribe is accepted. This will be when the dose and monitoring are stable. The duration of treatment will be determined by the specialist based on clinical response and tolerability. **Dosing information** All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. Dosage should be individualised according to the therapeutic needs and response of the patient. **Children and adolescents weighing up to 70 kg body weight:** Atomoxetine should be initiated at a total daily dose of approximately 0.5 mg/kg. The dose should be titrated after 7 days, if necessary up to a maximum of 1.8mg/kg/day, either as a single dose or in two divided doses, according to clinical response and tolerability. **Children and adolescents weighing over 70 kg body weight:** A total daily dose of 40 mg should be initiated. The dose should be titrated after 7 days according to response and tolerability to a usual maintenance dose of 80 mg/day. The maximum recommended total daily dose is 100mg. *A single daily dose can be given; however, two divided doses may be prescribed to minimise side effects.* **Adults:** A total daily dose of 40 mg should be initiated. The dose should be titrated after 7 days according to response and tolerability to a usual maintenance daily dose of 80 mg to 100mg. The maximum recommended total daily dose is 100mg. The dose should be titrated against symptoms and adverse effects in line with the BNF or BNF for Children until dose optimisation is achieved, that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects[2]. Dose reduction may be required in patients with different degrees of hepatic impairment – refer to SPC **Ongoing prescribing** **Shared Care may only be commenced following initiation, stabilisation and review of treatment. In addition, formal agreement must have been received from the primary care prescriber. Termination will be the responsibility of the specialist.** Review the use of Atomoxetine at least once a year and discuss with the patient (and their families and carers as appropriate) whether medication should be continued. (NICE NG87)

<table>
<tr><td></td><td colspan="2">Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. (NICE NG87)</td></tr>
<tr><td>5. Baseline investigations, initial monitoring, and dose titration to be undertaken by specialist</td><td colspan="2">Baseline: - Pre-treatment screening
Before starting medication for ADHD, a full assessment should be completed which should include:
• a review to confirm they continue to meet the criteria for ADHD and need treatment
• a review of mental health and social circumstances, including:
o presence of coexisting mental health and neurodevelopmental conditions
o current educational or employment circumstances
o risk assessment for substance misuse and drug diversion
o care needs
• a review of physical health, including:
o a medical history, taking into account conditions that may be contraindications for specific medicines
o current medication
o height and weight (measured and recorded against the normal range for age, height and sex)
o baseline pulse and blood pressure
o A cardiovascular assessment.
An electrocardiogram (ECG) is not needed before starting atomoxetine, unless the person has any of the features mentioned in recommendation 1.7.5 of the NICE 2018 Attention deficit hyperactivity disorder diagnosis and management guidelines or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.

Refer to a paediatric hypertension specialist before starting medication for ADHD if blood pressure is consistently above the 95th centile for age and height for children and young people.</td></tr>
<tr><td rowspan="5">6. Ongoing monitoring requirements to be undertaken by primary care</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>Blood pressure and pulse (appropriate for age, using information supplied in attached request letter – children & adolescents only)</td><td>At every adjustment of dose or specialist visit and then every 6 months
Primary care – every 6 months</td></tr>
<tr><td>Weight (in adults); Height and weight (in children and adolescents)</td><td>At every adjustment of dose or visit or at least every 6 months
Primary care – every 6 months
Weight every 3 months in children 10 years and under</td></tr>
<tr><td>Side effects</td><td>Every 6 months</td></tr>
<tr><td>Compliance</td><td>Every 6 months</td></tr>
<tr><td></td><td>Clinical need, benefits, side effects</td><td>Annual review by Specialist</td></tr>
<tr><td colspan="3">Cardiovascular monitoring (blood pressure and heartrate) should be undertaken before and after each dose adjustment.
Refer to ‘Adverse Drug Reactions’ section for advice and actions to be taken.</td></tr>
</table>

<table>
<tr><td rowspan="3">7. Pharmaceutical aspects</td><td>Route of administration:</td><td>Oral</td></tr>
<tr><td>Formulation:</td><td>Hard capsules in 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg or 100 mg
Oral solution 4 mg/mL
It is more cost effective to prescribe the exact strength of atomoxetine instead of combining different strengths for an increased dose.</td></tr>
<tr><td>Administration details:</td><td>Capsules or liquid should be taken with or without food.
It is not recommended to mix oral solution in food or water as it can prevent the patient receiving a full dose or could negatively affect the taste.</td></tr>
<tr><td></td><td>Other important information:</td><td>No distinct withdrawal symptoms have been reported.
In cases of significant adverse effects, atomoxetine may be stopped abruptly; otherwise the drug may be tapered off over a suitable time period.
Atomoxetine may exacerbate hypertension in patients with end-stage renal disease.
Atomoxetine is a prescription only medicine (POM). It is not a controlled drug.</td></tr>
<tr><td>8. Contraindications</td><td colspan="2">Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.</td></tr>
<tr><td>9. Significant drug interactions</td><td colspan="2">For a comprehensive list consult the BNF or Summary of Product Characteristics</td></tr>
<tr><td>10. Adverse effects and management</td><td colspan="2">For a comprehensive list consult the BNF or Summary of Product Characteristics
In children, parents/patients will have been advised by the ADHD specialist to report any suspected side effects directly to them. GPs should refer any children with suspected side effects to the ADHD specialist irrespective of the advice in the table below.
Atomoxetine has been associated with increased rates of fatigue, somnolence, and dizziness in paediatric and adult patients. Patients should be advised caution when driving a car, cycling or operating hazardous machinery until they are reasonably certain that their performance is not affected by atomoxetine.</td></tr>
<tr><td></td><td colspan="2"><table>
<tr><th>Adverse effect</th><th>Management</th></tr>
<tr><td>Sustained resting tachycardia, cardiomyopathy, unexplained chest pains, dyspnoea and unexplained syncope</td><td>Seek prompt cardiac specialist advice and notify the ADHD specialist Team</td></tr>
<tr><td>Clinically significant increases in blood pressure, arrhythmia</td><td>Exclude other causes and seek ADHD specialist advice.</td></tr>
<tr><td>Development or worsening of psychiatric disorders including psychotic or manic symptoms, aggressive or hostile behaviour,</td><td>Continue treatment. Seek ADHD specialist advice. Discontinuation of treatment may be considered by the specialist</td></tr>
</table></td></tr>
</table>

	anxiety, agitation, motor or vocal tics and suicidal ideation	
	Reduced weight and growth retardation	Continue treatment. Provide advice on healthy diet and consider taking additional meals or snacks early in the morning or late in the evening when the effects of the drug have worn off. Refer to a dietician if appropriate. If weight loss becomes a concern, seek ADHD specialist advice.
	Increase in seizure frequency or new-onset seizures	Refer to the ADHD specialist Team. Discontinuation of treatment may be appropriate.
	Moderate to severe liver disorders	Exclude other causes. Repeat blood tests for confirmation. Seek ADHD specialist advice if the adverse effect is secondary to the drug. Discontinuation of treatment may be considered
	Constipation, abdominal pain, decreased appetite, nausea, vomiting, dyspepsia	Continue treatment, usually transient. Initial symptoms may be alleviated by concomitant food intake. Exclude other causes. Seek ADHD specialist advice if symptoms become severe. Dose reduction or discontinuation of treatment may be considered
	Insomnia	Continue treatment, usually transient. Provide sleep hygiene advice. Timing of doses may need to be adjusted with ADHD specialist advice.
	Headache, dizziness, fatigue, lethargy	Continue treatment. Exclude other causes. If severe seek ADHD specialist advice. Dose reduction or discontinuation of treatment may be considered.
	Sexual dysfunction (i.e. erectile and ejaculatory dysfunction) and dysmenorrhoea	Refer to the ADHD specialist Team. Discontinuation of treatment may be appropriate.
11. Advice to patients and carers	The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs. The patient should be advised to report any of the following signs or symptoms to their GP without delay: • Symptoms suggestive of cardiac or psychiatric (e.g. suicidal ideation, self-harming behavior) disorders, seizures. • Symptoms suggestive of liver damage e.g. abdominal pain, unexplained nausea, malaise, darkening of urine or jaundice In children, parents/patients will have been advised by the ADHD specialist to report the above signs or symptoms directly to them.	

Supporting information

12. Pregnancy and breastfeeding	Seek specialist advice for prescribing decision.
13. Specialist contact information	See appendix 2
14. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
15. References	1. Summary of product characteristics for atomoxetine Strattera® Atomoxetine-(emc) 2. NICE guidelines NG87 March 2018: Attention deficit hyperactivity disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87 3. NICE CKS for ADHD https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder 4. British National Formulary https://bnf.nice.org.uk/ 5. British National Formulary for Children https://bnfc.nice.org.uk/
16. To be read in conjunction with the following documents	• Policy for shared care (Appendix 1) • Shared care agreement (Appendix 2) • RMOC Shared Care for Medicines Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs NHSE 2019 • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care NHSE

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient, and it meets the criteria outlined in the Shared Care section of the Pan Mersey Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary document.

- Prescribing responsibility will only be transferred when the specialist and the patient's GP agree that the patient's condition is stable.
- Before prescribing responsibilities are transferred to primary care, all information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the shared care agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- To obtain patient informed consent for sharing of care between the specialist, primary care prescriber and patient. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily and must be documented in the patient's notes. Patients should be aware that shared care will not always be the best option for them. This is a mutual agreement between the specialist and primary care, which needs to be confirmed with the shared care agreement.
- To confirm the diagnosis.
- To confirm that the patient's care can be suitably maintained by primary care, following their medicine being optimised for approximately 3 months, with satisfactory investigation results.
- To initiate the medicine, prescribe, and monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Is provided with any necessary written information with regard to the individual medicine including patient information leaflets on individual drugs.
    - Provides informed consent when any medicine is prescribed for an off-label indication for any condition
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- Following the request to the patient's GP to initiate shared care; to ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place at the end of 28 days. Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
- To assess the patient regularly as necessary for the duration of therapy. The specialist will send a written summary within 14 days to the patient's primary care prescriber, confirm that ongoing treatment with the monitored medicine is appropriate and record test results on the patient-held monitoring booklet if applicable confirm the current dosage and clearly highlight any changes made both to the patient and in writing to the patient's primary care prescriber.

