SHARED CARE PROTOCOL - ATOMOXETINE FOR PATIENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

As well this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Provide a review:
  - to confirm the patient meets the criteria for ADHD and needs treatment
  - of the patient's mental health and social circumstances, including:
    - presence of coexisting mental health and neurodevelopmental conditions
    - current educational or employment circumstances
    - risk assessment for substance misuse and drug diversion
    - care needs
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable them to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside of their license
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required scheduled reviews, baseline investigations and monitoring (see section 8) and communicate the results to primary care.
- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.

- Explain the intention to share care for drug prescribing and monitoring to the patient and/or their carer. Explain the process and the potential timescales for this.
- Once treatment is optimised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter, detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations should be managed by the specialist.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Provide advice to the patient and/or primary care prescriber if a patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued

Primary care responsibilities

- To refer the patient for specialist advice using the ADHD referral pathway if not already known by a Dorset ADHD specialist team. Initial referral should include:
  - For Adults:
    - ❖ Adult Self-Report Scale Checklist (ASRS) to be completed by the patient prior to specialist assessment
    - ❖ Physical assessment (In accordance with the recommendations from NICE NG87) including:
      - Medical history
      - Medication history
      - Height and weight (measured and recorded against the normal range for age, height, and sex)
      - Baseline pulse and blood pressure (measured with an appropriately sized cuff and compared with the normal range for age)

- ❖ Cardiovascular assessment- Consider whether further physical testing/monitoring (such as blood tests, ECG, etc) or a cardiologist opinion is required.
- ❖ Drugs and alcohol screen
- ❖ Psychiatric history
- ❖ Previous treatment

- For Children and Adolescents: patients should be referred to either CAMHS or paediatric services.

- Acceptance of shared care is implied by nil response. Respond to the request from the specialist for shared care if further clarification or a refusal is intended. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of atomoxetine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for interactions with atomoxetine when starting new medicines (see section 7).
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop atomoxetine and make an urgent referral for appropriate care if cerebral ischaemia or new or worsening seizures occur.
- Refer the patient back to the specialist if the patient becomes or plans to become pregnant or if the clinical condition worsens or there is non-adherence to monitoring requirements
- Consider referring to the specialist if withdrawal of treatment might be indicated. This could be because the patient is well controlled and has been free of ADHD symptoms for at least one year whilst taking medication; ADHD symptoms are not evident on days when medication is forgotten or missed or there has been no need to increase the dose of medication in child or adolescent patients despite growth and weight gain over the preceding one to two years
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

Patient and/or carer responsibilities

- Take atomoxetine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping their contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend for the blood monitoring or review appointments
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Tell anyone who prescribes them a medicine that they are taking atomoxetine.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of atomoxetine with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if methylphenidate affects their ability to do so safely and inform the DVLA if their ability to drive safely is affected (see section 11).
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

Back to top

This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.
Atomoxetine is a sympathomimetic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It is an alternative treatment option in patients who cannot tolerate lisdexamfetamine or methylphenidate, or whose symptoms have not responded to separate 6-week trials of lisdexamfetamine or methylphenidate or where substance abuse/ dependence is a concern. (see NICE guidance for ADHD NG87). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural, and occupational or educational needs.

Atomoxetine is licensed for use in adults with ADHD of at least moderate severity. Adults should have ADHD symptoms pre-existing from childhood, which should ideally be confirmed by a third party.

Atomoxetine should be used as part of a comprehensive treatment programme, typically including psychological, educational, and social measures.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) or by a Paediatric Service and approaching their 18th birthday, it is expected that CAMHS or the Paediatric Service will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Overview | Transition from children's to adults' services for young people using health or social care services | Guidance | NICE should be followed.

The NICE guidance for ADHD makes a recommendation for treatment in children 5 years and over. Medicines for treating ADHD do not have a UK marketing authorisation for use in children under the age of 6 years so the use as per the NICE recommendation is off label. For children under 5 years old, an ADHD-focused group parent-training programme should be offered to parents or carers of children under 5 years with ADHD as first-line treatment. If this fails, the advice of a specialist ADHD service with expertise in managing ADHD in young children (ideally a tertiary service) should be sought.

Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. 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.

2. Indications

Back to top

- Attention deficit hyperactivity disorder (ADHD).

