Frimley Health and Care

NHS Frimley

For use in Surrey Heath & North East Hants & Farnham

AMBER shared care protocol: December 2024 – review after 3 years

Atomoxetine

To treat symptoms of ADHD in children aged 6 and over where the primary care provider is participating in the Locally Commissioned Service (LCS) for ADHD

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this 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 provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient 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.
- Transfer to primary care is normally after the patient has been treated at the maintenance dose for 2 months and with satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication (one month's supply) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. Check product details for pack sizes as most products manufactured in boxes of 28 dose units.
- Once treatment is optimised, complete the shared care documentation and send a request to prescribe to patient's GP practice detailing the diagnosis, current and ongoing dose, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact information (section 13).
- 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 the patient becomes or wishes to become pregnant.

- Reassume prescribing responsibilities if the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued. Trial discontinuations can be supported by the specialist.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If 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.
- Assess for possible interactions with atomoxetine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop atomoxetine and make an urgent referral to the specialist if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (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.

Patient and/or carer responsibilities

- Not to drive, use other modes of transport that require a high level of alertness eg bicycle, scooter, operate machines or undertake skilled tasks if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances
- Take atomoxetine as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist.
- Tell anyone who prescribes them a medicine that they are taking atomoxetine.

- Attend regularly for monitoring and review appointments with primary care and specialist. Failure to attend appointments may result in cessation of treatment and review of ongoing provision of care, with a possibility of discharge from the service.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their GP and be aware they should discuss the use of atomoxetine with their pharmacist before purchasing any OTC medicines.

  People 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). 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). 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 and adolescents aged 6 years and over with ADHD of at least moderate severity.

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) but is approaching their 18th birthday, it is expected that CAMHS 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.

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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- Attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate

3. Locally agreed off-label use

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The Surrey Heartlands Integrated Care System Area Prescribing Committee and Frimley ICB Medicines Board recommend the use of this document for the indications as outlined above.

The following information should be provided in correspondence to support prescribing in line with this shared care.

- Dosing specific to the indication
- Relevant interaction information
- Any additional monitoring requirements over and above the shared care.
- Duration of treatment
- Frequency of review.
- Specific features of adverse effects or deterioration pertinent to the specific indication for which it is used

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 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

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- 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.
- 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:

Recommended starting dose in ADHD:

Child 6–17 years (body-weight up to 70 kg)
Initially 500 micrograms/kg daily for 7 days.
Child 6–17 years (body-weight 70 kg and above)
Initially 40 mg daily for 7 days.

The stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

The dose of atomoxetine should be titrated to response, usually at weekly intervals.

Child 6–17 years (body-weight up to 70 kg)
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, high daily doses to be given under the direction of a specialist.
Child 6–17 years (body-weight 70 kg and above)
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, high daily doses to be given under the direction of a specialist.

Maximum dose in ADHD in children

Child 6–17 years (body-weight up to 70 kg)
Usual maximum 1.8 mg/kg per day; maximum 120 mg per day.
Child 6–17 years (body-weight 70 kg and above)
Maximum 120 mg per day.
consult BNF and SPC.

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:

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

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. This should be undertaken and supervised by the specialist who will advise the patient, their family or carer, and GP of the outcome.

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
Administration details:	Atomoxetine can be taken with or without food. Capsules should not be opened for administration: risk of 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**: 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

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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.

Pre-treatment: (Specialist Clinician)

- A medical history and full cardiovascular assessment,
- Pulse, BP
- Weight, Height, (use centiles in children), Appetite
- Psychiatric symptoms

- ECG (if history of congenital heart disease or previous cardiac surgery, sudden death in a first-degree relative under 40 years suggesting a cardiac disease, family history of CVD or arrhythmia, 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: (Specialist Clinician)

- Assess heart rate and blood pressure after every change of dose
- Weight and height (using centiles)
- Assessment for new or worsening psychiatric symptoms following every change of dose including development or worsening of tic and movement disorders
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and 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

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

Monitoring and actions	Frequency
Maintenance: • Weight • Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms • Height and weight using centiles and appetite • Assessment for new or worsening psychiatric and neurological signs or symptoms	Every 6 months *Specialist Clinician until Primary Care Prescriber has agreed to take on prescribing. At this point the GP is requested to carry out the 6-monthly review and the specialist clinician will carry out the annual review* NICE: measure weight 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 concerns arise

