Protocol 02: Methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine prescribing and monitoring guidance for treatment of Attention Deficit Hyperactivity Disorder in children, young people and adults
Version 1.1
Shared Care Protocol

This protocol provides prescribing and monitoring guidance for methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine therapy. It should be read in conjunction with the HMMC shared care principles document, Summary of Product Characteristics (SPC) available on www.medicines.org.uk/emc and the BNF.

This shared care agreement outlines suggested management for the prescribing of methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine for Attention Deficit Hyperactivity Disorder (ADHD) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient/parent(s) or carer(s). It is important that patients/parent(s) or carer(s) are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient/parent(s) or carer(s) by the doctor initiating treatment.

Prescribing of methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine for the above indication will be initiated in Hertfordshire Partnership University NHS Foundation Trust including HertsONE ADHD clinic by a hospital specialist for a minimum of 12 weeks or until stable (whichever is longer). The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of these drugs in stable patients. The questions below will help to confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge and skills to allow you to safely prescribe medication and to also monitor treatment for adults as indicated in this shared care document?
- Have you been provided with relevant clinical details including monitoring data?
- Has this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided to the specialist within two weeks of receipt of request to share care.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care using the form provided. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its use. Any associated monitoring is the responsibility of the hospital specialist for children and young people and the GP for adults, however all results from monitoring must be communicated to the patient's GP in order for them to continue to prescribe.

The GP assumes clinical responsibility for prescribing the medication to children, young people and adults following an agreement to shared care and in the case of children and young people, following confirmation of patient attendance at an out-patient appointment with the hospital specialist, via a clinic letter.

Prescribing responsibility (and monitoring responsibility for adults) will only be transferred when the consultant and the GP agree that the patient's condition is stable or predictable after at least 12 weeks of treatment.

This Shared Care Protocol has been produced following NICE guidance issued in 2018 on the diagnosis and management of ADHD[1]

BACKGROUND AND INDICATION(S) FOR USE

ADHD is a common neurodevelopmental disorder characterised by inappropriate levels of activity and impulsivity and an impaired ability to sustain attention.[2] Those affected have difficulty regulating their activities to conform to expected norms, and often fail to achieve their potential. Many have comorbid difficulties such as developmental delays, specific learning problems and other emotional and behavioural disorders. Severe ADHD may be diagnosed as hyperkinetic disorder, which is characterised by a more severe disturbance with significant hyperactivity.[3]

Although ADHD begins in childhood, research has shown that it can continue through to adulthood for some. Approximately 15% of children with ADHD retain the diagnosis by age 25. A much larger proportion (65%) are in partial remission, with persistence of some symptoms associated with continued impairment.[4] In adults, social and occupational problems can be caused by difficulties in concentrating, paying attention to detail and completing tasks, together with impulsivity and an inability to plan ahead. Moreover, ADHD is commonly associated with mental health, addiction or behavioural problems.[4]

The NICE ADHD guidelines (NG87)[1] state that a diagnosis of ADHD in children, young people and adults should only be made by a paediatrician, specialist psychiatrist, or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD. For a diagnosis of ADHD, based on a complete history and evaluation of the patient, symptoms of hyperactivity/impulsivity and/or inattention should:

- meet the diagnostic criteria in DSM- V or ICD-10 (hyperkinetic disorder), and
- be associated with 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 two or more important settings including social, familial, educational and/or occupational settings.

Drug treatment in ADHD is used for the control of symptoms but is not curative.[5] In the UK, methylphenidate, atomoxetine, lisdexamfetamine and guanfacine are licensed for the management of ADHD in children and young people from the age of six years.[6-10] Dexamfetamine oral solution is licensed for hyperkinetic states from three years of age, although NICE do not recommend drug treatment in those aged under 5 years of age.[1,11] Some modified release methylphenidate products are also licensed for use in adults with persisting symptoms, where they were initiated in childhood and showed clear benefit.[7,12-14] Atomoxetine and lisdexamfetamine are both licensed for initiation in adults, where the presence of ADHD symptoms in childhood are confirmed.[8,15] Guanfacine is licensed for six to 17 year olds for whom stimulants are not suitable. It is not licensed for use in combination with stimulants or for adults with ADHD.[10] **It should be noted that guanfacine is classed as a 'red' drug across Hertfordshire and therefore is not for primary care prescribing.**

PRESCRIBING[1]

- All Prescribers (specialists and GPs) should have good knowledge of the medicines used for the treatment of ADHD and their different preparations, including their pharmacokinetic profiles, thus allowing treatment to be tailored effectively to an individual (refer to BNF and relevant SPCs).
- All prescribers should be aware that effect size, duration of effect and adverse effects vary from person to person.
- Specialists should think about using immediate and modified release (m/r) preparations to optimise effect (e.g. m/r preparation of methylphenidate in the morning and an immediate-release preparation of methylphenidate at another time of the day to extend the duration of effect).
- All prescribers must be cautious about prescribing stimulants if there is a risk of diversion, for cognitive enhancement or appetite suppression.
- All prescribers must NOT offer immediate-release or m/r stimulants that can be easily injected or insufflated if there is a risk of stimulant misuse or diversion.
- All prescribers should be familiar with the requirements of CD legislation governing the prescription and supply of stimulants – see NICE NG46; Controlled drugs: safe use and management. Prescribing should not exceed 30 days in duration by any prescriber.
- After titration and dose stabilisation by the specialist, prescribing and monitoring of ADHD medication should be carried out under Shared Care Protocol arrangements with primary care.
- NICE recommends consideration to trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. The specialist should make this assessment. If the decision is made to continue medication, the reasons for this should be documented.

DOSE TITRATION[1]

- All dose titration is done by the specialists
- Titrate the dose 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.
- Ensure that dose titration is slower and monitoring more frequent if any of the following are present:
  - neurodevelopmental disorders, e.g. autism spectrum disorder, tic disorders, learning disability (intellectual disability),
  - mental health conditions e.g. anxiety disorders (including obsessive–compulsive disorder), schizophrenia or bipolar disorder, depression, personality disorder, eating disorder, post-traumatic stress disorder, substance misuse,
  - physical health conditions, e.g. cardiac disease, epilepsy or acquired brain injury.
- After titration and dose stabilisation, prescribing and monitoring of ADHD medication should be carried out under Shared Care Protocol arrangements with primary care.
- Effects and side-effects of drug treatment must be routinely monitored and recorded in the relevant electronic patient record (EPR).

CHOICE OF MEDICATION

Children/young people aged ≥6 years

- All initiations, switches and stabilisation should be done by the specialist service.
- First-line: offer methylphenidate (either short or long acting) for ADHD symptoms that are still causing a persistent significant impairment in at least one domain e.g. interpersonal relationships, education and occupational attainment, and risk awareness, after parents have received ADHD-focused information, group-based support has been offered and environmental modifications have been implemented and reviewed.
- Second-line: Consider switching to lisdexamfetamine for children/young people who have had a 6-week trial of methylphenidate at an adequate dose and not derived enough benefit in terms of reduced ADHD symptoms and associated impairment.
- Alternative second-line (reserved for when ADHD symptoms are responding to lisdexamfetamine but cannot tolerate the longer effect profile): Consider dexamfetamine
- Third-line: Offer atomoxetine (shared care) **OR** guanfacine (specialist supply only) if:
  - they cannot tolerate methylphenidate or lisdexamfetamine, **OR**
  - symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses.

Adults

- All initiations, switches and stabilisation should be done by the specialist service.
- First-line: offer methylphenidate.

- Second-line: Consider switching to lisdexamfetamine for adults who have had a 6-week trial of methylphenidate at an adequate dose but have not derived enough benefit in terms of reduced ADHD symptoms and associated impairment.
- Alternative second-line (reserved for when ADHD symptoms are responding to lisdexamfetamine but cannot tolerate the longer effect profile): Consider dexamfetamine
- Third-line: Offer atomoxetine to adults if they:
  - cannot tolerate methylphenidate or lisdexamfetamine, **OR**
  - have symptoms that have not responded to separate 6- week trials of methylphenidate and lisdexamfetamine, having considered alternative preparations and doses.

Not all medications used in ADHD have a UK marketing authorisation for treating symptoms of ADHD in adults. Check individual **SPC** for details.

People with coexisting conditions

- Offer the same medication choices to people with ADHD and anxiety disorder, tic disorder or autism spectrum disorder as other people with ADHD.
- For children/young people aged ≥6 years and adults experiencing an acute psychotic or manic episode:
  - stop any medication for ADHD,
  - consider restarting or starting new ADHD medication after the episode has resolved, taking into account the individual circumstances, risks and benefits of the ADHD medication.

RESPONSIBILITIES (in line with Hertfordshire shared care principles: https://hertsvalleysccg.nhs.uk/download_file/899/389)

Specialist

Assessment appointment	• Confirm a diagnosis of ADHD in children, young people and adults following a full baseline assessment as detailed in Table 3 • Decide on the most appropriate drug treatment and discuss benefits and side-effects with the patient and/or parent(s)/carer(s) and provide written information where appropriate. In the case of atomoxetine, this should also include an explanation of the very rare risk of adverse hepatic reactions, what symptoms to look out for and what action to take should they occur. • Provide pre-treatment counselling to the patient (and parent(s)/carers). This should include both written and verbal information on the rationale for treatment, benefits, time to response, potential side-effects and precautions, and obtain agreement to initiate treatment. Document discussion in electronic patient record (EPR). • Carry out **baseline monitoring** which must be recorded in the EPR, and on the relevant charts (see On-going Monitoring Schedule below).
Initial prescription appointment	• Prescribe to initiate ADHD medication and inform GP of commencement of treatment. • Adhere to the specific regulations for prescribing of methylphenidate, dexamfetamine and lisdexamfetamine which are controlled drugs. Prescriptions for methylphenidate, dexamfetamine and lisdexamfetamine are only valid for dispensing within 28 days from the date of signature and unless there are exceptional circumstances, each prescription should be for no more than 30 days supply. • Give consideration to specific school policies on the use of medicines in schools if multiple daily doses in school age children are required.
Dose stabilisation appointments	• Monitor effectiveness of medication and adverse effects. • Titrate initial dose against symptoms and side-effects over 4 - 6 weeks until dose optimisation has been reached and the patient's condition is stable. • Issue prescription (if needed). • Issue shared care information to GP, inviting GP to enter shared care at/after week 12 when patient is stabilised on treatment. i.e., drug tolerated, dose stabilised and blood monitoring parameters are satisfactory. (Refer to Appendix 1). **SHARED CARE MUST FORMALLY BE ACCEPTED BY THE GP BY COMPLETION AND RETURN OF THE FORM PROVIDED WITHIN THIS PROTOCOL TO THE SPECIALIST** (Refer to Appendix 2). • Write to GP with information on any dose change. • Record symptoms and side-effects at each dose change. The patient's progress should be reviewed regularly. Maintaining close clinical contact by means of a telephone review may be beneficial for some patients. • Monitor for the development of new seizures or a worsening of existing seizures at every dose adjustment and then at least six-monthly for children and young people and review the medication. • Monitor behavioural response to treatment and adjust medication as deemed appropriate. • Monitor changes in sleep pattern and adjust medication accordingly.
Further specialist review	• Carry out **on-going monitoring** for children and young people as specified in the On-going Monitoring Schedule below. For adults, the on-going monitoring should be performed by the GP (see On-going

appointments thereafter	Monitoring Schedule below); however an annual specialist review can be requested if deemed appropriate. • Review the child or young person on a 6-monthly basis. • Adults to be reviewed by a specialist annually if requested to do so by the GP. The review should include a comprehensive assessment of clinical need, benefits and side-effects of medication and monitoring of blood pressure, pulse, weight, height (children/adolescents) and BMI where appropriate. • Write to GP with any dose change following clinic review. The specialist will be responsible for supplying a prescription for any dose adjustment. • Communicate diagnosis, behavioural problems, cognitive and functional scores, any dose changes of the same formulation that are needed and results of any physical monitoring to the GP. • Continue prescribing in children aged less than 6 years. When it is felt that patients aged 6 years or older may benefit from continued care by the primary care team and the patient's condition/dose of methylphenidate, atomoxetine, dexamfetamine or lisdexamfetamine is stable, the GP may be asked to share care. (If prescribing of guanfacine is to continue, this responsibility including monitoring will remain with the specialist). • Monitor for changes in the potential for substance misuse and diversion. • Consider strategies to reduce weight loss if this is a concern. Consider monitoring BMI in adults if there has been weight changes as a result of treatment. See Ongoing Monitoring Schedule below. o If a child/young person's height over time is significantly affected by medication, i.e. they have not met the height expected for their age, consider a planned break in treatment over school holidays to allow 'catch-up' growth. See Ongoing Monitoring Schedule below. • For adults, or young people after transition to adult services, adult services healthcare professionals should carry out a comprehensive assessment of the person with ADHD that includes personal, educational, occupational and social functioning, and assessment of any co-existing conditions, especially drug misuse, personality disorders, emotional problems and learning difficulties. • Report serious adverse events to the MHRA and inform the GP. • Take responsibility for stopping treatment if appropriate, including any treatment breaks. The effect of missed doses, planned dose reductions and brief periods of no treatment should be taken into account for all treatments. • Provide support/advice to prescribing GP/primary care team as needed. • Communicate to the GP non-attendance of patients at outpatient appointments. The patient or their parent(s)/carer(s) should be sent a letter asking them to make another appointment as soon as possible. They will be informed that if they do not adhere to the follow-up plan at least once every 6 months, the specialist/GP will be unable to continue to prescribe medication. (Refer to Appendix 3). • Ensure that children/young people and adults receiving treatment for ADHD have review and follow-up according to the severity of their condition, regardless of whether or not they are taking medication. • The specialist should review medication at least once a year for children and young people and discuss with the person and their families/carers as appropriate, whether medication should be

	continued. • People with ADHD should be encouraged to discuss any preferences to stop or change medication and to be involved in any decisions about stopping treatments.

GP

First prescription appointment in specialist clinic	• GP to contact specialist if any concerns regarding prescribing of ADHD medication for patient.
Specialist dose stabilisation appointments	• Respond to specialist request for shared care (refer to Appendix 1) once dose is stabilized, within two weeks of receipt of request. **SHARED CARE MUST FORMALLY BE ACCEPTED BY THE GP BY COMPLETION AND RETURN OF THE FORM PROVIDED WITHIN THIS PROTOCOL TO THE SPECIALIST** (Refer to Appendix 2). • Ensure a full understanding of the responsibilities for managing a patient on methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine, including identification of side-effects in line with the relevant SPC. • If shared care is declined: clinical rationale to be provided and GP to copy patient/parent(s) or carer(s) into decline letter, so patient is aware hospital specialist will be providing the prescription.
Specialist Review Appointments (where shared care has been accepted)	• Ensure that any patient prescribed ADHD medication is appropriately coded on the GP clinical system to allow easy identification. • Issue prescriptions once patient has been stabilised on medication (usually after 12 weeks). • Provide repeat prescriptions after dose stabilisation. • Adhere to the specific regulations for prescribing of methylphenidate, dexamfetamine and lisdexamfetamine which are controlled drugs. Prescriptions for methylphenidate, dexamfetamine and lisdexamfetamine are only valid for dispensing within 28 days from the date of signature and, unless there are exceptional circumstances, each prescription should be for no more than 30 days' supply. • Carry out on-going monitoring for adults as detailed in the On-going Monitoring Schedule below. • Adults must be reviewed once a year and the GP can request that this annual review be completed by the specialist, if deemed appropriate. This review should include a comprehensive assessment of clinical need, benefits and side-effects of medication and monitoring of blood pressure, pulse, weight & height (with BMI if appropriate). • Monitor those adults prescribed stimulants for risk of diversion, misuse and abuse at least 6-monthly. • Consider strategies to reduce weight loss if this is a concern. Consider monitoring BMI in adults if there has been weight changes as a result of treatment. • For adults, monitor for the development of new seizures or a worsening of existing seizures and review the medication and stop any treatment that may be contributing towards the seizures and inform the specialist. • Report any evidence of change in symptom control to the specialist. • Ask the patient whether they are experiencing side-effects and liaise with the specialist if necessary.

	• Report to and seek advice from the specialist on any aspect of patient care which is of concern and which may affect treatment. Refer anyone who develops signs of cardiac disease to an adult physician/cardiologist and inform the specialist. • Report serious adverse events to the MHRA and inform the specialist. • Follow specialist advice on any changes in treatment. • Notify the specialist of the patient's failure to attend appointments.

Patient/parent(s) or carer(s)

Assessment appointment **First prescription appointment in a clinic** **Specialist dose stabilisation appointments** **Further specialist review & GP appointments thereafter**	• Attend all appointments with the specialist and GP. • Report any adverse effects to the specialist or GP whilst under treatment. • Parent(s)/carer(s) to closely monitor the response to treatment. As a child gets older, the dosage requirement of medication may change. If a child or young person is not getting an optimal response e.g. if the effect of medication wears off in the afternoon and there is variability of ADHD symptoms etc. the specialist must be contacted to arrange a review. This review may be sooner than the next scheduled appointment. • Share any concerns they have in relation to treatment with the specialist or GP. • Ask the specialist or GP if the patient/parent(s) or carer(s) do not have a clear understanding of the treatment.

Dispensing Pharmacist

First prescription appointment in a clinic **Specialist dose stabilisation appointments** **Further specialist review appointments thereafter**	• Ensure appropriate dose is prescribed with clear instructions on use, NOT 'as directed'. • Ensure that the specific regulations for prescribing of methylphenidate, dexamfetamine and lisdexamfetamine which are controlled drugs have been adhered to. Prescriptions for methylphenidate, dexamfetamine and lisdexamfetamine are only valid for dispensing within 28 days from the date of signature and unless there are exceptional circumstances, each prescription should be for no more than 30 days' supply. • Provide advice on adverse effects. • Provide advice on drug interactions with prescription and OTC medication. • Issue patient information leaflets. • Monitor frequency of prescription requests and contact prescriber if quantities in excess. • Confirm counselling has been received by the patient/parent(s) or carer(s) and provide additional information where appropriate. • Refer the patient back to the prescriber if there are any concerns with the ADHD therapy.

CONTRAINDICATIONS

Please refer to the relevant SPC via www.medicines.org for additional information.

PRECAUTIONS

Please refer to the relevant SPC via www.medicines.org for additional information.

DOSAGE

Table 1 – Dosing Guidance, Formulation(s) and Additional Prescribing Information [1,6-19]

Medication	Dosing Guidance	Formulation(s)	Additional Prescribing Information
First line: **METHYLPHENIDATE** (CNS Stimulant) *Schedule 2 CD*	***CHILDREN 6 – 17 YEARS:*** **Immediate release (IR) formulations** 5mg once or twice daily (breakfast and lunch), increasing daily dose by weekly increments of 5-10mg. Licensed max. dose 60mg daily **Modified release (MR) formulations** **Delmosart XL** 18mg once daily in the morning, increased in steps of 18mg every 1 week, then adjusted according to response. Licensed max. dose 54mg daily (preferred brand choice) **Concerta XL** 18mg once daily in the morning, increased in steps of 18mg every 1 week, then adjusted according to response. Licensed max. dose 54mg daily **Equasym XL** 10mg once daily in the morning, before breakfast, increased at weekly intervals if necessary. Licensed max. dose 60mg daily **Medikinet XL** 10mg once daily in the morning, with breakfast, adjusted at weekly intervals according to response. Licensed max. dose 60mg daily	**IR formulations:** Ritalin® 10mg Medikinet® 5mg, 10mg and 20mg tablets (preferable during initial dose titration, particularly if flexible dose regime required) **MR formulations*:** Delmosart® XL (18mg, 27mg, 36mg and 54mg tablets) (preferred brand choice) Concerta XL® (18mg, 27mg, 36mg and 54mg tablets) Equasym XL® (10mg, 20mg and 30mg capsules) Medikinet XL® (10mg, 20mg, 30mg and 40mg capsules) *MR preparations should be prescribed by BRAND to ensure correct formulation is dispensed **See Table 2 below for IR and MR dose equivalents**	▪ Methylphenidate is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient ▪ Begin with low doses and titrate dose against symptoms and side-effects over 4-6 weeks, until dose optimisation is achieved ▪ MR formulations may be preferred over IR formulations for the following reasons: ➢ convenience, ➢ improving adherence, ➢ reducing stigma (no need to take medication at school or in the workplace), ➢ reducing problems of storing and administering CDs at school, ➢ the risk of stimulant misuse and diversion with immediate release preparations, ➢ pharmacokinetic profiles ▪ The different types of products are not interchangeable and the BNF recommends prescribing by brand name to avoid the risk of de-stabilisation from different release characteristics of the XL products dispensed generically ▪ Common adverse effects include insomnia, nervousness, headache,

	ADULTS: ***(unlicensed for initiation in adults)*** Begin with low doses (5 mg three times daily for IR formulations or the equivalent MR dose) Increase dose according to response up to a maximum of 100 mg/day **Higher doses than the licensed maximum daily doses needs to be prescribed by the specialist**		decreased appetite, abdominal pain and other gastrointestinal symptoms, and cardiovascular effects such as tachycardia, palpitations and minor increases in blood pressure. For full details refer to relevant Summary of Product Characteristics (SPC) ▪ Associated with a worsening of pre-existing anxiety, agitation or tension and also with the onset or exacerbation of motor and verbal tics; monitor regularly
Second line: LISDEXAMFETAMINE (CNS stimulant) *Schedule 2 CD*	***CHILDREN*** **Child 6-17 years:** Initially 30mg once daily in the morning, increased in steps of 20mg every 1 week if required. Maximum dose 70mg/day ***ADULTS*** ***(licensed in adults)*** Initially 30mg once daily in the morning, increased in steps of 20mg every 1 week if required. Maximum dose 70mg/day	Elvanse® 20mg, 30mg, 40mg, 50mg, 60mg and 70mg capsules Elvanse Adult® 30mg, 50mg and 70mg capsules	▪ Elvanse is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate ▪ Elvanse Adult is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults ▪ 25mg of lisdexamfetamine is the molecular equivalent to 10mg of dexamfetamine ▪ Common adverse effects include insomnia, nervousness, headache, decreased appetite, abdominal pain and other gastrointestinal symptoms, and cardiovascular effects such as tachycardia, palpitations and minor increases in blood pressure. For full details refer to relevant SPC
Second line (reserved for when ADHD	***CHILDREN*** Child aged 6-17 years: initially 2.5mg	5mg tablets 1mg/ml oral solution	▪ Dexamfetamine is indicated for children with refractory hyperkinetic states

symptoms are responding to lisdexamfetamine but the longer effect profile cannot be tolerated): **DEXAMFETAMINE** (CNS stimulant) *Schedule 2 CD*	two or three times daily, increased according to response by 5mg at weekly intervals, increasing to a maximum of 20mg/day. Up to 40mg/day may occasionally be required ***ADULTS*** ***(unlicensed in adults)*** Begin with low doses of 5 mg twice daily. Increase dose weekly according to response, up to a maximum of 60 mg/day. Offer divided doses, usually between 2 and 4 times daily.		▪ Begin with low doses and titrate dose against symptoms and side-effects over 4-6 weeks, until dose optimisation is achieved ▪ Common adverse effects include insomnia, nervousness, headache, decreased appetite, abdominal pain and other gastrointestinal symptoms, and cardiovascular effects such as tachycardia, palpitations and minor increases in blood pressure. For full details refer to relevant SPC
Third line: **ATOMOXETINE** *(Selective noradrenaline reuptake inhibitor)*	***CHILDREN*** **Child 6-17 years up to 70 kg body weight**: initially 0.5mg/kg/day. Increase dose after 7 days according to response, to a maintenance dose of approximately 1.2mg/kg/day *High daily doses to be given under the direction of a specialist; maximum 1.8mg/kg/day; maximum 120mg/day **(Doses above 100mg/day not licensed and so not part of shared care)** **Child 6-17 years over 70 kg body weight**: use a total starting dose of 40mg/day. Increase dose after 7 days according to response up to a maintenance dose of 80mg/day. *High daily doses to be given by the	Strattera®10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg capsules Strattera® 4mg/1ml oral solution sugar-free	▪ Atomoxetine is indicated for the treatment of ADHD in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme, under specialist supervision ▪ Offer a single daily dose, or 2 divided doses to minimise side-effects ▪ Where a satisfactory clinical response is not achieved when taken as a single daily dose, individuals may benefit from taking it as twice daily evenly divided doses in the morning and late afternoon or early evening ▪ When switching from a stimulant to atomoxetine, continue stimulant for first 4 weeks of treatment ▪ Trial the maintenance dose for 6 weeks to determine effectiveness (specialist responsibility)

	specialist; maximum 120mg/day **(Doses above 100mg/day not licensed and so should be prescribed by the specialist only)** ***<u>ADULTS</u> – Atomoxetine doses in BNF may differ from those in product literature*** ***(licensed in adults)*** **Up to 70 kg body weight**: initially 0.5mg/kg/day. Increase dose after 7 days according to response, to a maintenance dose of approximately 1.2 mg/kg/day *High daily doses to be given by the specialist; maximum 1.8mg/kg/day; maximum 120mg/day. **(Doses over 100mg not licensed and so not part of shared care. Prescribing will be done by the specialist).** **Over 70 kg body weight**: initially 40mg/day. Increase dose after 7 days according to response; maintenance 80-100mg daily *High daily doses over 100mg to be given by the a specialist; maximum 120mg/day **(Doses of >100mg to a maximum of 120mg not licensed)**		▪ Common adverse effects of treatment include abdominal pain, decreased appetite, nausea and vomiting, early morning awakening, irritability and mood swings. Increased heart rate and small increases in blood pressure were observed in clinical trials. For full details refer to SPC ▪ Suicidal thoughts and behaviours have been reported; ensure patients and their parents/carers are informed and told to promptly report clinical worsening, suicidal thoughts/behaviour, irritability, agitation or depression. Observe closely during initial months of treatment or after a dose change ▪ In rare cases may cause liver damage; advise individuals of this risk and to seek prompt medical attention in the case of abdominal pain, unexplained nausea, malaise, darkening of the urine, or jaundice. Routine liver function tests are not recommended ▪ In young people and adults monitor for sexual dysfunction and dysmenorrhoea ▪ In January 2012 the MHRA published the following safety guidance regarding BP: Atomoxetine causes clinically important increases in blood pressure or heart rate, or both, in a small proportion of patients. Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders Thorough pre-treatment screening and regular monitoring of cardiovascular status is recommended. Specialist cardiac evaluation and advice should be

			sought if pre-treatment findings suggest cardiac disease or history, or if symptoms suggesting cardiac disease are found during treatment

Table 2 – Methylphenidate-immediate and modified- release dose equivalents (mg)[1]

IR methylphenidate	Delmosart XL	Equasym XL	Medikinet XL
10	-	10	10
15	18	-	-
20	-	20	20
30	36	30	30
-	-	-	40
45	54	-	-
60	72 (above licensed max. dose)	60	-

TIME TO RESPONSE

Please refer to the relevant SPC via www.medicines.org for additional information

PRE-TREATMENT ASSESSMENT BY THE SPECIALIST[1]

Table 3 – Pre-treatment assessment by specialist (children, young people and adults)

	Initiation and Titration
Baseline monitoring (must be recorded in the Electronic Patient Record and on the relevant charts)	A review of mental health and social circumstances, including: ➢ presence of co-existing 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 BP (measured with an appropriately sized cuff and compared with the normal range for age), ➢ a cardiac examination (including checking for murmurs), ➢ an ECG if the treatment may affect the QT interval.

ON-GOING MONITORING SCHEDULE[1,10] INCLUDING MONITORING, SIDE EFFECTS AND ACTIONS TO BE TAKEN

Table 4 – Children and young people: monitoring by specialist

	Frequency	**Action**	**Intervention**
Height	6 monthly	Record in Electonic Patient Record and plot height on a growth chart	If growth is affected significantly, consider a break in drug treatment over the school holidays to allow “catch-up” growth
Weight and appetite	3-6 monthly in children 10 years and under	Record in Electronic Patient Record and plot weight on a growth chart	Monitor weight more frequently than 6 monthly if concerns arise Strategies to reduce weight loss, or manage decreased weight gain include:

	At 3 and 6 months after starting medication in children over 10 years and young people, and 6 monthly thereafter		➢ Taking medication with or after food rather than before meals ➢ Eating additional meals or snacks early morning or late evening when stimulant effects have worn off ➢ Obtaining dietary advice and eating high calorie foods of good nutritional value ➢ Taking a planned break from treatment or changing medication
Heart rate	6 monthly and before and after each dose change	Compare result with normal range for age Record on Electronic Patient Record and plot on a centile chart Send result in clinic letter to GP	If there is sustained resting tachycardia (more than 120 beats per minute) or arrhythmia measured on 2 occasions, reduce the dose of medication and refer to a paediatric hypertension specialist
Blood pressure	6 monthly and before and after each dose change	Compare result with normal range for age Record on Electronic Patient Record and plot on a centile chart Send result in clinic letter to GP	If the systolic blood pressure is greater than the 95th percentile (or a clinically significant increase) measured on two occasions, reduce the dose of medication and refer to a paediatric hypertension specialist
Risk of diversion, misuse and abuse	6 monthly	Record in Electronic Patient Record and inform GP of any changes	Patients should be monitored for the risk of diversion, misuse and abuse of CNS stimulants such as methylphenidate, dexamphetamine and lisdexamfetamine Monitor for changes in the potential for drug misuse and diversion, which may come with changes in circumstances and age.

The GP/primary care team is not required to carry out routine heart rate and blood pressure monitoring for children and young people, this responsibility remains with the specialist.

Table 5 – Adults: monitoring by GP

	Frequency	Action	Intervention
Weight and appetite	6 monthly	If there is evidence of weight loss, measure the BMI. Record in Electronic Patient Record	Strategies to reduce weight loss, or manage decreased weight gain include: ➢ Taking medication with or after food rather than before meals ➢ Eating additional meals or snacks early morning or late evening when stimulant effects have worn off ➢ Obtaining dietary advice and eating high calorie foods of good nutritional value ➢ Taking a planned break from treatment or changing medication
Heart rate	6 monthly	Record in Electronic Patient Record	If there is sustained resting tachycardia (more than 120 beats per minute) or arrhythmia measured on 2 occasions, reduce the dose of medication and refer to an adult physician.
Blood Pressure	6 monthly	Record in Electronic Patient Record	If there is a clinically significant increase in blood pressure measured on two occasions, refer to an adult physician.
Risk of diversion, misuse and abuse	6 monthly	Record in Electronic Patient Record	Patients should be monitored for the risk of diversion, misuse and abuse of CNS stimulants such as methylphenidate, dexamphetamine and lisdexamfetamine.

Adults must be reviewed once a year and the GP can request that this annual review be completed by the specialist, if deemed appropriate.

NOTABLE DRUG INTERACTIONS (REFER TO BNF AND SPC)

Please refer to the relevant SPC via www.medicines.org for additional information and BNF via Medicines Complete

BACK-UP INFORMATION / ADVICE (including out of hours contact details)

CONTACT DETAILS
Single Point of Access (SPA) (including queries for HertsONE clinic) Tel: 0300 777 0707 Email: hpft.spa@nhs.net
North Herts CAMHS ***Saffron Ground, Stevenage*;** Tel: 01438 792600
East Herts CAMHS ***Rosanne House, WGC*;** Tel: 01707 364001 ***Hoddesdon Health Centre, Hoddesdon*;** Tel: 01992 465042 ***Oxford House, Bishop Stortford*;** Tel: 01279 698920
South Herts CAMHS ***Peace Children's Centre, Watford*;** Tel: 01923 470610 ***Civic Centre, Hertsmere*;** Tel: 020 8731 3000
West Herts CAMHS ***Waverley Road, St. Albans*;** 01727 804806 / 804214 ***Churchill Ward, Hemel Hempstead*;** 01442 259132 / 216062

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Title of Guideline	Methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine prescribing and monitoring guidance for treatment of Attention Deficit Hyperactivity Disorder in children, young people and adults
Guideline Number	02
Version	1.1
Effective Date	14th September 2023
Review Date	14th September 2025
Original Version Produced	2010
Approvals:	
Provider Trust Drug / Formulary Management Group (e.g. MUSP, TPC)	Hertfordshire Partnership University NHS Foundation Trust July 2017
Hertfordshire Medicines Management Committee	Treatment pathway update – October 2018; full shared care protocol for noting at February 2019 meeting.
Hertfordshire & West Essex Area Prescribing Committee	Minor amendments to incorporate use by the new HertsONE service for noting at September 2023 meeting.
Author/s	Promilla Singh
Department(s) responsible for updating the guideline	Hertfordshire Partnership University NHS Foundation Trust Pharmacy and Medicines Optimisation Team

Hertfordshire Shared Care Agreement Request Form (Appendix 1)

This form is used to agree shared care between the specialist, patient and GP for methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine for use in children, young people and adults with ADHD as follows:

1. Specialist to provide pre-treatment counseling and discuss patient responsibilities.
2. Specialist to prescribe for a minimum of the initial 12 weeks of treatment. Thereafter a GP can be requested to continue treatment provided the patient is stable.
3. Establish that the clinician responsible for prescribing assumes clinical responsibility for the drug and the consequences of its use. Any associated monitoring is the responsibility of the hospital specialist for children and young people; the results of such monitoring must be available to the GP in order for the GP to take on legal responsibility for prescribing. The GP is responsible for any associated monitoring in adults.
4. The specialist and patient to complete and sign the shared care agreement form.
5. Copy to be filed in patient's electronic patient record (EPR).
6. Agreement form, drug specific protocol and responsibilities to be promptly communicated to the GP (by fax or secure e-mail) and copies given to patient.
7. GP must formally accept transfer to shared care and have the right to refuse if they do not feel confident in managing the medicine/patient. GP to respond to the specialist within two weeks of receipt of the shared care agreement either accepting or declining shared care by returning the form below.
8. Scan copy of shared care agreement form, protocol and responsibilities into patient's notes

For completion by specialist

Drug(s) ……
(for methylphenidate modified release preparations, please specify the brand name above)

Indication ……..……..

Date of first prescription by specialist …… Patient weight (kg) ……

Estimated date for prescribing to be continued by the GP ……..……

Specialist additional comments/advice ……..……..

……

We accept:

- the HMMC shared care principles and
- the requirements defined in the drug specific shared care protocol(s)

	Contact details	**Signature and date**

Patient name, NHS number and address or sticker		
Specialist name and designation	Tel Fax Email	

Monitoring completed

Monitoring requirements	Date last measured/monitored	Result
Heart rate		
Blood pressure		
Height (children and adolescents)		
Weight		
Appetite assessed		
Development/worsening of psychiatric disorders		
Risk of diversion, misuse and abuse		

GP response to shared care (Appendix 2)
(Please return to specialist within <u>two weeks</u> of receipt of request to share care)

This form is to be completed by the GP who is requested to share care. A copy of the completed form should be retained by the GP and a copy should be returned to the specialist.

Patient details:	
Name:	**NHS number:**
D.O.B:	**Drug requested for shared care:**
Consultant:	

I agree to accept shared care for this patient as set out in the shared care protocol ☐

I do not accept shared care for this patient. ☐
My reason(s) for not prescribing are given below:

_____
_____
_____

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

GP name	**Practice address /stamp:**
Direct telephone number:	
Email:	
Date:	**Signature:**

Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).

HertsOne
GP Federation

as One

Hertfordshire Partnership NHS
University NHS Foundation Trust

Ref:
Date:
Address:

Team Details:

Tel No:

Dear Parents / Carers

Re:…… DOB:…… NHS No:……...

I am sorry that you have not been able to attend our clinic on:……

An appointment letter was sent out and our admin team have sent you a text message notification before your appointment. Please let us know whether you have not received any of the above, as we need to ensure that we have the most up-to-date contact details.

Please contact the clinic ASAP to organise another appointment so that ……. can be reviewed.

As we have mentioned previously, it is really important that …..…… is **seen regularly for follow-up appointments at least once in every six months, as per the shared care protocol** we have agreed with the GP.

If you are unable to attend the above appointment, we and the GP **will not be able to continue to prescribe the ADHD medications under the shared care protocol.**

If you have any urgent concerns about ……, especially any risk of harm to self or others, please attend your nearest A&E or dial 999; alternatively for telephone support contact the Hertfordshire Partnership Mental Health Helpline on 01483 843 322 (between 5.00pm and 9.00am Monday to Friday and 24 hours on weekends and bank holidays). If possible, contact your GP for an urgent review.

If you have any queries please do not hesitate to contact me.

Yours sincerely,

Consultant Psychiatrist