# BNSSG Shared Care Guidance
Please complete all sections

**Section 1: Heading**

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| **Drug** | **Atomoxetine** |
| **Amber** ***three months*** | |
| **Indication** | As part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and adolescents of 5* years of age and over, where:<br>• Treatment with methylphenidate or lisdexamfetamine has been considered to be:<br>○ Inadequate (Their symptoms have not responded to separate 6-week trials of each medicine.)<br>○ Not tolerated<br>○ Contraindicated<br>○ Inappropriate (eg concerns about misappropriation of stimulants).<br>*'Atomoxetine is licensed from 6 years, off-label' use for 5 year old patients, but supported by NICE Guideline (NG87; 1.5.13) |

**Section 2: Treatment Schedule**

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| **Usual dose and frequency of administration** *(Please indicate if this is licensed or unlicensed and any relevant dosing information)* | Atomoxetine is a non-stimulant selective noradrenaline reuptake inhibitor. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or ADHD specialist non-medial prescriber.<br><br>Dose in children and young people 5 years and above:<br>Up to 70kg body weight:<br>0.5 mg / kg daily, increased after 7 days according to response to approximately 1.2 mg / kg daily ; maximum 1.8 mg / kg daily or 120 mg daily*<br>Over 70kg body weight:<br>40 mg daily, increased after 7 days according to response to 80 mg daily<br>Usual maximum dose (BNF): Children – 1.2 mg / kg daily or 120 mg daily*<br><br>* *Doses above 100mg/day are off label*<br><br>N.B. total daily dose may be given either as a single dose in the morning or in two divided doses with last dose no later than early evening. |

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| | **The initial maintenance dose must be prescribed by the initiating specialist.** |
| **Route and formulation** | Oral.<br>10mg,18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules<br>4mg/ml oral solution<br><br>Atomoxetine can be administered with or without food. |
| **Duration of treatment** | Continued for as long as it is effective. Discontinue if there is no response after 1 month of maximum tolerated dose. |

**Section 3: Monitoring**

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

**Baseline tests - where appropriate**

Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain the with the specialist clinician in secondary care, unless specific arrangements are made with the GP. Patients will be reviewed by a specialist clinician annually as a minimum.

Baseline investigations include:

- Cardiovascular status, including blood pressure, heart rate, height and weight on growth chart (see table below)
- Comprehensive history of concomitant medicines (past and present), co-morbid physical and psychiatric disorders or symptoms, and family history of sudden cardiac/unexplained death

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients.

**Subsequent tests - where appropriate** *(Please indicate who takes responsibility for taking bloods and interpreting results)*

| **Test** | **Frequency** | **Who by** | **Action/management**<br>**For paediatric patients the use of a centile chart is recommended** |
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| **Blood pressure (BP), pulse, weight, height** | Prior to medication initiation | Initiating clinician (CAMHS* or Community Paediatrics department) | To prepare for medication titration |
| **BP** | After each dose increase, every 6 months and at annual review | CAMHS or Community Paediatrics | Compare with normal range for age, if there is a clinically significant increase in blood pressure or systolic |

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| | | department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care). | blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment. |
| **Pulse** | | | Compare with normal range for age. NICE guidance suggest to investigate a resting tachycardia of > 120pbm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed. |
| **Height** | Every 6 months | | Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment. |
| **Weight** | **Children 10 years and under:**<br>3 monthly<br><br>**Children over 10 years and young people:**<br>3 and 6 months following initiation and 6 monthly thereafter<br><br>*More often if concerns arise.* | | If there is evidence of significant weight loss or nil weight gain where expected, measure BMI and discuss with patient and family/ carer as appropriate.<br><br>Strategies to manage weight loss include:<br>-Taking medication with or after food<br>-Additional meals/snacks early morning or late evening when stimulant effects have worn off<br>-Choosing high calorie foods of good nutritional value<br>-Taking a planned break from treatment or changing medication.<br><br>Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment. |
| **Assessment of adherence and monitoring for effectiveness and adverse effects including suicidal ideation or behaviour, tics, sexual dysfunction, seizures and sleep.** | After each dose adjustments, every 6 months, at annual review and as required based on the patient's needs and individual circumstances. | CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care) | 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 rationale.<br>Seek secondary care advice. With stimulant medication, this should include review of potential misuse and diversion. |

*Children and Adolescent Mental Health Service

**Section 4: Side Effects**

*Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.*

**Side effects and management**

| Side effect | Frequency | Action/management |
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| GI effects: abdominal pain, nausea and vomiting, decreased appetite, constipation, dyspepsia. | Very common/ common | Often transient. Take medication after breakfast/food; Maximise food intake at times of least appetite suppression, inc. liquid calories (smoothies etc.) Consult specialist clinic if this persists. |
| Headache, somnolence | Very common | Split dose to BD regime; take medication at night; reduce dose. |
| Dry Mouth | Very common | Sugar free sweets and water to counteract dry mouth. |
| Urinary retention/ hesitancy | Common | Split dose; reduce dose. Seek expert advice. |
| Sleep disturbances: Early wakening | Common | Split dose; change timing of medication. |
| Decreased libido/Erectile disorder | Common | Reduce dose; seek expert advice. |
| Menstrual irregularities | Common | Reduce dose; seek expert advice. |
| Hot flushes | Common | Split dose; reduce dose. |
| Rash | Common | Stop medication; seek expert advice |
| Cardiac effects: pulse and BP increase | Common | Monitor the BP, pulse, and if necessary perform an ECG. If the resting pulse is consistently >100bpm, contact the specialist team (consideration must be given to child/young person's age and what is expected for age) |
| Suicidal ideation | Uncommon | Stop medication and seek medical review/input (see section 5). |
| Development of new or worsening of tics | Rare | Reduce dose, or switch to alternative drug |

**Referral back to specialist**

Contact specialist for advice if:

- There is a query regarding medication efficacy
- Patient finds the medication intolerable for any given reason
- If there is concern about observed mental/psychological or physical side effects (e.g. depression, hepatic impairment or hypertension)
- If medication side effects persist despite intervention
- If patient is pregnant or breastfeeding

**Section 5: Other Issues**

**(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)**

*Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)*

**Issues**

Significant drug interactions of atomoxetine

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| MAOIs | Contraindicated due to risk of hypertensive crisis. |
| Caution is advised due to potential for additive pharmacological effects in co-administration of the following: | |
| Beta-2 agonists | e.g. high dose nebulised or systemically administered salbutamol. |
| Pressor agents | e.g. the decongestants pseudoephedrine or phenylephrine. |
| Noradrenaline antagonists | e.g. antidepressants such as imipramine, venlafaxine and mirtazapine. |
| CYP2D6 inhibitors | e.g. fluoxetine and paroxetine – slower titration and a lower final dosage may be necessary. |

Potential drug interactions of atomoxetine

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| QT prolonging drugs | e.g. neuroleptics, tricyclic antidepressants, lithium, erythromycin, drugs that cause electrolyte imbalance (such as thiazide diuretics) and drugs that inhibit CYP2D6. |
| Seizure threshold lowering drugs | e.g. tricyclic antidepressants or SSRIs, neuroleptics, phenothiazines or butyrophenone, mefloquine, chloroquine, buproprion or tramadol.<br>In addition, caution is advised when stopping concomitant treatment with benzodiazepines due to potential withdrawal seizures. |

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Atomoxetine use in combination with monoamine oxidase inhibitors (MAOIs). Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with a MAOI. Treatment with a MAOI should not be initiated within 2 weeks after discontinuing atomoxetine.
- Atomoxetine should not be used in patients with:
  - narrow-angle glaucoma (associated with an increased incidence of mydriasis in trials).
  - severe cardiovascular or cerebrovascular disorders (including cerebral aneurysm or stroke).
  - phaeochromocytoma or a history of phaeochromocytoma.

Cautions

- Suicide attempts and suicidal ideation have been reported - carefully monitor for the appearance or worsening of suicide related behaviour.
- Use with caution in patients with known serious structural cardiac abnormalities and in consultation with a cardiac specialist.
- A modest increase in BP and pulse is common - monitor as above. Refer for a prompt specialist cardiac evaluation if appropriate. Use with caution in patients with, or a family history of, QT prolongation.
- Incidents of psychotic or manic symptoms: e.g. hallucinations, delusional thinking, mania or agitation in patients – consider discontinuation.

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| | • Behavioural changes: Hostility (predominantly aggression, oppositional behaviour and anger) - patients should closely monitor for worsening of aggressive behaviour or emotional lability.<br>• Seizures- Introduce with caution in patients with a history of seizure, and consider discontinuation if new onset or worsening of seizures where no other cause is identified.<br>• Breastfeeding – Avoid atomoxetine during breastfeeding.<br>• Pregnancy - Avoid unless the potential benefit justifies the potential risk to the foetus.<br><br>**Dose reduction and discontinuation**<br>If the symptoms of ADHD do not improve after appropriate dosage adjustment, or serious adverse event occurs, then atomoxetine treatment must be stopped by the clinic. If paradoxical aggravation of symptoms occurs, the dosage should be reduced or discontinued. |
| **Reminder to ask patient about specific problems** | Ask about emergence of any possible side effects/compliance to treatment issues. Ask about suicidal ideation. |

**Section 6: Advice to the patient**

Advice for prescribing clinician to inform patient:

**The patient and/or family/carer should be advised:**

1. Not to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Atomoxetine.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the AWP team or GP.
3. Failure to attend annual reviews could result in the medication being stopped.
4. They can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Where they can find information on the medicine prescribed, including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found here:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Medicines for Children leaflet: Atomoxetine for ADHD
Atomoxetine Patient Information Leaflet

**Section 7: Generic principles of shared care for SECONDARY CARE**

*Please do not amend.*

**Core responsibilities**

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (i.e. within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood

test is due.
6. To provide advice to primary care when appropriate including queries about medication efficacy and side effects.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

**Section 8: Generic principles of shared care for PRIMARY CARE**

*Please do not amend.*

**Core responsibilities**

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

**Section 9: Contact Details**

| Name | Organisation | Telephone Number | E mail address |
|---|---|---|---|
| Initiating Clinician | AWP/Sirona | As provided on correspondence | As provided on correspondence |
| Sarah Steel<br>Highly Specialised Clinical Pharmacist | AWP | 01249 474542 | Sarah.steel6@nhs.net |

**Section 10: Document Details**

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| Date prepared | 28th April 2023 |
| Prepared by | Sarah Steel |
| Date approved by JFG | October 2023 |
| Date of review | October 2026 |
| Document Identification: Version | V2 |

**Section 11: Collaboration**

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel highly specialised clinical pharmacist AWP
2. Samantha Hayer CAMHS consultant AWP
3. Alfred Perrera CAMHS consultant AWP
4. Richard Williams consultant paediatrician Sirona care & health
5. Richard Lee-Kelland, consultant community paediatrician Sirona care & health – from June 2023

**Section 12: References**

Please list references


1. NICE Guideline [NG87]. Attention Deficit Hyperactivity Disorder: diagnosis and management. Updated 13.09.2019. Accessed Feb 2023.
2. SPC Atomoxetine. Updated 08.12.2020. https://www.medicines.org.uk/emc/product/10507/smpc. Accessed Feb 2023.
3. BNF Online. Atomoxetine. Updated September 2022. Accessed Feb 2023.
4. Cortese S, *et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open*. Accessed May 2023.