• Assessment for any indication of abuse, misuse, or diversion • In people of child-bearing potential, assess whether there is a risk of pregnancy. Consider pregnancy testing where appropriate	
• Review of ADHD medication, including preferences of the patient, their family or carer, benefits, adverse effects, and ongoing clinical need. Consider trial period off medication	Annually *Specialist Clinician* *Note: Do not offer routine blood tests (including liver function tests) or ECGs to people taking medication for ADHD unless there is a clinical indication.*
If dose change when on maintenance: • Pulse, BP • Weight, Height, (use centiles), Appetite • Psychiatric symptoms	*Specialist clinician*
(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

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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

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	Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation

	Hypertension	Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see section 7). If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice
Weight or BMI	outside healthy range, including anorexia or weight loss	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.
Gastrointestinal	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.
Hepatic effects	**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).
Psychiatric disorders	New or worsening psychiatric symptoms, e.g. suicide related	Contact specialist team and refer for psychiatric assessment if appropriate. Refer

	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	for urgent psychiatric assessment if suicide related behaviour or ideation occurs. Discuss ongoing benefit of treatment 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.
	New onset of seizures, or increased seizure frequency	Discuss with specialist team. Discontinuation of atomoxetine should be considered.

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.

- Discuss the benefits and risks of the treatment with the patient, their family or carer, and provide the appropriate counselling, to enable the patient, their family or carer, to reach an informed decision. Provide a patient information leaflet. Advise that treatment may be discharged to primary care if the person's condition is stable for a year or more, and there are no other concurrent medical conditions requiring treatment by SABP.

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 stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.

Patient information:

- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
- Choice and medication
  - https://www.choiceandmedication.org/sabp/condition/attention-deficit-hyperactivity-disorder/
    https://www.choiceandmedication.org/sabp/medication/atomoxetine/

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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Email address: neurodevworkrequests@sabp.nhs.uk (Response within 72 hours)

To contact the specialist on the following telephone number if urgent advice needed: 01372 216555

Alternative contacts

Specialist Pharmacy Services Medicines Advice - on 0300 770 8564 or via email at asksps.nhs@sps.direct (Service operates Monday to Friday 9am-5pm)

SABP Pharmacy Service - pharmacy@sabp.nhs.uk , 01483 443717

Out of hours contact details: No SABP service providing this level of care for ADHD. Consider emergency services

Families and carers can contact the specialist service on the following telephone number 01372 216555 (Monday - Friday, 9-12.30pm) or email neurodevworkrequests@sabp.nhs.uk for urgent advice and guidance related to their ADHD treatment.

A free out-of-hours phone line - 0300 222 5755 (5pm -11pm, 365 days a year) provides advice to parents and carers who are struggling with behaviours or difficulties which could be related to neurodevelopmental need, such as autism or ADHD.

In addition, advice for the young person and their family or carer can be accessed through:

https://www.mindworks-surrey.org/our-services/access-and-advice

If a patient requires additional support, which is not related to their ADHD treatment, then referral via a health, education or social care practitioner, would normally be required.

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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- eBNF. Atomoxetine. Accessed via https://bnf.nice.org.uk/drug/atomoxetine.html on 01/09/2021
- Atomoxetine hydrochloride 10 mg hard capsules (Strattera®). Date of revision of the text 26/01/2021. Accessed via https://www.medicines.org.uk/emc/product/5531
- 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's 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
- UKTIS. Use of atomoxetine in pregnancy. Last updated December 2017. Accessed via https://www.toxbase.org/poisons-index-a-z/a-products/atomoxetine-in-pregnancy/ on 26/05/2021
- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/ on 26/05/2021
- Specialist Pharmacy Service. Atomoxetine Lactation Safety Information. Last updated January 2018. Accessed via https://www.sps.nhs.uk/medicines/atomoxetine/ on 26/05/2021
- 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

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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.

See section 13 for details of advice relating to management of ADHD for an individual continuing with shared care

Where a second mental health or neurodevelopmental condition has emerged:

1. and the primary need remains related to their ADHD, and the person may need to be transferred to cohort 3 with the cessation of shared care - access SABP care via email - neurodevworkrequests@sabp.nhs.uk
2. and the primary need is NOT related to their ADHD (ie, concerns regarding emotional wellbeing or other mental health needs), please refer as usual to Access and Advice (AAT) which is available from 8am to 8pm, Monday to Friday and 9am to 12pm, Saturday. Tel.: 0300 222 5755

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]* 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 patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
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 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.

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

Specialist* signature: _____

Specialist name (PRINT): _____

Specialist qualification(s): _____
Date: _____

** A healthcare professional with training and expertise in managing ADHD. This may include a consultant, doctor, nurse or pharmacist specialising in diagnosing and managing ADHD.*

Appendix 2: 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/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 apply
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 patients 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 in order 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 in order 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 in order 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