Effective Shared Care Agreement (ESCA)

Atomoxetine (from age 6 years)

Approved for Solihull locality only.

ESCA: For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of atomoxetine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are 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.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary.
2. Specialist assessment and confirmation of the diagnosis of attention deficit/hyperactivity disorder.
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
5. Do baseline monitoring prior to initiation of this agent: • weight, blood pressure, pulse and essential medical history, cardiovascular examination and ECG where indicated. • full mental health and social assessment, full history and physical examination, family history of cardiac disease and an ECG if there is past medical and/or family history of cardiac or cerebrovascular problems. • risk assessment for substance misuse and potential for drug diversion.
6. Initiate treatment and stabilise dose of atomoxetine
7. Advise the patient on the importance of good adherence with the prescribed medication. Check adherence at each clinic appointment.
8. Review the patient's condition and response to treatment every 6 months. Advise patients, families/ carers to report any side effects and/ or concerns. At 6 monthly reviews (unless otherwise indicated): • Monitor efficacy of long term treatment and consider whether benefit can be gained from continued treatment. • Monitor height, weight, appetite, heart rate and BP and any psychiatric symptoms. • Request any further investigations that are clinically indicated such as ECG, blood investigations. • Assess progress with regards to psychological, behavioural, educational and occupational needs. • Assess ongoing need for medication. • Assess any side effects.
9. Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
10. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
11. Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.
12. Advise GP on the management of side effects and raise awareness at which point these will be reviewed and/ or managed by the specialist.
13. Advise the GP when to stop treatment and on management of discontinuation if necessary.
14. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
15. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days						
2. Ensure: • Patient/ family are clear who will be responsible for monitoring and what this will entail. • Patient/ family are aware of any significant adverse effects/ events, which should be urgently reported and who these should be reported to. (GP/ specialist)						
3. Prescribe atomoxetine at the dose recommended.						
4. Adjust the dose as advised by the specialist.						
5. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
6. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist.						
7. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment						
8. Refer back to specialist if condition deteriorates.						
9. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.						
10. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
11. Stop treatment on advice of specialist.						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment.
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with atomoxetine with the specialist, clinical nurse specialist or GP.
4. Report any adverse effects to the specialist or GP whilst taking atomoxetine.
5. Attend regular outpatient appointments with the specialist.
6. Female patient: Inform the specialist, clinical nurse specialist or GP if she becomes or wishes to become pregnant.

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Indication	Atomoxetine is licensed for the treatment of attention deficit/hyperactivity disorder in children of at least 6 years of age and adolescents, as part of a comprehensive treatment programme. Atomoxetine is licensed for the treatment of adults with attention deficit/hyperactivity disorder, provided that the patient was symptomatic before the age of 18. The prescription of atomoxetine for the first time after the age of 18 is 'off-label'. NICE recommends drug treatment as first-line in adults with ADHD with either moderate or severe levels of impairment (see NICE Clinical Guideline 72).	
Dosage and Administration	Dosing of paediatric population up to 70 kg Body Weight:	Atomoxetine should be initiated at a total daily dose of approximately 0.5mg/kg. The initial dose should be maintained for a minimum of 7 days prior to 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. The safety of single doses over 1.8mg/kg/day and total daily doses above 1.8 mg/kg have not been systematically evaluated. In some cases it might be appropriate to continue treatment into adulthood.
	Dosing of paediatric population over 70 kg Body Weight:	Atomoxetine should be initiated at a total daily dose of 40 mg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. The recommended maintenance dose is 80mg. No additional benefit has been demonstrated for doses higher than 80 mg. The maximum recommended total daily dose is 100 mg. The safety of single doses over 120mg and total daily doses above 150mg have not been systematically evaluated.
	Adults:	Atomoxetine should be initiated at a total daily dose of 40 mg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. The recommended maintenance daily dose is 80mg to 100mg. The maximum recommended total daily dose is 100 mg. The safety of single doses over 120mg and total daily doses above 150mg have not been systematically evaluated.
	Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary.	
Renal Impairment	No adjustment required	
Hepatic impairment	Mild	No adjustment required
	Moderate	Reduce dose to 50% of standard dose
	Severe	Reduce dose to 25% of standard dose
Contra-indications / Special precautions Please refer to SPC for full list- link under references.	Hypersensitivity to atomoxetine or to any of the excipients. Atomoxetine is contraindicated for use in patients with narrow angle glaucoma and should be used with caution in patients with hypertension, tachycardia or cardiovascular disease and hepatic disorders. Atomoxetine should be used with caution in patients with congenital or acquired long QT interval or a family history of QT prolongation. Seizures are a potential risk. Atomoxetine should be used with caution in patients with a history of seizure. Discontinuation should be considered where seizures develop or there is an increase in seizure frequency. Suicide-related behaviour (suicide attempts and suicidal ideation) has been reported in patients treated with atomoxetine. Patients who are being treated for ADHD should be carefully monitored for the appearance or worsening of suicide-related behaviour. Hepatic disorders – following rare reports of hepatic disorders, patients and carers should be advised of the risk and be told how to recognise symptoms; prompt medical attention should be sought in case of abdominal pain, unexplained nausea, malaise, darkening of the urine or jaundice.	
Side Effects	Very common	Decreased appetite, nausea, dry mouth, insomnia
	Common	Weight loss, abdominal pain, constipation, irritability, mood swings, increased heart rate and small increases in blood pressure

Monitoring	Pre-treatment assessment	Height and weight, heart rate, blood pressure. Full blood count and ECG: If clinically indicated. LFT: If clinically indicated.	
	After commencing treatment	Height and weight, heart rate, blood pressure 6 monthly. Suicidal behaviour/ ideation, self-harm/ hostility: ongoing basis. Side effect monitoring: Ongoing basis including sexual dysfunction. Full blood count and ECG: If clinically indicated. LFT: If clinically indicated.	
	Actions to be taken:		
	Liver toxicity, abnormal LFTs, jaundice, hepatitis	Discontinue and refer back to specialist team.	
	Suicidal thoughts or behaviour	Refer back to specialist team.	
Drug Interactions (significant interaction as outlined in BNF, please see BNF and SPC for more detail)	• Atomoxetine should not be used with MAOIs and there must be a minimum of two weeks in between taking the medications. • There is the potential for an increased risk of QT interval prolongation when atomoxetine is administered with other QT prolonging drugs, drugs that cause electrolyte imbalance and drugs which inhibit CYP2D6. • Seizures are a potential risk with atomoxetine. Caution is advised with concomitant use of medicinal drugs which are known to lower the seizure threshold. • Caution with concomitant use of antihypertensive agents and with high dose bronchodilators. • Medicines that affect noradrenaline should be used cautiously with atomoxetine because of the potential for additive pharmacological effect.		

References

1) NICE TA98 - Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents
2) NICE CG72 - Attention deficit hyperactivity disorder: diagnosis and management
3) SmPC Atomoxetine (Strattera)
4) BNF

Appendix 1:

Effective Shared Care Agreement (ESCA)

Atomoxetine (from age 6 years)

Approved for Solihull CCG only.

For the treatment of in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Transitioning patients Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary	Adult service consultant to tick and sign please

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with atomoxetine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care