3. Locally agreed off-label use

Back to top

Nil identified

4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to the active substance or to any of the excipients
- During treatment with monoamine oxidase inhibitors (MAOI), or within 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Narrow angle glaucoma
- Severe cardiovascular or cerebrovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, cerebral aneurysm, or stroke
- History of phaeochromocytoma

Cautions:

- Psychiatric and neuropsychiatric symptoms or disorders, including psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, and mania
- Known serious structural cardiac abnormalities; consultation with a cardiac specialist required before treatment
- Underlying medical conditions which could be worsened by increases in blood pressure and heart rate, including hypertension, tachycardia, or cardiovascular or cerebrovascular disease
- Prolonged QT interval (congenital or acquired, e.g. drug-induced) or family history of QT prolongation
- Any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes (risk of orthostatic hypotension)

- Concomitant medications that elevate blood pressure: assess for neurological signs and symptoms at every monitoring visit
- Other conditions that may precipitate or otherwise induce cerebrovascular conditions: assess for neurological signs and symptoms at every monitoring visit
- Hepatic insufficiency: dose adjustments required, see section 5.
- History of seizures
- Susceptibility to angle-closure glaucoma
- Age over 65 years; safety and efficacy has not been systematically evaluated
- Known CYP2D6 poor metaboliser genotype. Dose reduction required, see section 5.

5. Initiation and ongoing dose regimen

Back to top

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- Additional caution (smaller initial dosing) should be considered where there are other neurodevelopmental comorbidities
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

Additional caution (smaller initial dosing) should be considered where there are other neurodevelopmental comorbidities

Adult (body-weight up to 70 kg)

Initially 500 micrograms/kg daily for 7 days, dose is increased according to response

Adult (body-weight 70 kg and above)

Initially 40 mg daily for 7 days, dose is increased according to response

Child 6–17 years (body-weight up to 70 kg)

Initially 500 micrograms/kg daily for 7 days, dose is increased according to response;

Child 6–17 years (body-weight 70 kg and above)

Initially 40 mg daily for 7 days, dose is increased according to response

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Adult (body-weight up to 70 kg)

Dose increased to maintenance 1.2 mg/kg daily, total daily dose may be given either as a single dose in the morning or in 2 divided doses with last dose no later than early evening. Higher daily doses to be given under the direction of a specialist; maximum 1.8 mg/kg per day; maximum 120 mg per day. Doses above 100 mg daily not licensed.

Adult (body-weight 70 kg and above)

Dose increased to maintenance 80–100 mg daily, total daily dose may be given either as a single dose in the morning or in 2 divided doses with last dose no later than early evening. Higher daily doses to be given under the direction of a specialist; maximum 120 mg per day. Doses above 100 mg daily not licensed.

Child 6–17 years (body-weight up to 70 kg)

Doses increased to maintenance 1.2 mg/kg daily, total daily dose may be given either as a single dose in the morning or in 2 divided doses with last dose no later than early evening. Higer daily doses to be given under the direction of a specialist; maximum 1.8 mg/kg per day; maximum 120 mg per day. Doses above 100 mg daily not licensed.

Child 6–17 years (body-weight 70 kg and above)

Doses increased to maintenance 80 mg daily, total daily dose may be given either as a single dose in the morning or in 2 divided doses with last dose no later than early evening. Higher daily doses to be given under the direction of a specialist; maximum 120 mg per day. Doses above 100 mg daily not licensed.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Hepatic insufficiency:

- moderate hepatic insufficiency (Child-Pugh Class B) reduce starting and target doses to 50% of usual (reduce dose by half, i.e. starting dose should be 20mg daily, and total daily dose should not exceed 50mg daily)
- severe hepatic insufficiency (Child-Pugh Class C) reduce starting and target doses to 25% of usual (reduce dose by three quarters, i.e. starting dose should be 10mg daily, and total daily dose should not exceed 25mg daily)

Renal insufficiency:

- No adjustment is necessary but be aware that atomoxetine may exacerbate hypertension in patients with end stage renal disease.

Known CYP2D6 poor metaboliser genotype:

- Approximately 7% of Caucasians have a genotype corresponding to a non-functional CYP2D6 enzyme (called CYP2D6 poor metabolisers). Patients with this genotype have a several fold higher exposure to atomoxetine when compared to patients with a functional enzyme. Poor metabolisers are therefore at higher risk of adverse events. For patients with a known poor metaboliser genotype, a lower starting dose and slower up titration of the dose may be considered.

6. Pharmaceutical aspects

Back to top

Route of administration:	Oral
Formulation:	Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg Atomoxetine hydrochloride 4 mg/mL oral solution
Administration details:	Atomoxetine can be taken with or without food. Capsules should not be opened and the contents inside the capsules should not be removed and taken in any other way Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste. Atomoxetine can be administered as a single daily dose in the morning. Patients who do not achieve a satisfactory clinical response (tolerability [e.g. nausea or somnolence] or efficacy) when taking Atomoxetine as a single daily dose might benefit from taking it as twice daily evenly divided doses in the morning and late afternoon or early evening

	If a dose is missed then take it as soon as possible, but no later than the early evening. Do not take more than the usual total daily dose in any 24-hour period. A double dose should not be taken to make up for a missed dose.
Other important information:	The initiating specialist will decide the formulation on an individual basis as this will depend on the needs and preferences of the patient.

7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- **MAOIs**: avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of adverse effects.
- **CYP2D6 inhibitors**: increased atomoxetine exposure. E.g. selective serotonin reuptake inhibitors (SSRIs), quinidine, terbinafine, bupropion, cinacalcet, dacomitinib, and panobinostat. Slower dose titration and lower final dose may be necessary. Clinical response and tolerability should be re-evaluated if a CYP2D6 inhibitor is started or stopped.
- **Potent inhibitors of other cytochrome P450 isoforms** in patients who are poor CYP2D6 metabolisers. It is not clear whether there is a clinically significant increase in atomoxetine exposure in this patient group.
- **Beta-2 agonists, including salbutamol**: high dose beta-2 agonists, such as salbutamol, may potentiate cardiovascular effects.
- **Drugs which prolong the QT interval**: risk of QT interval prolongation. E.g. antipsychotics, class IA and III anti arrhythmics, some antibiotics such as ciprofloxacin or erythromycin, methadone, mefloquine, tricyclic, antidepressants, lithium, and some selective serotonin reuptake inhibitors (SSRIs) such as citalopram.
- **Drugs which cause electrolyte imbalance:** risk of QT interval prolongation. E.g. thiazide diuretics.
- **Drugs which lower the seizure threshold:** risk of seizures. E.g. tricyclic antidepressants, SSRIs, antipsychotics, phenothiazines, mefloquine, chloroquine, bupropion, and tramadol. Use caution when stopping medications that may induce seizures on withdrawal, such as benzodiazepines.

- **Anti-hypertensive drugs:** effectiveness of anti-hypertensives may be decreased, monitoring is required.
- **Drugs that increase blood pressure:** possible additive effects, monitoring is required.
- **Drugs that affect noradrenaline:** possible additive or synergistic pharmacological effects. E.g. dexamfetamine, lisdexamfetamine, imipramine, venlafaxine, mirtazapine, pseudoephedrine, phenylephrine.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

Back to top

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A full assessment, as recommended by NICE guidance for ADHD. This should include a medical history and cardiovascular assessment, considering conditions that may present contraindications for atomoxetine, risk of pregnancy (where applicable) and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Appetite
- Blood pressure (BP) and heart rate
- Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:
    - history of congenital heart disease or previous cardiac surgery
    - sudden death in a first-degree relative under 40 years suggesting a cardiac disease
    - shortness of breath on exertion compared with peers
    - fainting on exertion or in response to fright or noise
    - palpitations
    - chest pain suggestive of cardiac origin
    - signs of heart failure, heart murmur or hypertension
    - current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- including development or worsening of tic and movement disorders
- Assessment of symptom improvement. Discontinue if no improvement is observed after 4-8 weeks.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate/pulse and assessment for cardiovascular signs or symptoms (exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during treatment) • Weight, height, and appetite	Every 6 months, and after any change of dose recommended by specialist team. NB: In children under 10 years measure weight every 3 months

• Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) • Explore whether patient is experiencing any difficulties with sleep	
• Assessment of adherence, and for any indication of atomoxetine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

10. Adverse effects and other management

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular Tachycardia (resting HR greater than 120bpm), arrhythmia, palpitations	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.

Hypertension- clinically significant increase in systolic BP	• Manage as per local pathways, considering risk of clinically significant interactions with several types of antihypertensive medication (see section 7). • If blood pressure is significantly raised reduce dose of atomoxetine by half and discuss with specialist for further advice.
Gastrointestinal disorders Including abdominal pain, vomiting, nausea, constipation, dyspepsia	• Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally, resolves. • Refer to specialist for advice if continues
Decreased appetite, Weight, or BMI outside healthy range, including anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • recommend small, frequent meals and/or snacks • obtaining dietary advice if required • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Psychiatric disorders New or worsening psychiatric symptoms, e.g. suicide related behaviour, psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor, or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, or depression	Stop treatment and discuss with specialist. Consider referral for urgent psychiatric assessment if suicide related behaviour, mania or psychosis are present. Discuss ongoing benefit of treatment with specialist team.

Hepatic effects Signs or symptoms of liver injury, e.g. abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine	Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team. Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist).
Nervous system disorders Somnolence or sedation	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in late afternoon or early evening). Generally, resolves. Give advice on sleep hygiene
New onset of seizures, or increased seizure frequency	If exacerbated in a young person with epilepsy or de novo seizures emerge, discontinue the drug immediately. Discuss with specialist team.

11. Advice to patients and carers

Back to top

The specialist will counsel the patient regarding the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient and/or carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections. **If an erection persists for more than 2 hours go to A&E**; this is an emergency.
- Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of **angle closure glaucoma**, seek immediate medical attention, ideally from an eye casualty unit or A&E.

- Symptoms suggestive of cardiac disease (e.g. palpitations, exertional chest pain, unexplained syncope, or dyspnoea).
- New or worsening psychiatric symptoms (e.g. psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania).
- Report **suicidal thoughts or behaviour**, and development or worsening of irritability, agitation, and depression.
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory).
- Risk of **hepatic injury**: report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistent abdominal pain.
- Symptoms of allergic or anaphylactic reactions (e.g. rash, angioedema, or urticaria).
- If they suspect they may be pregnant or are planning a pregnancy.

The patient should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Height and weight should be recorded as advised with maintenance of a growth chart as appropriate
- Keeping a sleep diary may help identify any changes in sleep patterns
- Not to drive or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, fatigue, or visual disturbances
- People who drive must inform the DVLA if their ADHD or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving.
- Not to stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- Royal College of Psychiatrists ADHD and hyperkinetic disorder for parents
- NHS – attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=atomoxetine

Patient leaflet for children: https://www.medicinesforchildren.org.uk/medicines/atomoxetine-for-adhd/

12. Pregnancy, paternal exposure, and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Atomoxetine is not recommended for use during pregnancy unless a clinical decision is made that the potential benefit outweighs the risk to the foetus.

Evidence on exposure to atomoxetine during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks, and additional monitoring should be considered on a case-by-case basis. Patients who become pregnant while taking atomoxetine, or who plan a pregnancy, should be referred to the specialist team for review.

Healthcare professional information available from: USE OF ATOMOXETINE IN PREGNANCY – UKTIS

Patient information available from: Atomoxetine

Breastfeeding:

There is no published evidence on the safety of atomoxetine in breastfeeding. Decisions to use atomoxetine while breastfeeding should be made on a case-by-case basis, considering the risks to the infant and the benefits of therapy. Long half-life in slow metabolisers increases risk of accumulation in some breastfed infants. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite or slow weight gain, sleep disturbances, gastrointestinal symptoms), although these may be difficult to detect.

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

13. Specialist contact information

Back to top

Please approach the patient's named secondary care clinician via the usual method of communication, mainly currently email or letter. Phone numbers and email available on clinic letters

14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed of any changes to the patient's GP or their contact details. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

Back to top

- eBNF. Atomoxetine. Accessed via https://bnf.nice.org.uk/drug/atomoxetine.html
- eBNF (children's) Atomoxetine | Drugs | BNFC | NICE
- Atomoxetine 10 mg Capsules, Hard - Summary of Product Characteristics (SmPC) - (emc)
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 14/04/21
- NICE NG43: Transition from children to adults' services for young people using health or social care services. Last updated February 2016. Accessed via https://www.nice.org.uk/guidance/ng43/ on 01/09/21
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Atomoxetine. Last updated January 2021. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/atomoxetine/ on 09/06/21.
- MHRA. Drug Safety Update: Atomoxetine (Strattera▼): increases in blood pressure and heart rate. January 2021. Accessed via https://www.gov.uk/drug-safety-update/atomoxetine-strattera-increases-in-blood-pressure-and-heart-rate on 09/06/21.

16. Other relevant national guidance

Back to top

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-

guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care

- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

To be agreed and completed locally

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

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]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* 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 regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*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*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*

I have included with the letter copies of the information the patient has received	*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	

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

If you agree, 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.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.

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/oraddress]*

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.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

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

NHS Number*[insert NHS Number]*

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

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which applies
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care	

	medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason, I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp