

## **GATESHEAD SHARED CARE GUIDELINE**

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

**Implementation Date: April 2015  
Review Date: April 2017**

This guidance has been prepared and approved for use within, Gateshead 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 these treatments within a shared care setting

**Approved by:**

<b>Committee</b>	<b>Date</b>
Gateshead Medicines Management Committee	11 <sup>th</sup> March 2015
Newcastle Gateshead CCG Optimisation of Medicines, Pathways and Guidelines Committee	16 <sup>th</sup> April 2015

**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 for use in children of 6 years and older and in adolescents. It is licensed in adults if used to continue treatment for patients progressing into adulthood.

SHARED CARE GUIDELINE			
Non-proprietary name	<b>Atomoxetine</b>	Brand Name	Strattera®
Dosage form and strength	Available as 10mg, 18mg, 25mg, 40mg, 60mg or 80mg capsules. It is not a controlled drug.	BNF class	4.4
<b>Indication</b>			
Atomoxetine is a CNS stimulant drug used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). It should only be initiated following assessment and diagnosis by a specialist with expertise in ADHD, as part of a comprehensive treatment plan.			
<b>Dosage and Administration</b>			
<b>See BNF, BNFC and NICE ADHD TG 72 Clinical Guideline 2008</b>			
Total dose may be given <i>either</i> as a single dose in the morning <i>or</i> 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”.			
	<b>Body Weight</b>	<b>Recommended initiation dose &amp; dosage titrations</b>	<b>Recommended maintenance dose</b>
	< 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)
	>70kg	Usually 40mg/day, titrate upwards if necessary, in 7 day intervals	Usually 80 mg/day (max 100mg/day)
<b>Eligibility criteria for shared care</b>			
Children over 6 years of age and adults who have been assessed by a specialist and have a diagnosis of ADHD			
<b>Excluded patients</b>			
Children under 6 years of age			
<b>Initiation</b>			
The patient is initiated on treatment, titrated to a therapeutic dose then supplied with a further month’s treatment by the specialist to give time for shared care to be arranged.			
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.			
Both the Specialist and the GP must agree to the shared care arrangement.			
<b>Specialist Responsibilities</b>			
<b>Pre-Treatment</b> - Diagnose the condition and assess suitability for treatment with atomoxetine (as per the pre-drug assessment in NICE guidance)			
Review the patient’s relevant medical history and physical examination including:			
<ul style="list-style-type: none"> <li>• history of exercise syncope or undue breathlessness</li> <li>• family history of serious cardiac disease</li> <li>• assessment of the cardiovascular system.</li> </ul>			
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			

	<p>information is available.</p> <p><b>Request an ECG if there 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</b></p> <p>Carry out a pre-drug treatment assessment, including</p> <ul style="list-style-type: none"> <li>• a full mental health and social assessment,</li> <li>• baseline weight and height, heart rate and blood pressure</li> <li>• request GP to undertake any necessary further investigations.</li> </ul> <p>Provide patient/carer with relevant information on use, side effects and need for monitoring of medication. Counsel patients regarding recognition of symptoms of hepatic damage or suicidal ideation and the need to promptly report these - document this in the medical notes.</p> <p>Ensure that patient is informed that the use of atomoxetine in adults is an unlicensed indication unless it was started in childhood/adolescence with a corresponding entry in the medical notes.</p> <p><b>Contact the GP to seek formal agreement for the shared care.</b></p> <p>Provide the GP with relevant information including:</p> <ul style="list-style-type: none"> <li>• Treatment to be undertaken by GP (dose, any dosage titrations etc.)</li> <li>• System of monitoring and recording of progress and side effects</li> </ul> <p><b>Monitoring</b> - condition: Assess response to treatment and the need to continue therapy by reviewing the patient at regularly as per specialist review schedule.</p> <p>Monitoring side-effects:</p> <ul style="list-style-type: none"> <li>• Appetite, height (not applicable for adults) &amp; weight: Every 6 months</li> <li>• BP &amp; pulse: Approximately every 3 months as per specialist’s review schedule and with each dose change. Symptoms suggestive of heart disease should prompt specialist cardiac evaluation</li> <li>• Assess for development of: seizures, psychotic symptoms, anxiety, or suicidal thinking and self-harm</li> <li>• In young people and adults assess for dysmenorrhoea, erectile dysfunction or ejaculatory dysfunction if appropriate</li> </ul> <p>Advise discontinuation if no improvement after a reasonable trial</p> <p>Review treatment regularly, sending a written summary to the GP at each review.</p> <p>Provide any other advice or information for the GP if required</p> <p>Ensure changes to treatment are communicated in writing to the GP as soon as possible (Sending information via fax is not acceptable in Northumberland)</p> <p>Supervise treatment discontinuation, or onward referral to adult service if appropriate.</p> <p>Liaise with the GP if any other additional tests/monitoring is required.</p> <p>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.</p> <p>Notify the GP of failed attendance</p>
<p><b>GP Responsibilities</b></p>	<ul style="list-style-type: none"> <li>• Prescribe atomoxetine following recommendations of the specialist.</li> <li>• Provide the specialist with relevant medical history and background information.</li> <li>• Check/act upon any results communicated by the specialist and act upon requests for additional monitoring as agreed with the specialist.</li> <li>• Routine blood tests are not recommended unless there is a clinical indication. A full blood count <b>should</b> be considered immediately if a patient has prolonged or severe infection in order to exclude blood dyscrasia (very rarely reported). All of the relevant results should be copied to the specialist.</li> <li>• To contact the specialist if concerned about any aspects of the patient’s treatment.</li> <li>• Report significant deviations from the prescribing pattern to the specialist</li> <li>• Monitor and record the therapy in accordance with written directions of specialist</li> </ul>

	<ul style="list-style-type: none"> <li>Report any adverse events to the specialist, and the usual bodies. (Eg MHRA).</li> </ul>
<b>Adverse Effects, Precautions and Contraindications</b>	<p><b>Atomoxetine is contra-indicated in:</b></p> <ul style="list-style-type: none"> <li>Patients on MAOIs (or within 2 weeks after discontinuing therapy with a MAOI)</li> <li>Patients with narrow angle glaucoma.</li> </ul> <p><b>Increase in pulse and BP:</b> Patients may experience a modest increase in pulse (mean &lt;10 bpm) and/or increase in blood pressure (mean &lt;5 mmHg). In most cases these are not clinically important. Due to potential for additive pharmacological effects, caution is advised in patients with hypertension, tachycardia, cardiovascular or cerebrovascular disease.</p> <p><b>GI Disturbance:</b> Treatment may be associated with transient gastrointestinal side-effects of abdominal pain, vomiting, decreased appetite, constipation, dyspepsia and nausea. There is a rare risk of hepatic disorder.</p> <p><b>Other side-effects</b> include dry mouth, urinary retention or hesitancy, insomnia, early wakening, somnolence, irritability, dizziness, fatigue, headache, decreased libido, erectile or ejaculatory disorder, dysmenorrhoea or menstrual irregularities, palpitations, hot flushes and rash. Suicidal ideation is a rare side-effect which has been reported.</p>
<b>Common Drug Interactions</b>	<ul style="list-style-type: none"> <li>MAOIs</li> <li>Due to potential for additive pharmacological effects, caution is advised in patients on concomitant treatment with: <ul style="list-style-type: none"> <li>High dose nebulised or systemically administered salbutamol (or other beta2 agonists)</li> <li>Pressor agents (eg. the decongestants pseudoephedrine or phenylephrine)</li> <li>Drugs that affect noradrenaline (eg. antidepressants such as imipramine, venlafaxine and mirtazapine)</li> <li>Drugs which inhibit CYP2D6 isoenzyme (eg. fluoxetine, paroxetine) – slower titration may be necessary.</li> </ul> </li> <li>Concurrent use of atomoxetine and methylphenidate does not cause increased side effects of either drug. There is no interaction between atomoxetine and alcohol.</li> </ul>
<b>Communication/Contact Details</b>	For any queries relating to this patient's treatment with atomoxetine please contact the specialist named below.

**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**

<b>CONTACTS FOR FURTHER INFORMATION</b>		
<b>MON – FRI, 09:00 – 17:00:</b>		
<b>Specialist Teams</b>		
<b>Newcastle Sunderland and Gateshead</b>	<b>Benton House Monkwearmouth Hospital</b>	<b>0191 2466913 0191-5665500</b>

**Private and Confidential**

**Shared Care Request/Confirmation**

- 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

<p><b>Consultant</b> .....</p> <p><b>Department</b> .....</p> <p><b>Hospital</b> .....</p>	<p><b>Patient details (use hospital label if preferred)</b></p> <p><b>Name</b> .....</p> <p><b>Address</b> .....</p> <p>.....</p> <p><b>Postcode</b> .....      <b>Sex</b> .....</p> <p><b>NHS or Hosp. Reg. No.</b> .....      <b>DoB</b> .....</p>
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**Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement**

<b>Drug Name</b>	<b>Dose</b>	<b>Frequency</b>
<b>Indication</b>		
Other Information (if appropriate)		

<b>Signed (Specialist Prescriber)</b>	<b>Name (print)</b>	<b>Date</b>
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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**