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Coventry & Warwickshire Area Prescribing Committee

Shared Care Agreement

Atomoxetine: *for the treatment of children of 6 years of age and older with attention deficit/ hyperactivity disorder (ADHD)*

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE: This shared care agreement (SCA) outlines suggested ways in which the responsibilities for managing the prescribing of **Atomoxetine** can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so.

In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Specialist Responsibilities

1. Discuss the benefits, side effects, intended outcomes and possible drug interactions of treatment with the patient (and parent/guardian), including: Medicines and Healthcare products Regulatory Agency (MHRA) warnings (see cautions overleaf), that prompt medical attention (A/E) should be sought in case of abdominal pain, unexplained nausea, malaise, darkening of the urine, or jaundice, suicidal thoughts or behaviour. Patients (and parent/guardian) should also be advised to report clinical worsening, irritability, agitation, or depression to the specialist.
2. Initiate and stabilise treatment with atomoxetine as part of a care package (see licensed indications).
3. Ask the GP whether he or she is willing to participate in shared care by emailing the shared care request letter, (continue to prescribe until GP has agreed to take over prescribing).
4. Communicate to the GP re-established regimen, follow up arrangements and when to refer back.
5. Monitor treatment, including growth and development, as stated overleaf.
6. To obtain school and parental/carer's reports to assist with the assessment of the patient's progress.
7. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition.
8. To provide guidance to teachers regarding treatment with parental consent.
9. Notify GP of review date (at least annually), and give advice on stopping treatment.
10. Ensure that clear backup arrangements exist for GPs to obtain advice and support

Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard and to the GP and appropriate Medicines Optimisation team. *(If in CWPT via the Clinical Governance Pharmacist - see Medicines Policy section and associated guidance 20)*.

General Practitioner Responsibilities

1. Reply to the request for shared care as soon as practicable, preferably within 5 working days, by emailing back the shared care letter. If declining the request please indicate the reason for declining.
2. Prescribe the atomoxetine at the dose recommended, from the agreed date.
3. Adjust the dose as advised by the specialist.
4. Review patient annually between consultant appointments.
5. Monitor treatment as stated overleaf.
6. Report to and seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
7. Refer back to specialist if the patient's condition deteriorates, or if there are concerns over patient compliance.
8. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.

Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard and to the specialist and appropriate Medicines Optimisation team.

Patient/carer's Role

1. Attend all appointments with GP and specialist.
2. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3. Share any concerns in relation to treatment with atmoxetine.
5. Seek prompt medical attention (A and E) in case of abdominal pain, unexplained nausea, malaise, darkening of the urine, or jaundice; suicidal thoughts or behaviour.
6. Report clinical worsening, irritability, agitation or depression to the specialist.
7. Inform specialist or GP of any other medication being taken, including over-the-counter products.
8. Inform specialist if any changes in symptoms or behaviour occur.
9. Report any adverse effects or warning symptoms to the specialist or GP.

The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card, available at pharmacies, GP surgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours).
The form can also be downloaded from www.mhra.gov.uk/yellowcard

SUPPORTING INFORMATION:

Indications:	Licensed for the treatment of 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. Atomoxetine use should not be considered as first line (see NICE guideline NG87 for recommended pharmacological treatment options).
Dose and Administration:	Atomoxetine is normally given as a single dose in the morning. Patients who do not achieve a satisfactory clinical response (tolerability [e.g., nausea or somnolence] or efficacy) when taking atomoxetine as a single daily dose might benefit from taking it as twice daily evenly divided doses in the morning and late afternoon or early evening. In some cases it might be appropriate to continue treatment into adulthood. Consideration should be given to dose reduction or interrupting therapy in patients who are not growing or gaining weight satisfactorily. In cases of significant adverse effects, atomoxetine may be stopped abruptly; otherwise the drug may be tapered off over a suitable time period. Dosing up to 70 kg Body Weight: Initiate at a total daily dose of approximately 0.5mg/kg. This dose should be maintained for a minimum of 7 days before upward dose titration according to clinical response and tolerability. The recommended maintenance dose is approximately 1.2mg/kg/day (depending on the patient's weight and available dosage strengths of atomoxetine). No additional benefit has been demonstrated for doses higher than 1.2mg/kg/day. Dosing over 70 kg Body Weight: Initiate at a total daily dose of 40 mg. This dose should be maintained for a minimum of 7 days before upward dose titration according to clinical response and tolerability. The recommended maintenance dose is 80 mg. No additional benefit has been demonstrated for doses higher than 80 mg. The maximum recommended total daily dose is 100 mg. *Renal insufficiency:* Atomoxetine can be administered to ADHD patients with end-stage renal disease or lesser degrees of renal insufficiency using the usual dosing regimen. Atomoxetine may exacerbate hypertension in patients with end-stage renal disease. *Hepatic insufficiency:* For patients with moderate hepatic insufficiency (Child-Pugh Class B), initial and target doses should be reduced to 50% of the usual dose. For patients with severe hepatic insufficiency (Child-Pugh Class C), initial dose and target doses should be reduced to 25% of usual dose. *Metabolic Insufficiency:* Patients with the genotype corresponding to a non functional CYP2D6 enzyme (CYP2D6 poor metabolisers) have a several-fold higher exposure to atomoxetine when compared to patients with a functional enzyme and are therefore at higher risk of adverse events. A lower starting dose and slower up titration of the dose may be considered.
Monitoring:	*Specialist:* Baseline (and after dose change) annual – Evaluation of cardiovascular function (including blood pressure, pulse), weight and height; also any adverse effect on cognition or sexual maturation during long term therapy; for appearance or worsening of anxiety symptoms, depressed mood and depression, suicide related behaviour or tics. *GP:* annual (inbetween Specialist appointments) – Evaluation of cardiovascular function (including blood pressure, pulse), weight and height; for appearance or worsening of anxiety symptoms, depressed mood and depression, suicide related behaviour or tics.(A guide to expected diastolic and systolic blood pressures for children and adolescents can be found in the Journal of Hypertension 2009, 27:1719-1742, or Arch Dis Child 2007; 92:298-303).
Contra-indications:	Hypersensitivity to the active substance or to any of the excipients. Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOI), or within 2 weeks of discontinuing MAOI. Treatment with MAOI should not be initiated within 2 weeks after discontinuing atomoxetine. Atomoxetine should not be used in patients with narrow-angle glaucoma. Atomoxetine should not be used in patients with severe cardiovascular conditions (these may include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies or cerebrovascular disorders (these may include cerebral aneurysm or stroke). Atomoxetine should not be used in patients with pheochromocytoma or a history of this.
Cautions:	Monitor carefully for the appearance or worsening of suicide-related behaviour. Patients who are being considered for treatment should have a careful history and physical exam to assess for the presence of cardiac disease, and should receive further specialist cardiac evaluation if initial findings suggest such history/disease. Atomoxetine should only be used with caution in patients with known serious structural cardiac abnormalities in consultation with a cardiac specialist. Use with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure and heart rate, e.g. patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease. Patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other symptoms suggestive of cardiac disease during atomoxetine treatment should undergo a prompt specialist cardiac evaluation. Use with caution in patients with congenital or acquired long QT or a family history of QT prolongation or in any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate/blood pressure changes. Patients with additional risk factors for cerebrovascular conditions (e.g. history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed at every visit for neurological signs and symptoms. Very rarely, spontaneous reports of liver injury (manifested by elevated hepatic enzymes and bilirubin with jaundice) and very rarely, severe liver injury (including acute liver failure) have been reported. Discontinue atomoxetine in patients with jaundice or laboratory evidence of liver injury, and do not restart. Treatment-emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, mania or agitation in patients without a prior history of psychotic illness or mania can be caused by atomoxetine at usual doses; If these occur, consider discontinuation of treatment. Atomoxetine may cause the exacerbation of pre-existing psychotic or manic symptoms. Monitor closely for the appearance or worsening of aggressive behaviour, hostility or emotional lability, anxiety symptoms, depressed mood, depression or tics. Atomoxetine should be introduced with caution in patients with a history of seizures. Discontinuation of atomoxetine should be considered if seizures occur or if there is an increase in seizure frequency where no other cause is identified. Consideration should be given to dose reduction or interrupting therapy in children and adolescents who are not growing or gaining weight satisfactorily. Clinical data do not suggest a deleterious effect of atomoxetine on cognition or sexual maturation; however long-term data is limited. Therefore, patients requiring long-term therapy should be carefully monitored. Although uncommon, allergic reactions, including anaphylactic reactions, rash, angioneurotic oedema, and urticaria, have been reported.

Side effects:	Refer to Summary of Product Characteristics (SPC) for full list – see references. *Very common:* decreased appetite, headache, somnolence, abdominal pain, vomiting, nausea, blood pressure increased, increased heart rate. *Common:* anorexia (loss of appetite), irritability, mood swings, insomnia, agitation, anxiety, depression and depressed mood , tics, dizziness, mydriasis, constipation, dyspepsia, dermatitis, pruritis, rash, fatigue, lethargy, chest pain, decreased weight. Uncommon: suicide-related events, aggression, hostility, emotional lability, psychosis (including hallucinations), syncope, tremor, migraine, paraesthesia, hypoaesthesia, seizure , blurred vision, palpitations, sinus tachycardia, QT interval prolongation, dyspnoea, blood bilirubin increased, hyperhydrosis, allergic reactions, asthenia. *Rare:* Raynaud's phenomenon, abnormal/increased liver function tests, jaundice, hepatitis, liver injury, acute hepatic failure, urinary hesitation, urinary retention, priapism, male genital pain Atomoxetine does not have black triangle (▼) status. All serious suspected adverse reactions (even well recognised or causal link uncertain) should be reported to the MHRA.
Drug interactions:	*(see also above under cautions):* Atomoxetine should not be used with MAOIs (see contra-indications).Slower titration and final lower dosage of atomoxetine may be necessary in patients who are already taking CYP2D6 inhibitor drugs e.g. fluoxetine, paroxetine, quinidine, terbinafine. If a CYP2D6 inhibitor is prescribed/discontinued after stabilisation of atomoxetine dose, adjustment of dose may be required to ensure efficacy/tolerability. Caution when combining atomoxetine with potent inhibitors of cytochrome P450 enzymes other than CYP2D6 in patients who are poor CYP2D6 metabolisers (risk of clinically relevant increases in atomoxetine exposure in vivo is unknown). Atomoxetine should be administered with caution to patients treated with high dose nebulised/systemically administered salbutamol (or other beta2 agonists) because cardiovascular effects can be potentiated. Increased risk of QT interval prolongation when atomoxetine is administered with other QT prolonging drugs (e.g. antipsychotics, class IA and III anti-arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants, lithium, or cisapride), those that cause electrolyte imbalance (such as thiazide diuretics), and those that inhibit CYP2D6.Caution is advised with concomitant use of medicines known to lower the seizure threshold (e.g. tricyclic antidepressants, SSRIs, neuroleptics, phenothiazines or butyrophenone, mefloquine, chloroquine, bupropion or tramadol); caution is advised when stopping concomitant treatment with benzodiazepines (potential withdrawal seizures). Atomoxetine may decrease the effectiveness of anti-hypertensive drugs. Attention should be paid to monitoring of blood pressure and review of treatment of atomoxetine or anti-hypertensive drugs may be justified in the case of significant changes of blood pressure; use cautiously with pressor agents or medications that may increase blood pressure. Drugs that affect noradrenaline should be used cautiously when co-administered with atomoxetine because of the potential for additive or synergistic pharmacological effects e.g. antidepressants, such as imipramine, venlafaxine, and mirtazapine, or the decongestants pseudoephedrine or phenylephrine.
Cost:	At current prices one year's treatment will cost £884 for 80 mg once daily (Drug Tariff December 2019)
Back-up advice and support:	See shared care request letter at the end of this agreement, and patient clinical summary letter for contact details of clinician(s) initiating and stabilising patient prior to request for shared care.

References:

1. SPC Strattera. www.medicines.org.uk accessed 17/12/19
2. https://www.gov.uk/drug-safety-update/atomoxetine-strattera-increases-in-blood-pressure-and-heart-rate#further-information
3. https://bnfc.nice.org.uk/drug/atomoxetine.html#indicationsAndDoses accessed 24/12/19
4. NICE Guideline NG87. Attention deficit hyperactivity disorder: diagnosis and management March 2018 www.nice.org.uk/guidance/ng87

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Shared Care Drug Information	
Date:	
Patient name:	
NHS number:	
Drug:	

Provider Trust Logo here

Dear Dr

Request to continue prescribing of a shared care drug

I have started this patient on the above drug that has been deemed as appropriate for shared care by the Coventry and Warwickshire Area Prescribing Committee (APC).

The last prescription for a month's supply was issued on_____. The dose is_____ _____*(include strength and frequency).*

I would be grateful if you could consider participating in shared care. I am sending you a copy of the shared care agreement *(previous pages to this document)* locally approved by the APC.

If you are agreeable, please could you complete the section below and return it to me by email as soon as possible but at the latest within 5 working days. If you wish to discuss this with me, please contact me via my secretary. *(see telephone below).*

On receipt of your agreement to participate, I will write to the patient to inform them that they will be able to order the medication from your surgery. That letter will be used as the written request for the medication. It states that patients DO NOT need to make an appointment to see their GP to request the medication.

Yours sincerely,

Specialist name: _____

Telephone number: _____

NHS.net Email Address: _____

For completion by GP: (complete section below and send back to the Specialist within 5 working days)						
I agree to prescribe *(tick as appropriate)*	**Yes**		**No**		**I would like to discuss further:**	
Reasons if "No"						
Prescriber name:						
Signature:						