Somerset NHS Foundation Trust

Somerset Clinical Commissioning Group

# *Somerset Healthcare Community Shared Care Protocol*
# *Attention Deficit Hyperactivity Disorder (ADHD)*
# ***Atomoxetine***
# ***Dexamfetamine***
# ***Lisdexamfetamine***
# ***Methylphenidate***

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*This shared care protocol (SCP) sets out details for the sharing of care for patients prescribed any of the following drugs for ADHD – atomoxetine, dexamfetamine, lisdexamfetamine or methylphenidate. It should be read in conjunction with the latest Summary of Products Characteristics (SPC) available for each drug at http://www.medicines.org.uk/emc/*

*As outlined in NHS England Guidance 2018 (07573), 'Responsibility for Prescribing Between Primary & Secondary/Tertiary Care': When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.*

*This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they 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. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.*

*N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 2 weeks of receipt of a request to share care: https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/*

**Introduction**
This shared care guideline sets out details to support the transfer of responsibility for prescribing any of the above drugs to treat ADHD, from specialist to primary care.

It is intended to apply to children, over the age of 6 years and adolescents, who have been initiated and stabilised on any of the drugs by a specialist experienced in the treatment of ADHD as part of a comprehensive treatment programme. It also applies to adults with ADHD who have been transferred from CAMHs or adults with a diagnosis of ADHD that was established in childhood who have been continued, initiated and stabilised on any of the drugs by a specialist experienced in the treatment of ADHD.

**For further information please click on the links below or visit;** British National Formulary
http://www.medicines.org.uk/emc/

**Licensed Indications** The treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older and in adolescents as part of a comprehensive treatment programme.

Methylphenidate will be first line therapy in either the immediate release or sustained release formulation depending upon patient acceptability and concordance.

Dexamfetamine, Lisdexamfetamine and Atomoxetine will be second line alternatives when response to previous methylphenidate treatment is considered clinically inadequate.

**Dose (posology & method of administration): see individual SPCs at** http://www.medicines.org.uk/emc/

N.B. CCG and SomPar preferred brands of Modified release methylphenidate with a 10-12 hour duration of action are Xenidate® XL tablets, Matoride® XL tablets and Xaggitin XL tablets.

**Contra-indications see individual SPCs at**:
http://www.medicines.org.uk/emc/

**Special warnings and precautions for use**:
http://www.medicines.org.uk/emc/

**Atomoxetine:**

**MHRA Drug safety advice March 2009** (click for details)
Atomoxetine is associated with treatment-emergent psychotic or manic symptoms in children and adolescents without a history of such disorders.

**MHRA Drug safety advice May 2012** ( click for details)
Atomoxetine causes clinically important increases in blood pressure or heart rate, or both, in a small proportion of patients. It should not be used in patients with pre-existing severe cardiovascular or cerebrovascular disorders such as severe hypertension; heart failure; inherited heart conditions or disease; heart attack or stroke; cardiomyopathy; or cerebral aneurysm.

**Methylphenidate:**
Reminder for healthcare professionals to support safer use of methylphenidate (click for details)
The product information for prescribers of methylphenidate has been updated with guidance to support safer use:

- Treatment with methylphenidate should be supervised by a specialist in childhood or adolescent behavioural disorders.
- Diagnosis should be made according to the criteria in DSM-5 - (Diagnostic and statistical Manual of Mental Disorders, 5th edition) or ICD-10 (International Classification of Diseases 10th revision) guideline, and should be based on a complete history and evaluation and not solely on the presence of one or more symptom(s).
- Children and adolescents should have rigorous pretreatment screening, including a complete history and relevant examination (including psychiatric disorders or symptoms, cardiovascular status, height, and weight)
- Patients should be monitored regularly during methylphenidate treatment, including: blood pressure and pulse; height, weight, and appetite; onset or worsening of psychiatric symptoms (such as depression, suicidal thoughts, hostility, anxiety, agitation, psychosis, or mania); and symptoms suggestive of heart disease (which should prompt specialist cardiac evaluation)
- Treatment should be interrupted at least yearly to determine whether continuation is needed

**Driving and skilled tasks**

Prescribers and other healthcare professionals should advise patients if treatment is likely to affect their ability to perform skilled tasks (e.g. driving). This applies especially to drugs with sedative effects; patients should be warned that these effects are increased by alcohol. General information about a patient's fitness to drive is available from the Driver and Vehicle Licensing Agency at www.dvla.gov.uk. 2015 legislation regarding driving whilst taking certain drugs including amfetamines may also apply to methylphenidate, see *Drugs and driving* under Guidance on prescribing

**Drug interactions:** see individual SPCs at http://www.medicines.org.uk/emc/

**Pregnancy and lactation:** see individual SPCs at: http://www.medicines.org.uk/emc/

Supplementary sources for lactation at Lactmed: https://www.ncbi.nlm.nih.gov/books/NBK501922/

**Adverse effects**: see individual SPCs at http://www.medicines.org.uk/emc/

## Shared Care Responsibilities

A diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD, on the basis of:

- a full clinical and psychosocial assessment of the person; this should include discussion about behaviour and symptoms in the different domains and settings of the person's everyday life **and**
- a full developmental and psychiatric history **and**
- observer reports and assessment of the person's mental state.

A diagnosis of ADHD should not be made solely on the basis of rating scale or observational data. However, rating scales such as the Conners' rating scales and the Strengths and Difficulties Questionnaire are valuable adjuncts, and observations (for example, at school) are useful when there is doubt about symptoms.

**For a diagnosis of ADHD, symptoms of hyperactivity/impulsivity and/or inattention should:**

- meet the diagnostic criteria in DSM-5 or ICD-10 (hyperkinetic disorder) **and**
- cause at least moderate psychological, social and/or educational or occupational impairment based on interview and/or direct observation in multiple settings **and**
- be pervasive, occurring in 2 or more important settings including social, familial, educational and/or occupational settings.

  As part of the diagnostic process, include an assessment of the person's needs, coexisting conditions, social, familial and educational or occupational circumstances and physical health. For children and young people, there should also be an assessment of their parents' or carers' mental health.

- ADHD should be considered in all age groups, with symptom criteria adjusted for age-appropriate changes in behaviour.
- In determining the clinical significance of impairment resulting from the symptoms of ADHD in children and young people, their views should be taken into account wherever possible.

- Discuss the potential benefits and adverse effects of pharmacological and non-pharmacological treatments

Before starting medication for ADHD, people with ADHD should have a full assessment, 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 (measured with an appropriately sized cuff and compared with the normal range for age)
  - a cardiovascular assessment.

Consider arranging an ECG and requesting a cardiology opinion before starting medication for ADHD if any of the following apply:

- history of congenital heart disease or previous cardiac surgery
- history of sudden death in a first-degree relative under 40 years suggesting a cardiac disease
- shortness of breath on exertion compared with peers
- fainting on exertion or in response to fright or noise
- palpitations that are rapid, regular and start and stop suddenly (fleeting occasional bumps are usually ectopic and do not need investigation)
- chest pain suggesting cardiac origin
- signs of heart failure
- a murmur heard on cardiac examination
- blood pressure that is classified as hypertensive for adults (see NICE's guideline on hypertension in adults).

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.

- obtain any relevant information/history from the GP practice and feedback any relevant information to the GP practice
- To initiate and stabilize treatment (titrate therapy to determine optimal dose level and timing).
- Monitor patients starting treatment for side effects. Consider dose reduction if side effects become troublesome.
- Closely observe patients for agitation, irritability, suicidal thinking and self-harming behavior, and unusual changes in behavior, particularly during the initial months of treatment, or after a dose change.
- To arrange transfer of prescribing and monitoring to the patient's GP, where there has been an improvement in symptoms and a maintenance dose has been determined. Note: Arrangements to transfer responsibility for prescribing to primary care may be made between 6 weeks and 6 months from the initiation of treatment, once the condition has been stabilised.

- To provide the GP with appropriate information to include diagnosis and follow up such as monitoring arrangements to support the transfer of clinical responsibility.
- To provide patients and/or parents and teachers with comprehensive advice and information, covering symptoms of ADHD, social impact, treatment approaches, and guidance on storage and administration.
- To consider referral of patient / family to other support agencies.
- Warn parents/carers/adult patients about the potential for suicidal thinking and self-harm and ask them to report these effects.
- Warn parents/carers/adult patients about the potential for liver damage in rare cases, usually presenting as abdominal pain, unexplained nausea, malaise, darkening of the urine or jaundice). Any hepatic reactions should be investigated but routine liver tests are not recommended.
- Warn patients/ carers/ adult patients about the potential for clinically important increases in heart rate (**≥**20 beats per minute) or blood pressure (≥15–20 mm Hg) and ask them to report any concerns.
- To notify the GP of the results of patient reviews, including any changes in prescribed therapy, and ensure that the patient has sufficient medication until the GP has received this notification. GPs should also be provided with information on the response and continued need for treatment.
- Where patients are continuing treatment beyond 1 year, re-evaluation of the need for therapy is recommended and where appropriate, to discontinue treatment at intervals, in order to assess both the child's progress and the need for continuation of therapy.
- To review the patient at least annually.
- To notify the patients GP of any failure to attend such reviews.
- To notify the patients GP when to withhold prescriptions.
- To be available for advice and receive rapid referral of a patient if the patient's condition deteriorates or adverse events to medication occur.

## Monitoring

### Ideal Specialist service monitoring

Review patients regularly normally 6 monthly, but at least annually. Include in the review:

- clinical need, benefits and side effects.
- Any compliance issues
- the views of the person with ADHD, and those of parents, carers and teachers, a spouse or close friend, as appropriate.
- the effect of missed doses, planned dose reduction and brief periods of no treatment.
- the preferred pattern of drug use.
- coexisting conditions; treat or refer if necessary.
- the need for psychological, social and occupational support for the person and their parents or carers if appropriate.
- Safe keeping and administration

Monitoring of weight and height:

- measure height every 6 months in children and young people
- measure weight every 3 months in children 10 years and under

- measure weight at 3 and 6 months after starting treatment in children over 10 years and young people, and every 6 months thereafter, or more often if concerns arise
- measure weight every 6 months in adults
- plot height and weight of children and young people on a growth chart and ensure review by the healthcare professional responsible for treatment

**Monitoring of cardiovascular system:**

- Monitor heart rate and blood pressure and compare with the normal range for age before and after each dose change and every 6 months.

If a person taking ADHD medication has sustained resting tachycardia (more than 120 beats per minute), arrhythmia or systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on 2 occasions, reduce their dose and refer them to a paediatrician or adult physician

- Feedback clinical results and interpretation of the specialist review to the patients GP.
- Notify the GP of any failure to attend review and whether the GP should halt prescribing in those circumstances

**GP responsibilities**

- Accept shared clinical responsibility for the patient, provided the above criteria have been met.
- Reinforce educational points provided by the specialist (what the drug is, why it has been prescribed, how it should be taken, potential side-effects, the need to report and signs of suicidal thinking or self-harm, the small risk of liver damage and how to recognize signs).
- Repeat prescribing of medication no sooner than six weeks after initiation, and once stable. Inform specialist of any changes in the patients' medical condition, especially adverse effects and / or changes to prescribed medication.
- Refer back to the specialist (urgently) should any of the following occur; failure to thrive/retardation of growth, persistent sleep disturbance, persistent problems with poor attention, pronounced change in mental state.
- Refer patients with continuing ADHD symptoms and moderate or severe impairment as they transfer from adolescence to adulthood and where appropriate, continue shared care prescribing.

**Ideal GP monitoring responsibilities**

- Height and Weight: (make urgent arrangements for re-referral in the event of failure to thrive / retardation of growth).
- Monitor heart rate and blood pressure and record on a centile chart before and after each dose change, and every 3 months. (where monitoring results are already obtained from specialist every 6 months – then GP should monitor at 6 monthly intervals eg GP – specialist – GP - specialist)
- Sustained resting tachycardia, arrhythmia or systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on two occasions should prompt dose reduction and discussion / referral to a paediatrician or physician.
- Exacerbation of epilepsy or stimulant-related tics
- Mental state including psychotic symptoms, worsening anxiety symptoms including panic.
- Response to medication and progress.

- Changes in potential for misuse and diversion (monitor repeat prescribing closely).

**Patient/ carer responsibilities**

- After counseling, to be willing to administer prescribed medication as directed at home.
- Report any concerns in relation to treatment with medication
- Report any other medication being taken, including over-the-counter products.
- Report any adverse effects or warning symptoms whilst taking medication.
- Report any patient concordance decisions
- Advise GP and specialist at review of any prolonged (greater than 3 days) periods off medication and if possible any differences in the patient

**Further support**

- Medicines Information department, Musgrove Park Hospital: 01823 342253
- Medicines Information department, Yeovil District Hospital: 01935 384327
- Prescribing & Medicines Management Team, NHS Somerset: 01935 384123
- Medicines Management Team, Somerset Partnership: 01823 368265

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**References**


- NICE Guideline[NG87] Attention deficit Hyperactivity disorder: diagnosis and management September 2019
- Summaries of Product Characteristics at: http://www.medicines.org.uk/emc/
- British National Formulary (Last update 2nd December 2020): https://bnf.nice.org.uk/
- https://www.ncbi.nlm.nih.gov/books/NBK501922/