- The specialist team will:

  - provide training, advice, and guidance (as appropriate) for primary care prescribers if necessary to support the shared care agreement
  - provide contact details for both working and non-working hours
  - supply details for fast-track referral back to secondary/specialist care
  - provide the patient with details of their treatment, follow up appointments, monitoring requirements and, where appropriate, nurse specialist contact details

- To review the patient promptly if required by the GP.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate the failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.
- Following the addition of a new drug to an existing regime covered by a shared care agreement, the Specialist must initiate, prescribe, and monitor the new drug in accordance with the relevant shared care agreement including subsequent review and inform the GP of this. A new shared care agreement must then be initiated for the new drug.
- Prior to transfer of prescribing, the specialist will ensure that patients (and their caregivers, where appropriate) are aware of and understand their responsibilities to attend appointments and the need for continued monitoring arrangements.

Primary Care Responsibilities in Shared Care

- To prescribe within their own level of competence.
- To reply to a written request for shared care within 21 days ensuring both copies of the shared care agreement are signed if appropriate.

If agreeing to shared care, the GP is asked:

- To prescribe, manage and monitor the medicine as advised by the specialist and in line with the individual shared care framework.
- To review the patient as required by the shared care framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the shared care agreement on the patient`s clinical record. A Snomed code “268529002 Shared Care- Specialist/GP” can be used. Where applicable, keep the patient-held monitoring record up to date with the results of investigations, changes in dose and alterations in management.
- To be familiar with the individual shared care framework, have the information and knowledge to understand the therapeutic issues relating to the patient’s clinical condition and undergo any additional training if necessary.
- To report any adverse effect in the treatment of the patient to the specialist team, and via the MHRA Yellow Card Scheme https://yellowcard.mhra.gov.uk/.
- To inform the specialist of any relevant change in the patient’s circumstances.
- To seek specialist advice as appropriate.
- To meet any additional requirements as required by the individual shared care framework.
- To respond to specialist communication relating to any change or addition to the patient’s treatment or monitoring covered by the shared care agreement.
- Where community nurse involvement is required in the administration of medicines under a shared care framework, nurses should be provided with adequate information and guidance by the prescriber or the specialist. Arrangements should be made in good time for any potential problems to be resolved to ensure that patient care is not compromised

Where the GP wishes to withdraw prescribing, for example when the patient fails to attend for monitoring, they need to give the specialist team a minimum of 14 days’ notice of their need to resume responsibility for prescribing. The specialist is required to acknowledge this request within the 14-day time period.

Patient Responsibilities in Shared Care

- To provide their informed consent for sharing of their care with the specialist and primary care prescriber. Consenting parties must have sufficient, accurate, timely information in an understandable and accessible format. Consent must be given voluntarily and must be documented in the patient's notes. Supporting information is available from NICE Making decisions about your care
- To take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
- To meet all necessary monitoring arrangements to ensure the safe prescribing of their medication, and to alert the prescriber where these arrangements are not met.
- To attend all follow-up appointments with the primary care prescriber and specialist. If the patient is unable to attend any appointments, they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
- Inform healthcare professionals of their current medications, both prescribed and purchased elsewhere prior to receiving any new prescribed or over-the-counter medication.
- Report all suspected adverse reactions to medicines to their primary care prescriber.
- Store their medication securely away from children and according to the medication instructions.
- Read the information supplied by their primary care prescriber, specialist and pharmacist and contact the relevant practitioner if they do not understand any of the information given.

Appendix 2

Shared Care Request letter (Specialist to Primary Care Prescriber)

Request by specialist clinician for the patient's GP to enter into a shared care agreement

To be signed by consultant / prescribing member of specialist team (circle or underline as appropriate)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*

Date of birth: *[insert date of birth]*

NHS Number: *[insert NHS Number]*

Diagnosis: *[insert diagnosis]*

Please add patient addressograph here

As per the agreed Pan Mersey APC shared care framework for *[insert medicine name and dose]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The risks and benefits of treatment have been explained to the patient	Yes / No
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	Yes / No
A copy of the shared care framework which covers this treatment/the shared care framework can be found here (*insert electronic/ web link*)	Yes / No
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you have provided supporting information to the patient, please insert a copy here

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency].*

If you are in agreement, please undertake monitoring and treatment from *[insert date*] NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Frequency of blood test: .....

I confirm that if this is a shared care agreement for a drug indication which is unlicensed or off label, informed consent has been received.

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Supporting information

Details of Specialist Clinicians

Name ..... Date .....

Consultant / prescribing member of specialist team (circle or underline as appropriate)

Signature .....

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a prescriber who is not the specialist, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: .....

Contact details

Telephone number: ..... Ext: .....

Address for return of documentation .....

.....

.....

Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & Frequency

I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Usual GP signature: ..... Date .....

Usual GP name: ..... (please print)

GP: Please sign and return a copy within 21 calendar days to the address above

GP Practice address/practice stamp

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: