

# Shared Care Protocol: Atomoxetine for patients within adult services

Title:	Shared Care Protocol: Atomoxetine for patients within adult services – For use in Berkshire East and Berkshire West only
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# Atomoxetine for patients within adult services in Berkshire East and Berkshire West

As well these protocols, please ensure that <u>summaries of product</u> <u>characteristics</u> (SPCs), <u>British national formulary</u> (BNF) or the <u>Medicines and Healthcare</u> <u>products Regulatory Agency</u> (MHRA) or <u>NICE</u> 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.
- 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).
- Review baseline investigations and initial monitoring (see section 8 and section 17).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment until optimised.
- Once treatment is optimised, send report to patient's GP practice 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 and 17).
- Prescribe sufficient medication to enable transfer to primary care.
- Conduct the required 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.
- Provide specialist advice if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).
- Provide advice to primary care on the management of adverse effects if required.

### **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 shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per <u>section</u> <u>5</u>, taking into any account potential drug interactions in <u>section 7</u>.
- Adjust the dose of atomoxetine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in <u>section 9</u>. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7).
- Manage adverse effects as detailed in <u>section 10</u> 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.

- Seek specialist advice if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).
- Stop treatment as appropriate (See Section 17).

### 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 use effective contraception, 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 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) 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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Licensed indication: attention deficit hyperactivity disorder (ADHD)

Nil.

## 4. Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see <u>BNF</u> & <u>SPC</u> 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 <u>section 5</u>.

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## 5. Initiation and ongoing dose regimen

- 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.

#### Initial stabilisation:

- Adults weighing 70 kg or above: 40 mg daily for at least 7 days,
- Adults weighing up to 70 kg: 500 micrograms/kilogram 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):

- Adults weighing 70 kg or above: 80 mg to 100 mg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 100 mg. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.
- Adults weighing up to 70 kg: up to 1.2 mg/kg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 1.8 mg/kg daily. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.

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

#### Conditions requiring dose adjustment:

Hepatic insufficiency:

- moderate hepatic insufficiency (<u>Child-Pugh</u> 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 (<u>Child-Pugh</u> 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.

6. Pharmaceutical aspects Back to t	
Route of administration:	Oral
Formulation:	Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg 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. <u>A double dose should not be</u> 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 <u>BNF</u> or <u>SPC</u> 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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The GP completes the following referral form <u>https://www.berkshirehealthcare.nhs.uk/media/109514410/adhd-</u> <u>clinic-shared-care-actions-form.pdf</u> (See Section 17) which includes providing baseline investigations. Review of 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 <u>NICE guidance for ADHD</u>. 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, 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
  - o sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - o shortness of breath on exertion compared with peers
  - o fainting on exertion or in response to fright or noise
  - o palpitations
  - o chest pain suggestive of cardiac origin
  - o signs of heart failure, heart murmur or hypertension
  - o current treatment with a medicine that may increase cardiac risk

#### Initial monitoring:

- Before every change of dose: assess heart rate and blood pressure.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms, including development or worsening of tic and movement disorders. The specialist should determine the appropriate timing for this monitoring.
- 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 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 <u>section 9</u> remains appropriate.

# 9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
<ul> <li>Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms</li> <li>Weight and appetite</li> <li>Assessment for new or worsening psychiatric and neurological signs or symptoms</li> </ul>	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
<ul> <li>Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD</li> </ul>	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

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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	Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP		
Hypertension	Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see <u>section 7</u> ). If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice.		
Gastrointestinal disorders	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided		

Including abdominal pain, vomiting, nausea, constipation, dyspepsia	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	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.
<b>Psychiatric disorders</b> 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	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.
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.

## 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 <a href="https://www.gov.uk/adhd-and-driving">https://www.gov.uk/adhd-and-driving</a>.

• 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. <u>https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults</u>
- NHS Attention deficit hyperactivity disorder. <u>https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/</u>

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

## **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 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.

Specialists will provide specialist advice to primary care if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).

#### 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**

- Erleigh Road Clinic: <u>Neuropsychology@berkshire.nhs.uk</u> / 0118 929 6477/6472, though this is a very small service and cannot guarantee an urgent response.
- Common Point of Entry (CPE): Berkshire Healthcare NHS Foundation Trust 2nd Floor, The Old Forge 45-47 Peach Street Wokingham RG40 1XJ Phone number 0300 365 2000 (Press option 4)
- Medicines Information Service at Prospect Park Hospital via 0118 960 5075 between 9am and 1pm on weekdays or via email: <u>medicines.information@berkshire.nhs.uk</u>

## **14. Additional information**

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

## **15. References**

- eBNF. Atomoxetine. Accessed via <u>https://bnf.nice.org.uk/drug/atomoxetine.html</u> on 01/09/2021
- Atomoxetine hydrochloride 10 mg hard capsules (Strattera®). Date of revision of the text 26/01/2021. Accessed via <a href="https://www.medicines.org.uk/emc/product/5531">https://www.medicines.org.uk/emc/product/5531</a>
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <u>https://www.nice.org.uk/guidance/ng87/</u> 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 <u>https://www.nice.org.uk/guidance/ng43/</u> on 01/09/21
- UKTIS. Use of atomoxetine in pregnancy. Last updated December 2017. Accessed via
   <u>https://www.toxbase.org/poisons-index-a-z/a-products/atomoxetine-in-pregnancy/</u> on 26/05/2021
- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via <a href="https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/">https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/</a> on 26/05/2021
- Specialist Pharmacy Service. Atomoxetine Lactation Safety Information. Last updated January 2018. Accessed via <a href="https://www.sps.nhs.uk/medicines/atomoxetine/">https://www.sps.nhs.uk/medicines/atomoxetine/</a> on 26/05/2021
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Atomoxetine. Last updated January 2021. Accessed via <u>https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/atomoxetine/</u> on 09/06/21.
- MHRA. Drug Safety Update: Atomoxetine (Strattera ▼): increases in blood pressure and heart rate. January 2021. Accessed via <u>https://www.gov.uk/drug-safety-update/atomoxetine-strattera-increases-in-blood-pressure-and-heart-rate</u> on 09/06/21.

## 16. Other relevant national guidance

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- Shared Care for Medicines Guidance A Standard Approach (RMOC). Available from <u>https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/</u>
- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from <a href="https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/">https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/</a>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <u>https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care</u>
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

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## 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.

#### To be agreed and completed locally To be agreed and completed locally

The Berkshire Healthcare Adult ADHD Service operates solely for patients of GPs who have agreed Shared Care in advance, which is part of the initial referral process. Patients cannot be accepted for medication where there is not a GP agreeing to ongoing prescribing, since this is outside the remit of the service, and would divert resources from seeing new patients. Patients can be seen for diagnosis only.

The service provides: diagnostic (re)assessment for ADHD, initiation and titration of ADHD medication and yearly\* reviews of the efficacy and necessity of ongoing ADHD treatment.

\*The Service now offer a mixed model with remote appointments and aim to review patients within 2 years. If the patient requires an earlier review, GPs may contact the Service for advice. In East Berkshire, there is a scheme for GPs to carry out structured annual ADHD reviews. Frimley ICB have provided additional training to support this.

The service does not offer an ongoing prescribing or monitoring function and cannot provide urgent mental health input.

#### Referral Process

## STEP 1: GP to send initial referral request for Diagnostic Assessment to Common Point of Entry (CPE), including patient details and brief summary of concerns.

Once a referral is received, the service will perform an initial screen and add the patients name to the waiting list for an appointment. The patient is then seen for an ADHD assessment (for diagnosis, pending medical assessment).

#### STEP 2: Secondary Care Medical ADHD Assessment

Assessment includes physical health, mental health, social circumstances (including past and present medical and psychiatric disorders or symptoms), concomitant medicines and history or risk of substance misuse.

## STEP 3: A request is sent to the patients General Practitioner to complete Shared Care Actions (SCA) Form, available at:

https://www.berkshirehealthcare.nhs.uk/media/109514410/adhd-clinic-shared-care-actions-form.pdf

Full history and details of any diagnosis or history where caution is needed for potential medication treatment, including

- Assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms
- Past and present medical and psychiatric symptoms
- Physical assessment, including cardiovascular system examination, weight, blood pressure and heart rate
- If there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on previous cardiac examination, then provide ECG details with interpretation (consult a cardiologist for clarification as needed).
- Risk assessment for substance misuse and drug diversion.
- Provide details of current medication.

#### **STEP 4: First Prescribing Appointment with Specialist**

- 1. Review SCA form from GP
- 2. Review patient in line with Section 8. NB NICE advise; 'that an ECG is not needed before starting stimulants, atomoxetine or guanfacine if cardiovascular history and examination are normal and the person is not on medicine that poses an increased cardiovascular risk.'

3. Provide the initial FP10 prescription for the medication of choice (unless the patient is already receiving prescriptions from GP).

#### STEP 5: Follow-up with Specialist

- 4. Within 4 weeks of initial prescription (and usually within first 2 weeks)
  - review efficiency of the prescribed ADHD drug
  - monitor for side effects and document any problems discussed
  - adjust dose if necessary and correspond with GP as necessary for sharing of information
  - take pulse and blood pressure
- 5. Continue prescribing until patient is stabilised
- 6. Once the patient is stable, transfer to GP care for continuation of treatment.
- 7. The patient will be invited back to the specialist for a review (unless this need is being met by a GP choosing to participate in the East Berkshire enhanced Shared Care scheme). The Service now offer a mixed model with remote appointments and aim to review patients within 2 years. If the patient requires an earlier review, GPs may contact the Service for advice. Patients who do not attend their review appointment will have their name removed from the review list and the GP will be informed.

Note: The patient will only be open to the Specialist Service for the time medicines are being initiated and at the time of the review appointment. It is not possible to keep the patient 'open' on the Adult ADHD Clinic List at other times as referrals to other services would be delayed should they become necessary.

- 8. Review progress if requested by GP change in behaviour, treatment resistance, increased sedation, etc. Notify the GP of the results of any patient reviews, including changes in prescribed dose. Ensure the patient has sufficient medication until the GP has received this information, at least 14 days.
- 9. Receive and respond to feedback from GP as appropriate, e.g. progress/status of the patient and in particular noting any dose changes/alterations/discontinuation etc. of treatment under the agreement.

#### STEP 6: General Practitioner Responsibilities – Maintenance (See Section 9)