Northumberland, Tyne and Wear NHS Foundation Trust

NHS Sunderland Clinical Commissioning Group

**SHARED CARE GUIDELINE**

Atomoxetine in the treatment of Attention Deficit Hyperactivity Disorder in Children, Young People and Adults

**Implementation Date: June 2017**

**Review Date: June 2019**

**This guidance has been prepared and approved for use within Sunderland in consultation within the CCG, Secondary Care Trusts and Local Medical Committees.**

**The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting**

**Approved by:**

| Committee | Date |
|---|---|
| **Sunderland Joint Formulary** | **June 2017** |
| **Sunderland CCG Medicines Guidelines Group** | **June 2017** |

Licensed indications: Atomoxetine is a highly selective and potent inhibitor of pre-synaptic noradrenaline. It is used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) following a comprehensive assessment and diagnosis, and is licensed (amber) for use in children of 6 years, adolescents and adults. It is not a controlled drug.

| **SHARED CARE GUIDELINE** | | | |
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| Non-proprietary name | **Atomoxetine** | | |
| Dosage forms and strengths | Available as 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules | BNF class | 4.4 |

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| **Indication** | Atomoxetine is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD |
| **Eligibility criteria for shared care** | Children over 6 years of age and adults who have been assessed by a specialist and have a diagnosis of ADHD |
| **Excluded patients** | Children under 6 years of age |
| **Dosage and Administration** | **See BNF, BNFC and NICE ADHD CG 72 Clinical Guideline 2008**<br><br>Total 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, with or without food. Unlike other treatments for ADHD, atomoxetine should be taken every day without "drug holidays". |

| Body Weight | Recommended initiation dose & dosage titrations | Recommended maintenance dose |
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| **Child 6 – 17 years and adults up to 70kg** | Usually 0.5mg/kg/day, titrate upwards if necessary, in 7 day intervals | Usually 1.2 mg/kg/day (max. 1.8mg/kg/ day or 120mg per day) |
| **Child 6 - 17 years 70kg and over** | Usually 40mg/day, titrate upwards if necessary, in 7 day intervals | Usually 80 mg/day (max 120mg/day) |
| **Adults 70kg and over** | Initially 40 mg daily, titrate upwards if necessary, in 7 day intervals | maintenance 80–100 mg daily day (max 120mg/day) |

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| **Specialist Responsibilities** | **Pre-Treatment** - Diagnose the condition and assess suitability for treatment with atomoxetine (as per the pre-drug assessment in NICE guidance)<br>Conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate.<br>Document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death<br>Usually this information will be available to the specialist, if not; the specialist will work in collaboration with the GP. Only prescribe or ask the GP to prescribe if this information is available.<br>Request an ECG if there is a past medical or family history of serious cardiac disease or abnormal findings on cardiac examination - symptoms suggestive of heart disease should prompt specialist cardiac evaluation Routine blood tests are not recommended unless clinically indicated.<br>Carry out a pre-drug treatment assessment, including<br>• a full mental health + social assessment, substance misuse/drug diversion risk assessment<br>• baseline weight and height (children only), heart rate and blood pressure (centile charts for children)<br>• request GP to undertake any necessary further investigations.<br>Provide patient/carer with relevant information on use, side effects and need for monitoring of medication - document this is in the medical notes.<br><br>Initiate treatment and titrate to a therapeutic dose then supply a further month's treatment to give time for shared care to be arranged. The specialist should supply treatment for at least 3 months before asking GP to accept shared care.<br>In some circumstances it may be more appropriate for the GP to prescribe atomoxetine on the advice of a specialist during the initiation and titration phase. This must be done on a case by case basis by prior arrangement and all the necessary information for the GP to do this safely must be provided by the specialist.<br><br>Both the Specialist and the GP must agree to the shared care - contact the GP to seek formal agreement providing the GP with relevant information including:<br>• Treatment to be undertaken by GP (including any dose changes etc.)<br>• System of monitoring and recording of progress and side effects<br>**Monitoring – condition** - Assess response to treatment and the need to continue therapy by reviewing the patient at regularly as per specialist review schedule.<br>**Monitoring side-effects** - Appetite, height (children only) & weight: 6 monthly<br>• BP & heart rate: at least 6 monthly as per specialist's review schedule and with each dose change (record on growth/centile charts for children) Symptoms suggestive of heart disease should prompt specialist cardiac evaluation<br>Assess - development/worsening of tics, psychotic symptoms, anxiety, aggression + seizures<br>• Re-evaluate the usefulness of atomoxetine at least yearly<br>• Advise discontinuation if no improvement after a reasonable trial<br>• Review treatment regularly, sending a written summary to the GP at each review.<br>• Provide any other advice or information for the GP if required<br>• Communicate treatment changes in writing to the GP as soon as possible<br>• Supervise treatment discontinuation, or onward referral to adult service if appropriate.<br>• Liaise with the GP if any other additional tests/monitoring is required.<br>• Monitor and liaise with the GP regarding any adverse effects, which occur during treatment, including reporting of all serious adverse drug reactions to the MHRA.<br>• Notify the GP of failed attendance |
| **GP Responsibilities** | • Prescribe atomoxetine following specialist recommendations ensuring prescriptions are issued for a maximum of one month treatment, in line with good practice guidance for CDs<br>• Provide the specialist with relevant medical history and background information.<br>• Notify the specialist of any family/social circumstances which may preclude treatment (including current/past use of illicit drugs) If the patient misuses substances e.g. cocaine, heroin or amphetamines, transfer care back to the specialist<br>• To contact the specialist if concerned about any aspects of the patient's treatment. Report significant deviations from the prescribing pattern to the specialist<br>• Monitor and record the therapy in accordance with written directions of specialist<br>• Report any adverse events to the specialist, and the usual bodies. (E.g. MHRA) |

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| **Adverse Effects, Precautions and Contraindications** | **Contraindications** - Phaeochromocytoma; severe cardiovascular disease; severe cerebrovascular disease<br>**Special warnings and precautions for use** - QT-interval prolongation; aggressive behaviour; cardiovascular disease; cerebrovascular disease; emotional lability; history of seizures; hostility; hypertension; mania; psychosis; structural cardiac abnormalities; susceptibility to angle-closure glaucoma; tachycardia<br>**Adverse Effects**<br>**Common or very common -** Abdominal pain; anorexia; anxiety; chills; constipation; depression; dermatitis; dizziness; drowsiness; dry mouth; dyspepsia; flatulence; flushing; headache; increased blood pressure; irritability; lethargy; malaise; mydriasis; nausea; palpitation; paraesthesia; prostatitis; rash; sexual dysfunction; sleep disturbances; sweating; tachycardia; taste disturbances; tremor; urinary dysfunction; vomiting<br>**Uncommon -** Aggression; cold extremities; emotional lability; hostility; hypoaesthesia; menstrual disturbances; muscle spasms; pruritus; psychosis; QT-interval prolongation; suicidal ideation; syncope; tics<br>**Rare -** Raynaud's phenomenon; seizures<br>**Very rare -** Angle-closure glaucoma; hepatic disorders |
| **Common Drug Interactions** | Avoid concomitant use of drugs that prolong QT interval<br>**The following drugs may interact with atomoxetine and increase the risk of ventricular arrhythmias:**<br>Amiodarone, TCADs, antipsychotics which prolong the QT interval, disopyramide, diuretics, parenteral erythromycin, mefloquine, moxifloxacin, methadone and sotalol.<br>**The following drugs may interact with atomoxetine and increase the risk of convulsions –** antidepressants, bupropion and tramadol.<br>Paroxetine and fluoxetine reduce metabolism of atomoxetine<br>Atomoxetine and parenteral salbutamol increase the risk of cardiovascular side effects.<br>MAOI – there should be a two week gap between MAOI and atomoxetine treatment<br>• Concurrent use of atomoxetine and methylphenidate does not cause increased side effects of either drug. There is no interaction between atomoxetine and alcohol |
| **Communication/ Contact Details** | For any queries relating to this patient's treatment with atomoxetine please contact the specialist named below:<br>**Newcastle + Gateshead CYPS** **Benton House** **0191 2466913**<br>**Sunderland + South Tyneside CYPS** **Monkwearmouth Hospital** **0191 5665500**<br>**NTW Adult ADHD Team (all areas)** **Keegan Court** **0191 2876250** |

**This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF**

**Private and Confidential**

## Shared Care Request/Confirmation – Atomoxetine for ADHD

- Consultant to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 day

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| **Specialist Prescriber** …… | **Patient details (use hospital label if preferred)** |
| **Department** …… | **Name** …… |
| …… | **Address** …… |
| **Hospital** | …… |
| …… | |
| **Telephone** …… | **Postcode** ..... **M/F** ……... |
| | **NHS or Hosp. Reg. No.** …… **DoB** ……... |

**Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement**

**Drug Name – Atomoxetine** **Dose ……** **Frequency……**
**Indication – ADHD**
**Other info (if appropriate)** **……**

**Signed**
**(Specialist Prescriber)…… Name (print)……Date…….**

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**To be completed by GP**

Please tick one box

**I ACCEPT the proposed shared care arrangement for this patient** ❑

or

**I ACCEPT the proposed shared care arrangement with the caveats below** ❑

or

**I DO NOT ACCEPT the proposed shared care arrangement for this patient** ❑

My caveats / reason(s) for not accepting include:

……..

……..

**Signed** …… **Name (print)** ..... **Date** ……
**(Patients GP)**

**N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP**