Pending CCG approval

NHS
Pan Mersey
Area Prescribing Committee

SHARED CARE FRAMEWORK FOR CHILDREN

The Pan Mersey Area Prescribing Committee recommends the prescribing of ATOMOXETINE for ADHD in children under the care of Alder Hey Children's Hospital and Wirral University Teaching Hospitals Foundation Trust in accordance with NICE NG87.

SHARED CARE

Background

Attention deficit hyperactivity disorder (ADHD) is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness.

The National Institute for Health and Clinical Excellence (NICE) issued a clinical guideline, Attention Deficit Hyperactivity Disorder: diagnosis and management (NG87) in 2018. This document advises that treatment for ADHD should only be initiated by a healthcare professional with expertise in ADHD and should be based on a comprehensive assessment and diagnosis. Continued prescribing and monitoring of drug therapy may be performed by the primary care clinicians, under shared care arrangements.

NICE NG87 states: Offer atomoxetine to children aged 5 years and over and young people if they cannot tolerate methylphenidate or lisdexamfetamine or their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses.

Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist or psychiatrist.

Mode of action

Atomoxetine is an inhibitor of the pre-synaptic noradrenaline transporter. It is not a psychostimulant and is not an amphetamine derivative.

Licensed Indications

Atomoxetine is indicated for the treatment 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, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist.

Locally agreed off-label use

Children aged 5-6 years.

Initiation and ongoing dose regime

Careful dose titration is necessary at the start of treatment and should always be carried out under the supervision of the specialist.

Transfer of prescribing to Primary Care is after the dose has been stabilised and the patient has been reviewed by the specialist. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

Dosing information

All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.

Dosage should be individualised according to the therapeutic needs and response of the patient.

Children and adolescents weighing up to 70 kg body weight:

The initial total daily dose of approximately 0.5 mg/kg should be initiated. The dose should be titrated after 7 days, if necessary up to a maximum of 1.8mg/kg/day, either as a single dose or in two divided doses, according to clinical response and tolerability.

Children and adolescents weighing over 70 kg body weight:

A total daily dose of 40 mg should be initiated. The dose should be titrated after 7 days according to response and tolerability to a usual maintenance dose of 80 mg/day. The maximum recommended total daily dose is 100mg.

A single daily dose can be given; however, two divided doses may be prescribed to minimise side effects.

The dose should be titrated against symptoms and adverse effects in line with the BNF or BNF for Children until dose optimisation is achieved, that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects[2].

Dose reduction may be required in patients with different degrees of hepatic impairment – refer to SPC

Doses may need to be adjusted as a child grows. This does not indicate that the child is no longer stable but is facilitating the mg/kg daily dose schedule.

Ongoing prescribing

Shared Care may only be commenced following initiation, stabilisation and review of treatment. In addition, formal agreement must have been received from the primary care prescriber. Termination will be the responsibility of the specialist.

Review the use of atomoxetine at least once a year and discuss with the patient (and their families and carers as appropriate) whether medication should be continued. (NICE NG87).

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. (NICE NG87)

Baseline investigations and initial monitoring to be undertaken by the specialist

Baseline: - Pre-treatment screening

Before starting medication for ADHD, a full assessment should be completed which should include:

- a review to confirm they continue to meet the criteria for ADHD and need treatment

- a review of mental health and social circumstances, including:
    - presence of coexisting mental health and neurodevelopmental conditions
    - current educational or employment circumstances
    - risk assessment for substance misuse and drug diversion
    - care needs
- a review of physical health, including:
    - a medical history, taking into account conditions that may be contraindications for specific medicines
    - current medication
    - height and weight (measured and recorded against the normal range for age, height and sex)
    - baseline pulse and blood pressure
    - A cardiovascular assessment.

An electrocardiogram (ECG) is not needed before starting atomoxetine, unless the person has any of the features mentioned in recommendation 1.7.5 of the NICE 2018 Attention deficit hyperactivity disorder diagnosis and management guidelines or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.

Refer to a paediatric hypertension specialist before starting medication for ADHD if blood pressure is consistently above the 95th centile for age and height for children and young people.

Ongoing monitoring requirements to be undertaken by secondary care

Monitoring	Frequency
Blood pressure and pulse appropriate for age, using information supplied in attached request letter.	At every adjustment of dose or visit and then every 6 months
Height and weight	At 3 months then at every adjustment of dose or visit or at least every 6 months Weight every 3 months in children 10 years and under
Side Effects	Every 6 months
Compliance	Every 6 months
Clinical need, benefits, side effects	Annual review

Cardiovascular monitoring (blood pressure and heartrate) should be undertaken before and after each dose adjustment.

Secondary care will provide primary care with all monitoring results after each clinic appointment and date of next appointment.

Responsibility of primary care

- If in agreement with the shared care - prescribe atomoxetine according to specialist's instructions
- Record on clinical system results of monitoring completed by specialist after each clinic appointment.

Pharmaceutical aspects

Route of administration

Oral

Formulation

Hard capsules in 10mg, 18mg, 25mg, 40mg, 60mg, 80mg or 100mg

Oral solution 4 mg/mL

It is more cost effective to prescribe the exact strength of atomoxetine instead of combining different strengths for an increased dose.

Administration details

Capsules or liquid should be taken with or without food.

It is not recommended to mix oral solution in food or water as it can prevent the patient receiving a full dose or could negatively affect the taste.

Other important information

- No distinct withdrawal symptoms have been reported.
- In cases of significant adverse effects, atomoxetine may be stopped abruptly; otherwise the drug may be tapered off over a suitable time period.
- Atomoxetine may exacerbate hypertension in patients with end-stage renal disease.

Legal category

Atomoxetine is a prescription only medicine (POM). It is not a controlled drug.

Contraindications

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Significant drug interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Adverse effects and management

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Parents/patients will have been advised by the ADHD specialist to report any suspected side effects directly to them. GPs should refer any patients with suspected side effects to the ADHD specialist immediately.

WARNINGS: Atomoxetine has been associated with increased rates of fatigue, somnolence, and dizziness in pediatric and adult patients. Patients should be advised caution when driving a car, cycling or operating hazardous machinery until they are reasonably certain that their performance is not affected by atomoxetine.

Any serious reaction to atomoxetine should be reported to the MHRA via the "Yellow Card" scheme on http://yellowcard.mhra.gov.uk/

Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs.

Patients/parents/carers should be advised to report any of the following signs or symptoms to their ADHD specialist without delay:

- Symptoms suggestive of cardiac or psychiatric (e.g. suicidal ideation, self-harming behavior) disorders, seizures.
- Symptoms suggestive of liver damage e.g. abdominal pain, unexplained nausea, malaise, darkening of urine or jaundice

Pregnancy and breast feeding

Seek specialist advice for prescribing decision.

Specialist contact information

See appendix 2.

Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.

References

1. Summary of product characteristics for atomoxetine Strattera® Atomoxetine- (emc)
2. NICE guidelines NG87 March 2018: Attention deficit hyperactivity disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87
3. NICE CKS for ADHD https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder
4. British National Formulary https://bnf.nice.org.uk/
5. British National Formulary for Children https://bnfc.nice.org.uk/

To be read in conjunction with the following documents.

1. Policy for Shared Care
2. Shared care agreement.

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient and it meets the criteria outlined in the Shared Care section of the Pan Mersey Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary document.

Before prescribing responsibilities are transferred to primary care:

- Prescribing responsibility will only be transferred when the consultant and the patient's GP agree that the patient's condition is stable.
- All information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the Shared Care Agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- To initiate the medicine, prescribe, monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Provide any necessary written information to the patient with regard to the individual medicine including patient information leaflets on individual drugs.
    - Obtain and document informed consent from the patient when any medicines is prescribed for an off-label indication for any condition
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- To assess the patient regularly as necessary for the duration of therapy.
- To review the patient promptly if required by the GP concerned.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.

Primary Care Responsibilities in Shared Care

- To reply to a written request for Shared Care within 21 days ensuring both copies of the Shared Care Agreement are signed if appropriate.

If agreeing to shared care, the GP is asked to:

- To provide prescribe or manage and monitor the medicine as advised by the Specialist and in line with the individual Shared Care Framework.
- To review the patient as required by the Shared Care Framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the Shared Care Agreement on the patient`s clinical record. A READ code of “6652 Shared Care-Specialist/GP” can be used.
- To be familiar with the individual Shared Care Framework.
- To report any adverse effects of treatment to the specialist team.
- To inform the Specialist of any relevant change in the patient’s circumstances.
- To seek Specialist advice as appropriate.
- To meet any additional requirements as required by the individual Shared Care Framework.
- To respond to Specialist communication relating to any change or addition to the patients treatment covered by the Shared Care Agreement.

Appendix 2

Shared Care Agreement

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

Part 1

To be signed by Consultant / Prescribing member of the Specialist Team

Date _____

Name of patient_____

Address _____

_____

Patient NHS No _____

Patient hospital unit No _____

Diagnosed condition _____

Please add patient addressograph here if using.

Dear Dr_____

I request that you prescribe ATOMOXETINE

for the above patient in accordance with the enclosed shared care framework.

Last Prescription Issued: ..... / ..... / ..... Next Supply Due: ..... / ..... / .....

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care Framework and Policy.

I confirm that if this is a Shared Care Agreement for a drug indication which is unlicensed or off label, informed consent has been received.

Details of Specialist Clinicians

Name _____Date_____

Consultant / Prescribing member of the Specialist Team *circle or underline as appropriate

Signature _____

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a prescriber who is not the consultant, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: _____

Contact details:

Telephone number: _____Ext:_____

Address for return _____

of documentation _____

Shared Care Framework

Please add patient addressograph here

Part 2

To be completed by Primary Care Clinician

I agree to prescribe _____for the above patient in accordance with the enclosed shared care framework.

GP signature _____Date _____

GP name _____Please print

GP: Please sign and return a copy within 21 calendar days to the address above

OR

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: