Children and Young People ADHD - Atomoxetine Shared Care Protocol		
V1.0	Last reviewed: January 2024	Review date: January 2027

NHS
Nottinghamshire Area Prescribing Committee

Atomoxetine for patients within children and young people services

Adapted from local adult ADHD shared care protocol which is based on the national adult template published by NHS England.

Traffic light classification- AMBER

The content of this shared care protocol was correct as of January 2024. 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.

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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.
- 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 the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- 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 baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, write to the patient's GP and request shared care, detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include the specialist service contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- 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.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists 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.
- 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. See section 10
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.
- Ensure the patient is given the appropriate appointments for monitoring. If a patient fails to attend, contact the patient in a timely manner and arrange an alternative appointment.

Patient and/or carer responsibilities

- Take atomoxetine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber and consider recording adverse effects by using checklist. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- 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 atomoxetine 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

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Atomoxetine is a sympathomimetic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD). Atomoxetine is a noradrenaline reuptake inhibitor, although the precise mechanism by which it works on ADHD is unknown. It is thought to increase brain levels of noradrenaline and dopamine, predominantly in the cortex rather than in sub-cortical regions.

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 (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). Unlike methylphenidate, response to atomoxetine occurs gradually over 6-8 weeks. Family needs to be advised about this and supported during this time.

Atomoxetine may be considered for children aged 6 years and over and young people if

- Neurodevelopmental disorders
- Mental health conditions
- Physical health conditions

Use in combination with methylphenidate or lisdexamfetamine is felt to be clinically appropriate.

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 children of 6 years and older, in adolescents and in adults with ADHD of at least moderate severity. Treatment must be initiated under the supervision of a specialist in childhood behaviour disorders.

Whilst NICE guidance state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate shared care protocol.

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 Community Paediatrics team but is approaching their 18th birthday, it is expected that CAMHS or Community Paediatrics team will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed. Also see the

Nottinghamshire Area Prescribing Committee shared care protocol and medication information sheets for adult ADHD at:

https://www.nottsapc.nhs.uk/shared-care/.

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

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Licensed indication: attention deficit hyperactivity disorder (ADHD) in children of 6 years and over.

Whilst NICE guidance state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate shared care protocol.

3. Locally agreed off-label use

None identified

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4. Contraindications and cautions

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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 a minimum of 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Narrow angle glaucoma. In clinical trials the use of atomoxetine was associated with an increased incidence of mydriasis.
- Severe cardiovascular or cerebrovascular disorders whose condition would be expected to deteriorate if they experienced an increase in blood pressure or heart rate that could be clinically important (e.g. 15-20mmHg or 20bpm). This could include 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

- Patients with phaeochromocytoma or a history of phaeochromocytoma

Cautions:

Particular caution is needed in the following groups of patients:

- 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
- Known CYP2D6 poor metaboliser genotype. Dose reduction required, see section 5.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 4 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- 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 unless in the case of managing adverse effects as detailed in section 10

Initial stabilisation:

- **Child from 6 years body weight up to 70 kg:** 500 micrograms/kilogram daily for at least 7 days

- **Child from 6 years body weight 70 kg or above**: 40 mg daily for at least 7 days,

Then titrated according to clinical response and tolerability. Total daily dose may be given as a single dose in the morning or in two equally divided doses, with the last dose no later than the early evening.

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

Maintenance dose (following initial stabilisation):

- **Child from 6 years body weight up to 70 kg**: up to 1.2 mg/kg daily in a single dose, or in two equally divided doses, as above.
- **Child from 6 years body weight 70 kg or above** : 80 mg in a single dose, or in two equally divided doses, as above. The usual target therapeutic dose is 1.2 mg/kg/day.

Increasing the dose of atomoxetine to 1.8mg/kg/day (max. 120mg/day) may occasionally be undertaken by a specialist in cases of poor response to medication treatment. Doses above 100mg/day are unlicensed and patients should be closely monitored for side-effects during the titration period. The safety of single doses over 120mg and total daily doses above 150 mg have not been systematically evaluated.

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

Specialist will inform GP on any subsequent doses . GPs should not alter any doses without discussing with specialist unless stopping due to side effects. See section 10.

Where a patient has been switched between medications (i.e. methylphenidate to atomoxetine or vice-versa) further monitoring may be required, as per specialist instruction

Duration of treatment

Following an adequate treatment response, medication treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually by the specialist.

Conditions requiring dose adjustment:

Hepatic insufficiency:

- moderate hepatic insufficiency (Child-Pugh Class B) reduce starting and target doses to 50% of usual ()
- severe hepatic insufficiency (Child-Pugh Class C) reduce starting and target doses to 25% of usual ()

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:

Due to several-fold increase in atomoxetine exposure, consider a lower starting dose and slower up-titration.

6. Pharmaceutical aspects

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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 Atomoxetine (Strattera®) liquid – 4mg/mL. Cost x 300mL bottle = £85.00. This is restricted to patients that are unable to swallow capsules. As the unit cost of a dose of atomoxetine (except 80mg and 100mg capsule) is approximately the same regardless of strength, twice daily dosing could double the cost of treatment with this medication.
Administration details:	Atomoxetine can be taken with or without food. Capsules should not be opened for administration: risk of ocular irritation. Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste. 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

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

- **MAOIs**: including isocarboxazid, moclobemide, phenelzine and tranylcypromine avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of hypertensive crisis.
- **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

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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, taking into account conditions that may be contraindications for atomoxetine, 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(measured and recorded against normal range for age, height and sex), and body mass index (BMI)
- Appetite
- Baseline blood pressure (BP) and heart rate (measured with appropriately sized cuff and compared with normal range for age)
- Pre-treatment assessment to be performed will include diagnostic interview, behavioural rating scales (e.g., SDQ, Conners', CAARS self and observer report) and descriptive reports from parents and teachers. LFTs may occasionally be needed to be checked prior to starting and only in children with a known history of liver disease.
- A cardiovascular assessment.
  An electrocardiogram (ECG) is not needed before starting, atomoxetine unless the person has any features below or a co- existing condition being treated with a medicine that may pose an increased cardiac risk.
- Arrange for electrocardiogram (ECG)/ echocardiogram/ refer for cardiology opinion before starting medication, only if the patient has any of the following:
  - history of congenital heart disease or previous cardiac surgery
  - History of 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 that are rapid, regular and start and stop suddenly (fleeting occasional bumps are usually ectopic and do not need investigation)
  - chest pain suggestive of cardiac origin
  - signs of heart failure or heart murmur

- current treatment with a medicine that may increase cardiac risk
- Blood pressure that is classified as hypertensive.

Refer to a paediatric hypertension specialist before starting a medication for ADHD if blood pressure is consistently above the 95th centile for age and height for children and young people. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.

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 as no standard is given in literature.
- 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 or electronic records such as System1 where available. 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.

If the child / young person fails to attend for physical monitoring, despite attempts to re-appoint, do not issue any further prescriptions, contact the patient/carer and inform the specialist. The patient should be informed of this policy when treatment begins.

9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
• Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms	At least every 6 months, before and after any change of dose recommended by specialist team**. Compare with previous measurements and with the normal range for age. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website. Most patients taking atomoxetine experience a modest increase in heart rate (mean <10bpm) and/or increase in blood pressure (mean <5mmHg). Approximately 8-12% of under 18's experience more pronounced changes in heart rate (≥20bpm) or blood pressure (≥15-20mmHg). Of these, 15-32% had sustained or progressive increases See section 10 for further guidance on management
• Weight and appetite	Following initiation: • Every 3 months in children 10 years and under. • Measure weight at 3 and 6 months after starting treatment in children over 10 years and young people and every 6

	months thereafter, or more often if concern arise. Plot on a growth chart (link: http://www.rcpch.ac.uk/growthcharts). If weight loss or reduced weight gain this should be discussed with the specialist.
• Height	Six monthly. Plot on a growth chart. If growth is affected significantly this should be discussed with the specialist
• Medication related side-effects*	At each visit
• ECG, LFTs, FBC	Not recommended unless there is a clinical indication.
• Assessment for new or worsening psychiatric and neurological signs or symptoms	At least every 6 months
• 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
*Consider using standard symptom and side effect rating scales during treatment as an adjunct to clinical assessment. ** The specialist should determine the appropriate timing for this monitoring as no standard is given in literature	

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

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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

European guidelines on managing adverse effects of medication for ADHD were published in 2011. These provide additional guidance for clinicians

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

If the child in front of you is acutely unwell, please contact the oncall general paediatric team

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 Sustained resting tachycardia, arrhythmia/palpitations, clinically significant increase in systolic blood pressure is persistently above 95 th centile for age and height.	Withhold or reduce dose and review for acute additional symptoms. If present refer to general paediatric team. If no additional symptoms inform specialist and refer to a paediatric hypertension specialist as soon as possible Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.

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.
Weight or BMI outside healthy range, including anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87. Recommend small, frequent meals and/or snacks, and high calorie foods of good nutritional value. Recommend taking atomoxetine with or after meals, and not before. Obtain dietary advice if required. Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medicine 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.	Contact specialist team and refer for psychiatric assessment if appropriate. Refer for urgent psychiatric assessment if suicide related behaviour or ideation occurs. 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	Discuss with specialist team /oncall paediatric team urgently (same day) Perform liver function tests (LFTs), including serum bilirubin, 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).

Genital/Urinary effects Erectile or ejaculatory dysfunction	Possible side-effect of atomoxetine discuss with specialist team.
Dysmenorrhoea	Possible side-effect of atomoxetine discuss with specialist team.
Urinary retention/hesitancy	Discuss with specialist team
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.
Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue atomoxetine and discuss with specialist team or oncall team immediately.
New onset of seizures, or increased seizure frequency	Discontinue atomoxetine and discuss with specialist team or oncall team immediately.
Failure to attend for physical monitoring checks	Do not issue further prescriptions, discuss as soon as possible with specialist.

11. Advice to patients and carers

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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 medicines.

The patient 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:

- Not to drive or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or fatigue, and to inform the DVLA if their ability to drive safely is affected. 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 children and young people -ADHD and hyperkinetic disorder for parents | Royal College of Psychiatrists (rcpsych.ac.uk)
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
- Medicines for children - Atomoxetine patient information leaflet
- https://www.youngminds.org.uk/
- https://youthmed.info/medicines/

12. Pregnancy, paternal exposure and breast feeding

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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 fetus.

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.

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, taking into account 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.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/atomoxetine/

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

13. Specialist contact information

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IN HOURS

Child and Adolescent Mental Health Services (CAMHS) Mansfield-Ashfield 01623-65092

Newark-Sherwood 01636-670633

Child and Adolescent Mental Health Services (CAMHS 0115 8440500

Community Paediatrics ((Queens Medical Centre NUH) 0115 840 4848.

Community Paediatrics - Mansfield, Newark, Ollerton, Ashfield excluding Hucknall) at Sherwood Forest Hospitals NHS Foundation Trust

01623-622515

Nottinghamshire Healthcare NHS Foundation Trust Pharmacy advice line (for healthcare professionals): 0300 303 5808 and email: MI@nottshc.nhs.uk

Nottingham University Hospital QMC Pharmacy Medicines Information 0115 924 9924 Extension 84185/81200

Sherwood Forest Hospitals NHS Foundation Trust Pharmacy Medicine Information 01623-672213
Wells Road Centre Pharmacy Medicine information01159-555357

Out of Hours

Contact on-call CAMHS Psychiatrist via Nottinghamshire Healthcare NHS Foundation Trust 0118440500

On call Paediatricians

Nottinghamshire South (Nottingham University Hospital QMC) 0115-8831181
Nottinghamshire North (Sherwood Forest Hospitals NHS Foundation Trust) 01623-622515.

Other local NHS specialists may request shared care including local mental health teams and intellectual disability teams. The contact details for these teams will be detailed on the shared care request letter.

14. Additional information

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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 in writing of any changes to the patient's GP or their contact details.

15. References

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- Graham J et al. European guidelines on managing adverse effects of medication for ADHD. Eur Child Adolesc Psychiatry (2011), 20:17-37. On-line at European guidelines on managing adverse effects of medication for ADHD - PMC (nih.gov)
- Nottinghamshire Area Prescribing Committee. September 2020. Blood pressure and heart rate monitoring in children. Information Sheet for Primary Care Prescribers. Available from https://www.nottsapc.nhs.uk/media/1627/bp_and_hr_monitoring_for_children.pdf. Last accessed on 07/02/2023

16. Other relevant national guidance

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- 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

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

- Prescribing and monitoring responsibility will only be transferred when the patient's condition and medication are stable.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patients' management including prescribing reverts to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.