Document title:	SHARED CARE PROTOCOL FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)		
Document reference number:	N/A	Version number:	2.0
Document type: (Policy/ Guideline/ SOP)	Guideline	To be followed by: (Target Staff)	Mental Health Teams Learning disability Child Development Centre CAMHs Primary Care
Author:	Mental Health/Attention Deficit Hyperactive Disorder Pharmacist EPUT		
Approval group/ committee(s):	Medicines Management Group		07 November 2024
Professionally approved by: (Director)	Director of Pharmacy		
Executive Director:	Executive Chief Operating Officer		
Ratification group(s):	N/A		
CQC Quality Statement	N/A		
Key word(s) to search for document on Intranet / TAGs:	ADHD, Shared Care Protocol, Methylphenidate Lisdexamfetamine, Dexamfetamine, Atomoxetine, Guanfacine	Distribution method:	☒Intranet

Initial issue date:	20 February 2025	Last Review date:	03 March 2025	Next Review date:	06 November 2026	Expiry Date:	N/A

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Related Trust documents (to be read in conjunction with)
Formulary and Prescribing Guidelines – Section 6 – Treatment of ADHD

Document review history:			
Version No:	Authored/Reviewer:	Summary of amendments/ record documents superseded by:	Issue date:
1.0	Uzoma Ani, Advanced Mental Health/ADHD Pharmacist,	New Document	20 February 2025
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Essex Partnership University NHS Foundation Trust (EPUT) SHARED CARE PROTOCOL FOR THE PRESCRIBING AND MONITORING OF MEDICINES FOR ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD)

1 Introduction

EPUT ADHD shared care protocol should be read with updated summaries of product characteristics (SPCs),British national formulary (BNF), British National Formulary for children (BNFC), the Medicines and Healthcare products Regulatory Agency (MHRA) and NICE guidelines.

This protocol describes how patients prescribed medicines for ADHD can be managed safely in primary care, secondary care and across the interface. It sets out responsibilities for each party, to ensure that these medicines are initiated, prescribed, dispensed and monitored appropriately, and according to the BNF and NICE guidelines. This document is mainly concerned with those patients who are initiated on ADHD medicines within EPUT. However once the patient is managed in the community, their secondary care treatment might come from a non-EPUT provider of child and adolescent mental health services or through right to choose pathway. All parties involved should therefore be aware that such non EPUT providers such as CAMHS in Essex, e.g. NELFT https://www.nelft.nhs.uk/ , have their own protocols, therefore this protocol should be read alongside the formulary and shared care protocol published by those providers, as their agreements and arrangements may be different. Arrangement for referral to be agreed and completed by secondary/secondary ADHD services, primary care services and ICBs.

The protocol contains:

1. ADHD protocol for Children
2. Shared Care Protocol for Methylphenidate in Adult Services
3. Shared Care Protocol for Lisdexamfetamine in Adult Services
4. Shared Care Protocol for Dexamfetamine in Adult Services
5. Shared Care Protocol for Atomoxetine in Adult Services
6. Shared Care Protocol for Guanfacine in Adult Services
7. Shared Care Request, Agreement and Refusal letter/form.

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2 ADHD Shared Care Protocol for Children

Shared Care protocol Methylphenidate, Lisdexamfetamine, Dexamfetamine, Atomoxetine and Guanfacine prescribing and monitoring guidance for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children.

This protocol provides prescribing and monitoring guidance for methylphenidate, Lisdexamfetamine, Dexamfetamine, Atomoxetine and Guanfacine therapy for children and young adults. It should be read in conjunction with the, Summary of Product Characteristics (SPC) and British National Formulary for Children (BNFC).

This shared care agreement outlines responsibilities and suggested management for the prescribing of the above specified drugs 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 parents or carers. It is important that parents or carers are consulted about treatment and are in agreement with it. The intention to share care should be explained to the parents or carers by the specialist initiating treatment and consent obtained.

Prescribing of methylphenidate, Lisdexamfetamine, Atomoxetine, and Guanfacine for the above indication will be initiated in Essex Partnership University NHS Foundation Trust (EPUT), North East London NHS Foundation Trust (NELFT) by a 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, skills and access to equipment to allow you to safely prescribe and also to monitor treatment?
- Have you been provided with relevant clinical details including monitoring data?
- Has this document and BNFC/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 in this protocol 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 specialist 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 specialist for children, 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, following confirmation of patient attendance at an out-patient appointment with the specialist, via a clinic letter.

Prescribing responsibility will only be transferred when the specialist 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 (last updated September 2019) on the diagnosis and management of ADHD.

2.1 **Background**

ADHD is a common neurodevelopmental disorder characterised by age-inappropriate levels of hyperactivity, impulsivity and inattention. 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-impulsivity and inattentiveness.

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. 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.

The NICE ADHD guidelines (NG87) state that a diagnosis of ADHD in children 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-11.
- Associated with at least moderate psychological, social and/or educational or occupational impairment based on interview and/or direct observation in multiple settings.
- Pervasive, occurring in two or more important settings including social, familial, educational and/or occupational settings.

2.2 **Indications**

Drug treatment in ADHD is used for the control of symptoms but is not curative. In the UK, methylphenidate, Lisdexamfetamine, Dexamfetamine, Atomoxetine and Guanfacine are licensed for the management of ADHD in children and young people from the age of six years. Some Dexamfetamine preparations are licensed for hyperkinetic states from three years of age, although NICE do not recommend drug treatment in those aged under 5 years of age.

2.3 **Specialist Responsibilities**

Assessment appointment	• Confirm a diagnosis of ADHD and Pre-treatment assessment. • Decide on the most appropriate drug treatment and discuss benefits and side-effects with the patient and parents/carers and provide written information where appropriate. • Provide pre-treatment counselling to the patient and parents/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.
Initial prescription appointment	• Prescriber to initiate ADHD medication and inform GP of commencement of treatment and the monitoring parameters undertaken. • Adhere to the specific regulations for prescribing of Methylphenidate, Lisdexamfetamine and Dexamfetamine which are controlled drugs. Prescriptions for Methylphenidate, Lidexamfetamine and Dexamfetamine 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. • Ensure that the patient and carers understand their treatment regimen and any monitoring or follow up that is required. • Provide education on drug therapy to maximise compliance and ensure the patient and carers are aware of when to seek medical advice. • 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, taking into account the monitoring required for the specific ADHD medication. • 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. • 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. • Communicate with the GP a summary of the clinical review, including results of monitoring undertaken, changes to treatment and dose changes. • Issue shared care information to GP, inviting GP to enter shared care at or after week 12 when patient is stabilised on treatment. i.e., drug tolerated, dose stabilised and monitoring parameters are satisfactory.

	• Continue to issue prescriptions for the patient after treatment initiation until such time as the patient's GP agrees to the shared care arrangement.

SHARED CARE MUST FORMALLY BE ACCEPTED BY THE GP BY COMPLETION AND RETURN OF THE FORM PROVIDED WITHIN THIS PROTOCOL TO THE SPECIALIST. See the appendix for letters/forms for shared care agreement.

Further specialist review appointments thereafter	• Carry out on-going monitoring • Review at least a 6-monthly basis. The review should include a comprehensive assessment of clinical need, benefits and side-effects of medication and monitoring of blood pressure, pulse, weight, height 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, Lisdexamfetamine or Guanfacine is stable, the GP may be asked to share care. • Following 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 and advice to prescribing GP/primary care team as needed. • Communicate to the GP non-attendance of patients at outpatient appointments. The patient and parents/carers 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. • Ensure that children 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.

2.4 Primary Care Responsibilities

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 once dose is stabilised, 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. See the appendix for letters/forms for shared care agreement. • Ensure a full understanding of the responsibilities for managing a patient on Methylphenidate, Lisdexamfetamine, Dexamfetamine, Atomoxetine, and Guanfacine, 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, parents or carers into refusal 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, Lisdexamfetamine and Dexamfetamine which are controlled drugs. Prescriptions for Methylphenidate, Lisdexamfetamine and Dexamfetamine 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. • 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 cardiologist and inform the specialist. • Report serious adverse events to the MHRA and inform the specialist. • Follow specialist advice on any changes in treatment.

2.5 Patient/parents or carers Responsibilities

- Attend all appointments with the specialist and GP.
- Take Medication as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of ADHD medication with their pharmacist before purchasing any OTC medicines.

- Methylphenidate, Lisdexamfetamine and Dexamfetamine are schedule 2 controlled drugs. Parents and Carers may be required to prove their identity when collecting prescriptions and should store these medications safely and securely. It must not be shared with anyone else.
- Report any adverse effects to the specialist or GP whilst under treatment.
- Parents and carers 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, parents or carers do not have a clear understanding of the treatment.

2.6 **Initiation and ongoing dose regimen**

Children 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/carers/individual 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 OR Guanfacine 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.

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 and young people 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.

2.7 Prescribing

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 according to BNFC 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 preparations to optimise 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 modified release 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 controlled drug legislation governing the prescription and supply of stimulants NICE NG46; Controlled drugs: safe use and management.

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.

2.7.1 Dose Titration

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).

2.8 Adverse effects, Contraindications, cautions and Interactions.

For full adverse effects, contraindication, caution and interaction please see the following:

BNFC: https://bnfc.nice.org.uk/

Methylphenidate: https://www.medicines.org.uk/emc/product/8726/smpc#gref

Lisdexamfetamine: https://www.medicines.org.uk/emc/product/14091/smpc

Dexamfetamine: https://www.medicines.org.uk/emc/product/11004/smpc#gref

Atomoxetine: https://www.medicines.org.uk/emc/product/11126/smpc#gref

Guanfacine: https://www.medicines.org.uk/emc/product/5099/smpc#gref

2.9 Pharmaceutical aspects

2.9.1 **First line**: METHYLPHENIDATE (CNS Stimulant, Schedule 2 CD)

Formulations	Dosing Guidance Child 6 - 17 years	Additional Prescribing Information
Immediate Release (IR) tablets Should be prescribed generically. Ritalin® 10mg tablets Medikinet® Tranquilyn® Generics 5mg, 10mg and 20mg tablets	Initially 5mg once or twice daily, increased in steps of 5–10mg daily at weekly intervals, increased if necessary up to 2.1 mg/kg daily in 2–3 divided doses. The maximum licensed dose is 60mg daily in 2–3 doses. (Maximum of 90mg daily under the direction of a specialist).	Begin with low doses and titrate dose against symptoms and side-effects over 4-6 weeks, until dose optimisation is achieved. The IR tablets may be preferable during initial dose titration, particularly if flexible dose regimes are required. Common adverse effects of methylphenidate preparations include insomnia, nervousness, headache, decreased appetite, abdominal pain and other gastrointestinal symptoms, cardiovascular effects such as tachycardia, palpitations, minor increase in blood pressure. 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
Modified Release (MR) tablets Should be prescribed by brand. Concerta XL® and the bioequivalent branded generics: Delmosart XL®, Xaggitin XL®, Affenid XL®, Xenidate XL® (18mg, 27mg, 36mg and 54mg tablets) Matoride XL® (18mg, 36mg, 54mg tablets) IR:MR ratio = 22:78	Initially 18mg once daily in the morning, increased in steps of 18mg every week, then adjusted according to response. Licensed maximum dose 54mg daily	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 methylphenidate MR 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. Refer to the MHRA Drug Safety Update for further information.
Modified Release (MR) capsules 1. Should be prescribed by brand. Equasym XL® (10mg, 20mg and 30mg capsules) IR:MR ratio = 30:70	10mg once daily (in the morning), increased in steps of 10mg at weekly intervals if necessary. Licensed maximum dose 60mg daily.	Equasym XL capsules should be taken preferably before breakfast. Capsules can be opened, and contents sprinkled onto a small amount (tablespoon) of applesauce / yoghurt. Capsule contents should not be crushed or chewed.
Modified Release (MR) capsules 2. Should be prescribed by brand. Medikinet XL® (5mg, 10mg, 20mg, 30, 40mg, 50mg and 60mg capsules) IR:MR ratio = 50:50	10mg once daily (in the morning), increased in steps of 10mg at weekly intervals if necessary. Licensed maximum dose 60mg daily.	Take with or after breakfast (to obtain sufficiently prolonged action and to avoid high plasma peaks) Capsules can be opened, and contents sprinkled onto a small amount (tablespoon) of applesauce or yoghurt.

		Capsule contents should not be crushed or chewed
Modified Release (MR) capsules 3. Should be prescribed by brand. Metyrol XL® and Meflynate XL® (10mg, 20mg, 30mg, 40mg and 60mg capsules) IR:MR ratio = 50:50	20mg once daily in the morning (10mg can be used if considered appropriate), increased gradually as per response and tolerability. Licensed maximum dose 60mg daily.	Metyrol XL and Meflynate XL can be taken with or without food. Capsules can be opened, and contents sprinkled onto a small amount of soft food at e.g. applesauce. Capsule contents should not be crushed or chewed.

2.9.2 **Second Line:** LISDEXAMFETAMINE (CNS stimulant, Schedule 2 CD)

To be considered if Methylphenidate has not been successful or tolerated.

Formulation	Dosing Guidance Child 6 - 17 years	Additional Prescribing Information
Elvanse® 20mg, 30mg, 40mg, 50mg, 60mg, 70mg capsules	Initially 30mg once daily in the morning, increased in steps of 10 - 20mg at approximately weekly intervals if required. Maximum dose 70mg/day.	A lower starting dose of 20mg once daily in the morning may be needed in some patients. Capsules may be swallowed whole, or the capsule opened, and the entire content mixed with soft food (e.g. yoghurt) or in a glass of water or orange juice. 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.

2.9.3 **Second Line** (Alternative to Lisdexamfetamine): DEXAMFETAMINE (CNS stimulant, Schedule 2 CD)

Reserved for those who have benefitted from Lisdexamfetamine but are unable to tolerate its longer duration of action.

Formulation	Dosing Guidance Child 6 - 17 years	Additional Prescribing Information
Dexamfetamine generic 5mg tablets Should be prescribed generically. Amfexa® 5mg, 10mg and 20mg tablets Dexamfetamine 1mg/ml oral solution sugar-free	Initially 2.5 mg 2–3 times a day, increased in steps of 5 mg once weekly if required, usual maximum 1 mg/kg daily, up to 20 mg daily (40 mg daily has been required in some children); maintenance dose to be given in 2–4 divided doses.	More likely to be misused or/and diverted. Begin with low doses and titrate dose against symptoms and side-effects over 4-6 weeks, until dose optimisation is achieved. 25mg of Lisdexamfetamine is the molecular equivalent to 10mg of Dexamfetamine sulphate. Adverse effects are broadly similar to those of Lisdexamfetamine.

2.9.4 **Third line**: ATOMOXETINE Non-stimulant(Selective noradrenaline reuptake inhibitor)

To be considered if Methylphenidate or Lisdexamfetamine has not been successful or tolerated.

Formulation	Dosing Guidance	Additional Prescribing Information
Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg capsules Atomoxetine generic and Strattera® 4mg/ml oral solution NB: Should be prescribed generically	**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. **Child 6-17 years over 70 kg body weight:** Initially 40mg daily. Increase dose after 7 days according to response up to a maintenance dose of 80mg/day. *High daily doses to be given by the specialist; maximum 120mg/day.	Useful where stimulants misuse or/and diversion is a problem or when 'dopaminergic' adverse effects (such as tics, anxiety) become a problem on stimulants. Offer a single daily dose, or two evenly divided doses (morning and late afternoon or early evening) to minimise side effects or if response in inadequate with single daily dosing. When switching from a stimulant to Atomoxetine, continue stimulant for first 4 weeks of treatment. Trial the maintenance dose for 6 weeks to determine

	(N.B: Doses above 100mg/day in children is not licensed and so should be prescribed by the specialist only)	effectiveness (specialist responsibility). Common adverse effects include headache, somnolence, abdominal pain, nausea, vomiting, decreased appetite, early morning awakening, irritability and mood swings. Increased heart rate and small increases in blood pressure were observed in clinical trials. Suicidal thoughts and behaviours have been reported; ensure patients and their parents/carers are informed and told to promptly report clinical worsening or appearance of signs / symptoms e.g. suicidal thoughts/behaviour, irritability, agitation or depression. In rare cases may cause liver damage; advise individuals / carers 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. Use cautiously where there is a risk of QT interval prolongation (including other QT prolonging drugs) and with potent CYP2D6 inhibitors & poor metabolisers.

2.9.5 **Third Line**: GUANFACINE Non-stimulant (selective alpha 2A-adrenergic receptor agonist)

To be considered if Methylphenidate or Lisdexamfetamine has not been successful or tolerated.

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Formulation	Dosing Guidance *For optimal weight-adjusted dose titrations refer to SPC.	Additional Prescribing Information
Intuniv® modified release (MR) 1mg, 2mg, 3mg and 4mg tablets	Child 6 – 17 years: Initially 1mg daily, increased by 1mg at weekly intervals if necessary and tolerated. Maintenance dose 0.05 - 0.12mg/kg once daily. Maximum licensed dose dependent on age and weight (see below): **Children 6 – 12 years ≥ 25kg:** Maximum licensed dose 4mg once daily Children 13 – 17 years: **Weight 34 - 41.4kg:** Maximum licensed dose 4mg once daily **Weight 41.5 – 49.4kg:** Maximum licensed dose 5mg once daily **Weight 49.5 – 58.4kg:** Maximum licensed dose 6mg once daily **Weight ≥ 58.5kg:** Maximum licensed dose 7mg once daily	Careful dose titration and monitoring is necessary at the start of treatment since clinical improvement and risks for several clinically significant adverse reactions (syncope, hypotension, bradycardia, somnolence and sedation) are dose and exposure related. Patients or carers should be advised that somnolence and sedation can occur, particularly early in treatment or with dose increases. Patients and carers should be advised not to administer Guanfacine with high fat meals due to increased exposure. Avoid abrupt discontinuation as this may cause a rebound increase in blood pressure and pulse. When stopping treatment, the dose must be tapered with decrements of no more than 1 mg every 3 to 7 days, and blood pressure and pulse should be monitored to minimise potential withdrawal effects. Patients and carers should be instructed not to discontinue Guanfacine without consulting their physician. If a single dose is missed, the prescribed dose can resume the next day. If ≥ 2 consecutive doses are missed, re-titration is recommended based on the patient's tolerability to Guanfacine.

		Common side effects of Guanfacine include somnolence, headache, fatigue, abdominal pain and sedation. Use cautiously where there is a risk of QT interval prolongation (including with other QT prolonging drugs) and with moderate to strong CYP3A4/5 inhibitors or CYP3A4/5 inducers – dose adjustments may be required.

2.10 **Pre-treatment assessment by specialist**

A review to confirm that they continue to meet the criteria for ADHD and need treatment

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 cardiovascular assessment including (but not limited to):

- Family history of cardiac disease or previous cardiac surgery
- History of sudden death in 1st degree relative under 40 suggestive of cardiac disease
- Shortness of breath on exertion compared to peers
- Fainting on exertion or in response to fright / noise
- Palpitations that are rapid, regular and start and stop suddenly
- Chest pain suggesting cardiac origin
- Murmur on examination

Referral for a cardiology opinion before starting ADHD medication if any of the above apply or if there are any other concerns

An ECG is required if the individual has any of the above features or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.

NB. In addition to the above, before initiating Guanfacine, a baseline evaluation is required to identify patients at increased risk of somnolence and sedation, hypotension and bradycardia, weight increase / risk of obesity.

2.11 Initial monitoring and ongoing monitoring for ADHD medicines to be undertaken by specialist

Note: For monitoring of guanfacine, see section 7

	Frequency	Action	Intervention
Height	Initial: At baseline Ongoing: 6 monthly	Record in Electronic Patient Record and plot height on a growth chart Inform GP via clinic letter	If height is affected significantly over time, consider a planned break in drug treatment over the school holidays to allow “catch-up” growth
Weight and appetite	Children ≤ 10 years Initial: At baseline Ongoing: 3 monthly Children ≥ 10 years and young people Initial: At base line Ongoing: At 3 and 6 months after starting medication, and 6 monthly thereafter	Record in Electronic Patient Record and plot weight on a growth chart Inform GP via clinic letter	Monitor weight more frequently if concerns arise. 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 in the 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
Blood pressure Pulse	Initial: At baseline and before and after each dose change	Compare result	If the systolic blood pressure is greater than the 95th percentile (or a

	Ongoing: 6 monthly and before and after each dose change	with normal range for age Record on Electronic Patient Record and plot on a centile chart Send result in clinic letter to GP	clinically significant increase) measured on two occasions, reduce the dose of medication and refer to a paediatric hypertension specialist. 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.
Sleep disturbances	Initial: At every dose adjustment Ongoing: At appointments	Record on Electronic Patient Record and inform GP of any changes	Monitor changes in sleep pattern (for example, with a sleep diary) and adjust medication accordingly
Seizures	Initial: At every dose adjustment Ongoing: at appointments	Record on Electronic Patient Record and inform GP of any changes	If new seizures develop or there is worsening of existing seizures, review the ADHD medication and stop any medication that may be contributing to the seizures. After investigation, cautiously reintroduce ADHD medication if it is unlikely to be the cause of seizure

Mood and behaviour changes	Initial: At every dose adjustment and as required Ongoing: As required or at appointments (at least 6 monthly)	Record on Electronic Patient Record and inform GP of any changes	Monitor the behavioural response to medication and if behaviour and mood worsens (e.g. appearance or worsening of suicidal behaviour, self-harm, hostility, agitation) adjust medication accordingly and review diagnosis if necessary. Patients and carers should also be advised of this risk and made aware of possible signs and symptoms and if noticed to report back to the specialist immediately.
Risk of diversion, substance misuse and abuse	Initial: At base line and as required Ongoing: As required and at appointments (at least 6 monthly)	Record in Electronic Patient Record and inform GP of any changes	Patients and carers should be assessed and monitored for the risk of diversion, misuse and abuse of CNS stimulants such as Methylphenidate, Dexamfetamine and Lisdexamfetamine. Monitor for changes in the potential for drug misuse and diversion, which may come with changes in circumstances and age. Ongoing requests for frequent repeat prescriptions deemed unnecessary. Should be communicated to the specialist and GPs.

Tics	Initial: At dose adjustments Ongoing: At appointments	Record in Electronic Patient Record and inform GP of any changes	Consider a period of watchful waiting (3 months) as tics naturally wax and wane and if the impairment associated with the tics outweigh benefits of ADHD treatment. If the tics are stimulant related, consider: • Reducing the stimulant dose • Switching to Guanfacine or Atomoxetine • Stopping medication
Liver impairment (Atomoxetine only)	Initial: At dose adjustments Ongoing: At appointments	Record in Electronic Patient Record and inform GP of any changes	Rare side effect of Atomoxetine, however, it is important to be vigilant for signs and symptoms e.g. abdominal pain, unexplained nausea, malaise, darkening of urine, jaundice. Patients and carers should be advised to seek prompt medical attention if these symptoms develop. Routine LFT tests are not required unless clinically indicated.

2.12 **Initial and ongoing monitoring schedule of Guanfacine by specialist**

	Frequency	Action	Intervention
Height, Weight and BMI	Initial: At baseline Ongoing: Every 3 months for the first 12 months and 6 monthly thereafter, with more frequent monitoring following any dose adjustments.	Record in Electronic Patient Record and plot weight and height on a growth chart Inform GP via clinic letter	Children and adolescents treated with guanfacine may show an increase in their BMI. Provide support on healthy lifestyle interventions if weight and BMI outside healthy range. If difficulty persists consider a dose reduction, treatment break or a change in ADHD medication
Blood pressure & heart rate (including signs and symptoms of hypotension and bradycardia)	Initial: At baseline, then weekly during dose titration and stabilisation Ongoing: then every 3 months for the first 12 months and 6 monthly thereafter and more frequent monitoring following any dose adjustment. Monitor BP and pulse on dose reduction or discontinuation of treatment.	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	Patients and carers should be advised to report signs and symptoms of bradycardia and hypotension e.g. fatigue, dizziness, palpitations, feeling faint or fainting to the specialist without delay. If sustained hypotension or orthostatic hypotension or low pulse reduce the dose or consider switching to another ADHD medication; consider referral and seeking advice to a paediatrician if deemed necessary. Blood pressure and pulse may increase following discontinuation. Dose should be reduced gradually (see SPC) and BP and pulse

			monitored. If there are signs of clinically significant rebound hypertension or tachycardia, consider referring to a specialist paediatrician.
Somnolence and sedation (signs and symptoms)	Initial: Monitor at baseline, then weekly during dose titration and stabilisation Ongoing: then every 3 months for the first 12 months and 6 monthly thereafter with more frequent monitoring following any dose adjustments	Record in Electronic Patient Record and inform GP of any changes	Somnolence and sedation typically occur during the start of treatment and with dose increases. Review timing of dose and lifestyle factors. If somnolence and sedation are judged to be clinically concerning or persistent, a dose decrease, or discontinuation should be considered.
Mood, behaviour changes (e.g. appearance , worsening of suicidal behaviour, self-harm or hostility)	Initial: At dose adjustments during initiation and drug optimisation Ongoing: then every 3 months for the first 12 months and 6 monthly thereafter with more frequent monitoring following any dose adjustments	Record in Electronic Patient Record and inform GP of any changes	Monitor the behavioural response to medication, if behaviour and mood worsens (e.g. appearance or worsening of suicidal behaviour, self-harm, hostility, agitation). • Review patient and exclude other causes. • Treatment of an underlying psychiatric condition may be necessary. • Consider discontinuation or a change in ADHD treatment.

			Patients and carers should be advised of this risk and made aware of possible signs and symptoms to report back to the specialist immediately if noticed

2.13 **Advice to patients/parents 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 medicines

The patient, parents and carers should be advised to report any of the following signs or symptoms to specialists and primary care prescriber without delay:

- Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of angle closure glaucoma, seek immediate medical attention, ideally from an eye casualty unit or A&E.
- Symptoms suggestive of cardiac disease (e.g. palpitations, exertional chest pain, unexplained syncope, or dyspnoea).
- New or worsening psychiatric symptoms (e.g. psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania).
- Report suicidal thoughts or behaviour, and development or worsening of irritability, agitation, and depression.
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory).
- Risk of hepatic injury: report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistent abdominal pain.
- Symptoms of allergic or anaphylactic reactions (e.g. rash, angioedema, or urticaria).

2.14 **Transfer of Care**

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed. The CAMHS secondary care prescriber or Community Paediatric Prescriber will inform, in writing:

- Adult ADHD services of the details and history of the patient (presentation, progress, compliance with medication, etc.) who is approaching their 18th birthday and who has been identified as requiring continuation of their ADHD medicines beyond their 18th birthday.

- EPUT Adult mental health services of the details and history of the patient (presentation, progress, compliance with medication, etc.) who is approaching their 18th birthday and who has been identified as requiring continuation of their ADHD medicines beyond their 18th birthday.
- The GP regarding any decision to stop or alter the treatment plan prior to transition to adult services.

Should on-going prescription of psychostimulants be considered necessary, the patient will be advised of the need for safe storage to prevent diversion and potential abuse.

The Adult ADHD Services or EPUT adult mental health service as appropriate will accept patients who are approaching their 18th birthday and require on-going support and medication to manage their ADHD. They will review the patient regularly (at least annually) and liaise with the GP should treatment be varied or discontinued.

Should medication no longer be considered necessary it will be discontinued slowly upon the advice of the clinic, and the patient's on-going needs assessed by the adult community mental health team.

2.15 Specialist contact information

Name:

Role and speciality:

Daytime telephone:

Email address:

Alternative contact:

Out of hours contact details:

3 Shared Care Protocol for Methylphenidate in Adult Services

3.1 Background

Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD). It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Methylphenidate is available as immediate-release tablets, and modified-release tablets and capsules. The modified-release preparations contain both immediate-release and prolonged-release methylphenidate, and different brands have different proportions of each. Brands may therefore vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name.

Methylphenidate is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management. Risk of misuse can be reduced by using modified-release preparations.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Patients should be reviewed for ongoing need at least annually, and the manufacturers recommend a trial discontinuation at least once yearly to assess the patient's condition.

3.2 **Indication**

Attention deficit hyperactivity disorder (ADHD) in adults

Please note licensed indications vary by manufacturer; see SPC for full details. Some brands are not licensed in adults.

3.3 **Specialist Responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 3.2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 3.14), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions and interactions.
- Conduct required baseline investigations and initial monitoring (see section 3.11).
- Initiate and optimise treatment as outlined in section 3.8. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (section 3.9).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 3.16).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 3.11 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 3.12 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- See the appendix for letters/forms for shared care agreement.

3.4 Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 3.8, taking into account any potential drug interactions in section 3.10.
- Prescribe in line with controlled drug prescription requirements (section 3.6).
- Adjust the dose of methylphenidate prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 3.12. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 3.10).
- Manage any adverse effects as detailed in section 3.13 and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.
- See the appendix for letters/forms for shared care agreement.

3.5 Patient and/or carer responsibilities

- Take methylphenidate as prescribed, and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 3.14.
- Report the use of any over the counter medications (OTC) to their primary care prescriber and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if methylphenidate affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 3.14).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

3.6 Contraindications and cautions

Contraindications:

- Hypersensitivity to methylphenidate or to any of the excipients
- Glaucoma
- Phaeochromocytoma

- During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Hyperthyroidism or thyrotoxicosis
- Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder.
- Diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well-controlled).
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, and structural cardiac abnormalities.
- Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke.
- Medikinet XL only: history of pronounced acidity of the stomach with a pH value above 5.5, or during therapy with H2 receptor blockers, proton pump inhibitors or antacids.

Cautions:

- Family history of sudden cardiac or unexplained death, malignant arrhythmia.
- Cardiovascular status should be carefully monitored (see section 3.11 and section 3.12)
- Underlying conditions which might be compromised by increases in blood pressure or heart rate.
- Known drug or alcohol dependency or misuse of central nervous system (CNS) stimulants: potential for abuse, misuse or diversion.
- Alcohol consumption (not recommended during treatment)
- Epilepsy: may lower seizure threshold
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, depressive symptoms, bipolar disorder.
- Renal or hepatic insufficiency (due to lack of data)
- Leukopenia, thrombocytopenia, anaemia, or other haematological abnormalities.
- Prolonged-release tablets only: severe narrowing of the gastrointestinal tract or dysphagia; risk of obstruction
- Safety and efficacy has not been established in patients older than 60 years of age.
- Susceptibility to open-angle glaucoma.
- Pregnancy or breast-feeding (see section 3.15)
- Potential for abuse, misuse, or diversion.

3.7 **Initiation and ongoing dose regimen**

Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks. The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.

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

Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

Recommended starting dose in ADHD:

- Immediate release tablets: 5 mg, given 2-3 times daily
- Modified release tablets: 18 mg daily, given in the morning
- Modified release capsules: 10-20 mg daily

Adults with ADHD who have shown clear benefit from methylphenidate in childhood or adolescence may continue treatment into adulthood at the same daily dose. Consult SPC for the prescribed brand for more information.

Maintenance dose (following initial stabilisation):

The dose of methylphenidate should be titrated to response, usually at weekly intervals.

Maximum dose in ADHD:

- Immediate release tablets: up to 100 mg daily in 2-3 divided doses
- Modified release tablets: up to 108 mg once daily, given in the morning
- Modified release capsules: up to 100 mg daily. May be given as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.

The maximum licensed daily dose varies with formulation and brand; consult BNF and SPC.

Conditions requiring dose adjustment:

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. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome

3.8 Pharmaceutical aspects

Route of administration:	Oral
Formulation:	Methylphenidate hydrochloride. Standard release tablets: Medikinet®: 5mg, 10mg, 20mg Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg Ritalin®: 10mg Tranquilyn®: 5mg, 10mg, 20mg NB: Methylphenidate standard release tablets are not licensed for use in adults. Use is considered off-label. Brand name prescribing is not necessary for standard release tablets. Prolonged-release tablets: NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed.

	Concerta XL®: 18mg, 27mg, 36mg, 54mg Delmosart®: 18mg, 27mg, 36mg, 54mg Matoride XL®: 18mg, 36mg, 54mg Xaggitin XL®: 18mg, 27mg, 36mg, 54mg Xenidate XL®: 18mg, 27mg, 36mg, 54mg NB: Methylphenidate prolonged-release tablets are licensed for continuation in adults who have shown clear benefit from treatment in childhood and/or adolescence. They are not licensed for initiation in adults. Use in this way is considered off-label. Modified-release capsules: NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed. Equasym XL®: 10mg, 20mg, 30mg Medikinet XL®▼: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg NB: Ritalin XL and Medikinet XL modified-release capsules are licensed for initiation and continuation in adults. Equasym XL is not licensed for use in adults Please consult the relevant SPC for brand-specific licensing information.
Administration details:	Methylphenidate can be taken with or without food, but patients should standardise which method is chosen. Administration requirements vary by formulation and brand. Methylphenidate capsules can be opened and sprinkled on a small amount of soft food for administration. Please consult the relevant SPC for brand-specific information. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.
Other important information:	Methylphenidate is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. The choice of formulation will be decided by the treating specialist on an individual basis, and depends on the intended duration of effect. Risk of misuse can be reduced by using modified-release preparations. Alcohol may exacerbate CNS adverse effects of methylphenidate and should be avoided during use. Methylphenidate may cause false positive laboratory test results for amphetamines.

3.9 **Significant medicine interactions**

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Monoamine oxidase inhibitors (MAOIs): risk of hypertensive crisis. The combination should be avoided, and use of methylphenidate and MAOIs should be separated by at least 14 days
- Coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants: metabolism may be inhibited by methylphenidate.Dose adjustment may be required when starting or stopping methylphenidate.
- Anti-hypertensive drugs: effectiveness may be reduced by methylphenidate
- Other drugs which elevate blood pressure: risk of additive effects (e.g. linezolid)
- Alcohol: may exacerbate adverse CNS effects of methylphenidate
- Serotonergic drugs, including SSRIs and MAOIs: increased risk of central nervous system (CNS) adverse effects, risk of serotonin syndrome
- Halogenated anaesthetics: risk of sudden blood pressure increase during surgery. Avoid methylphenidate on the day of planned surgery.
- Dopaminergic drugs, including antipsychotics: increased risk of pharmacodynamic interactions including dyskinesias or hypertensive crisis (e.g. risperidone, paliperidone, selegiline, rasagiline)
- Apraclonidine: effects decreased by methylphenidate.
- Carbamazepine: may decrease methylphenidate levels
- Ozanimod: may increase risk of hypertensive crisis

3.10 Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Blood pressure (BP) and heart rate

Arrange for electrocardiogram (ECG) and cardiology opinion are recommended, only if the patient has any of the following:

- History of congenital heart disease or previous cardiac surgery
- 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
- Chest pain suggestive of cardiac origin
- Signs of heart failure, heart murmur or hypertension
- Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.

- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

3.11 Ongoing monitoring requirements to be undertaken by primary care

Monitoring	Frequency
Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms Weight and appetite Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) Explore whether patient is experiencing any difficulties with sleep	Every 6 months for the first year, after any change of dose and annually thereafter. Note: patients require monitoring every 6 months so monitoring will alternate with the secondary care provider
Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

3.12 Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard .

For information on incidence of ADRs see relevant summaries of product characteristics

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Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Cardiovascular Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
Weight or BMI outside healthy range, Anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87: • Take medication with or after food, not before • Additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • Obtaining dietary advice • Consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Haematological disorders Including leukopenia, thrombocytopenia, anaemia or other alterations NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.	Contact specialist team. Discontinuation should be considered. Referral to haematology may be warranted; use clinical discretion.
Psychiatric disorders New or worsening psychiatric symptoms, e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present Methylphenidate should not be continued unless the benefits outweigh the risks.
Nervous system disorders Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue methylphenidate, refer urgently for neurological assessment

New or worsening seizures	Discontinue methylphenidate. Discuss with specialist team.
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue methylphenidate as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether methylphenidate can be re-started.
Insomnia or other sleep disturbance	Review timing of methylphenidate dose and advice as appropriate. Give advice on sleep hygiene. Discuss with specialist if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

3.13 **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 medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections: seek immediate medical attention.
- Signs or symptoms of serotonin syndrome (e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea)
- Any mood changes, for example. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, anxiety, depression
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory)
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Not to drive or operate machines if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances.
- People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving or
- Avoid alcohol while taking methylphenidate, as it may make side effects worse. Avoid recreational drugs.

- Not to stop taking methylphenidate without talking to their doctor. Medical supervision of withdrawal is required, since this may unmask depression or chronic over-activity.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences .

Patient information:

Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

3.14 Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this **advice rests with both the primary care prescriber and the specialist.**

Pregnancy:

Methylphenidate is not recommended for use during pregnancy unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy.

Evidence on exposure to methylphenidate during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks.

Patients who become pregnant while taking methylphenidate, or who plan a pregnancy, should be referred to the specialist team for review. The specialist will reassume prescribing responsibility, ending the shared care agreement.

Healthcare professional information available from:
https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-METHYLPHENIDATE-IN-PREGNANCY/

Patient information available from: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Methylphenidate/

Breastfeeding:

Methylphenidate has been found in breast milk in small amounts. Evidence for safety in breastfeeding is limited. Decisions to use while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and benefits of therapy. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect. High doses may interfere with lactation, although this is not confirmed in practice.

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Healthcare professional information available from: **https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/**

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

Further information for patients: bumps - Best use of medicines in pregnancy

3.15 Specialist contact information

Name:

Role and speciality:

Daytime telephone:

Email address:

Alternative contact:

Out of hours contact details:

3.16 Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

4 Shared Care Protocol for Lisdexamfetamine in Adult Services

4.1 Background

Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity. It is indicated as part of a comprehensive treatment programme for the treatment of attention deficit hyperactivity disorder (ADHD) when the response to a 6-week trial of methylphenidate treatment is considered clinically inadequate. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Lisdexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

Pharmacological treatment of ADHD may be needed for extended periods. When lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly by a healthcare professional with expertise in ADHD, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy.

4.2 **Indication**

Licensed indication: attention deficit hyperactivity disorder (ADHD) in adults

See SPC for full details of licensed indication.

4.3 **Specialist responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 4.2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and carer, and provide the appropriate counselling (see section 4.13), to enable them to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4.7) and interactions (see section 4.10).
- Conduct required baseline investigations and initial monitoring (see section 4.11).
- Initiate and optimise treatment as outlined in section 4.8. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (section 4.9).
- Once treatment is optimised, complete the shared care documentation and send to patient’s GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 4.16).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 4.11 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 4.12 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

4.4 **Primary care responsibilities**

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 4.8 taking into account any potential drug interactions in section 4.10.

- Prescribe in line with controlled drug prescription requirements (section 4.9).
- Adjust the dose of lisdexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 4.12. Communicate any abnormal results to the specialist.
- Assess for possible interactions with lisdexamfetamine when starting new medicines (see section 4.10)
- Manage adverse effects as detailed in section 4.13 and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

4.5 **Patient and/or carer responsibilities**

- Take lisdexamfetamine as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their GP. Seek immediate medical attention if they develop any symptoms as detailed in section 4.14.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of lisdexamfetamine with their pharmacist before purchasing any OTC medicines.
- Be aware that lisdexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see section 4.14).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs. Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store lisdexamfetamine safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

4.6 **Contraindications and cautions**

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines.
- Glaucoma.
- Symptomatic cardiovascular disease.
- Moderate or severe hypertension.
- Advanced arteriosclerosis.
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment.

- Hyperthyroidism or thyrotoxicosis.
- Agitated states.

Cautions:

- History of substance or alcohol abuse.
- Cardiovascular disorders such as structural cardiac abnormalities, cardiomyopathy, arrhythmias, coronary artery disease, mild hypertension, recent myocardial infarction, or heart failure.
- Family history of sudden cardiac or unexplained death, ventricular arrhythmia, tics or Tourette's syndrome.
- Underlying medical conditions or concomitant drugs which can increase the QT-interval or heart rate, or elevate blood pressure (e.g. cardiac disease, electrolyte disturbance).
- History of seizure disorders (discontinue if seizures occur).
- Susceptibility to angle-closure glaucoma.
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour), tics, Tourette's syndrome, anxiety, or bipolar disorder.
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Severe renal impairment; GFR 15-30mL/min/1.73m2 or CrCl less than 30mL/min. Dose reduction is required, see section 4.8.
- Hepatic insufficiency (due to lack of data).
- Pregnancy or breast-feeding (see section 4.15).
- Potential for abuse, misuse, or diversion.

4.7 Initiation and ongoing dose regimen

- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

30 mg taken once daily in the morning, increased in increments of 20 mg at intervals no shorter than 1 week. Lower starting doses may be used if clinically appropriate (off-label use).

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Maximum 70 mg per day.

Lisdexamfetamine must be prescribed by the initiating specialist during initiation and dose stabilisation.

Conditions requiring dose adjustment:

In severe renal impairment (GFR 15-30mL/min/1.73m2 or CrCl less than 30mL/min), the recommended maximum dose is 50 mg per day.

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. This should be undertaken and supervised by the specialist who will advise the patient and GP of the outcome.

4.8 Pharmaceutical aspects

Route of administration	Oral
Formulation	Lisdexamfetamine dimesylate 30mg 50mg and 70mg hard capsules (Elvanse Adult®) Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®) – use in adults may be considered off-label. See SPC for full details.
Administration details	The dose may be taken with or without food Lisdexamfetamine capsules may be swallowed whole, or the capsule opened and the entire contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. See SPC for further information If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. Afternoon doses should be avoided because of the potential for insomnia
Other important information	Lisdexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of Lisdexamfetamine Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations

4.9 Significant medicine interactions

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following medicines must not be prescribed without consultation with the specialist:

Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect

Other clinically significant interactions

- Selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine, paroxetine): may increase exposure to Lisdexamfetamine, risk of serotonin syndrome
- Serotonergic drugs, bupropion, tapentadol, tramadol: Risk of serotonin syndrome
- Tricyclic antidepressants (TCAs) and nabilone: may increase risk of cardiovascular adverse events.
- Ascorbic acid and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis) that acidify urine increase urinary excretion and decrease the half-life of amfetamine.
- Sodium bicarbonate and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting) that alkalinise urine decrease urinary excretion and extend the half-life of lisdexamfetamine.
- Antihypertensives, including guanethidine: effects may be reduced by lisdexamfetamine
- Lithium, phenothiazines, haloperidol: may reduce the effects of lisdexamfetamine
- Opioids (including tapentadol and tramadol): analgesic effects may be increased by lisdexamfetamine
- Alcohol: Limited data is available, therefore caution is advised as alcohol may exacerbate the CNS side effects of lisdexamfetamine
- Apraclonidine: effects decreased by lisdexamfetamine.
- Ritonavir, tipranavir: may increase exposure to lisdexamfetamine
- Safinamide: predicted to increase the risk of severe hypertension when given with lisdexamfetamine
- Atomoxetine: increased risk of adverse effects

4.10 Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)

Arrange for electrocardiogram (ECG) and cardiology opinion are recommended , only if the patient has any of the following:

- History of congenital heart disease or previous cardiac surgery
- 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
- Chest pain suggestive of cardiac origin
- Signs of heart failure, heart murmur or hypertension
- Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Monitor for aggressive behaviour or hostility
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

4.11 Ongoing monitoring requirements to be undertaken by primary care

See section 4.13 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms • Weight and appetite • Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) • Explore whether patient is experiencing any difficulties with sleep	Every 6 months for the first year, after any change of dose and annually thereafter. Note: patients require monitoring every 6 months so monitoring will alternate with the secondary care provider.
• Assessment of adherence, and for any indication of Lisdexamfetamine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

4.12 Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
New or worsening seizures	Stop treatment and discuss with specialist. Discontinuation may be indicated.
Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, depression, paranoia, anxiety and agitation	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue Lisdexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether Lisdexamfetamine can be re-started.

Suspicion of abuse, misuse, or diversion	Discuss with specialist team

4.13 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 medicines.

The patient and carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- Any visual changes such as difficulty with accommodation or blurring of vision
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient and carer should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Lisdexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including Amfetamines, see drugs and driving: the law. People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving
- Avoid alcohol while taking lisdexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, and fatigue, abrupt withdrawal after a prolonged period of intake of high doses of lisdexamfetamine should be avoided. Patients wishing to reduce their dose or stop Lisdexamfetamine treatment should discuss with their specialist before doing so.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store Lisdexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

4.14 Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

The active metabolite of Lisdexamfetamine, Dexamfetamine, is thought to cross the placenta. The limited data available shows an increased risk of premature birth and preeclampsia. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. The specialist will reassume prescribing responsibility, ending the shared care agreement. Lisdexamfetamine should only be used during pregnancy if the potential benefit outweighs the risks.

Healthcare professional information available from:
https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/

Breastfeeding:

There is no published evidence for safety of lisdexamfetamine in breastfeeding. The manufacturers recommend against use, and the UK Drugs in Lactation Service recommend caution (see link below). Lisdexamfetamine metabolites, including dexamfetamine, are excreted in human milk, therefore a risk to infants cannot be excluded. An individual risk assessment must be made, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Healthcare professional information available from: **https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/**

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

4.15 Specialist contact information

Name:
Role and speciality:
Daytime telephone:
Email address:
Alternative contact:
Out of hours contact details:

4.16 Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed of any changes to the patient's GP or their contact details.

All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

5 Shared Care Protocol for Dexamfetamine in Adult Services

5.1 Background

Dexamfetamine sulfate is a sympathomimetic amine with central stimulant and anorectic activity indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It may be offered as an alternative treatment in patients who have been appropriately diagnosed and whose symptoms are responding to lisdexamfetamine but are unable to tolerate the drug's longer effect profile (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Dexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

Long-term usefulness of dexamfetamine for extended periods (over 12 months) should be periodically re-evaluated by a healthcare professional with expertise in ADHD for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended a trial discontinuation at least once yearly to assess the patient's condition. Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.

5.2 Indication

Attention deficit hyperactivity disorder (ADHD) in adults

(Please note licensed indications vary by manufacturer. See SPCs for full details).

5.3 Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 5.2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 5.14), to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.

- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 5.7) and interactions (see section 5.10).
- Conduct required baseline investigations and initial monitoring (see section 5.11).
- Initiate and optimise treatment as outlined in section 5.8 Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (section 5.9).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 5.16). Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 5.11 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 5.12 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

5.4 Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5.8 taking into account any potential drug interactions in section 5.10.
- Prescribe in line with controlled drug prescription requirements (section 5.9).
- Adjust the dose of dexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 5.12. Communicate any abnormal results to the specialist.
- Assess for possible interactions with dexamfetamine when starting new medicines (see section 5.10)
- Manage adverse effects as detailed in section 5.13 and discuss with specialist team when required.
- Stop dexamfetamine and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

5.5 Patient and/or carer responsibilities

- Take dexamfetamine as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.

- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 5.14.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of dexamfetamine with their pharmacist before purchasing any OTC medicines.
- Be aware that dexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see section 5.14).
- Avoid alcohol while during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Dexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store dexamfetamine safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

5.6 Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines
- Glaucoma
- Phaeochromocytoma
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include; structural cardiac abnormalities and/or moderate or severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)
- Advanced arteriosclerosis
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment
- Hyperthyroidism or thyrotoxicosis.
- Severe depression, anorexia nervosa/anorexic disorders, suicidal ideation, hyperexcitability, psychotic symptoms, severe and episodic (Type I) Bipolar (affective) Disorder (that is not well-controlled), schizophrenia, psychopathic/borderline personality disorder
- Gilles de la Tourette syndrome or similar dystonias
- Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)
- Porphyria
- History of drug abuse or alcohol abuse
- Pregnancy (see section 5.15)

Cautions:

- History of epilepsy (discontinue if seizures occur)
- Mild hypertension, history of cardiovascular disease, or concomitant medications that elevate blood pressure

- susceptibility to angle-closure glaucoma
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, tics, anxiety/agitation, or bipolar disorder
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Renal and hepatic insufficiency (due to lack of data).
- Family history of sudden cardiac or unexplained death or malignant arrhythmia
- Breast-feeding (see section 5.15)
- Potential for abuse, misuse, or diversion.

5.7 Initiation and ongoing dose regimen

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

ADHD: Initially 5 mg twice daily, dose should be increased according to response at intervals no shorter than 1 week.

Dexamfetamine must be prescribed by the initiating specialist during initiation and dose stabilisation.

Maintenance dose (following initial stabilisation):

ADHD and: maximum 60 mg per day to be given in 2–4 divided doses;

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

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. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome.

5.8 Pharmaceutical aspects

Route of Administration	Oral
Formulation	Dexamfetamine sulfate 5mg, 10mg and 20mg immediate release tablets (Amfexa®▼) Dexamfetamine sulfate 5mg immediate release tablets Dexamfetamine sulfate 5mg/5mL sugar-free oral solution▼

	Please note licensed indications vary by manufacturer. See SPCs for full details
Administration details	Tablets can be halved Dexamfetamine should not be taken too late after lunch time to avoid disturbances of sleep If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose
Other important information	Dexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of Dexamfetamine. Dexamfetamine is subject to additional monitoring by the Medicines and Healthcare products Regulatory Agency (MHRA) and healthcare professionals are encouraged to report any suspected adverse reactions Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations

5.9 Significant medicine interactions

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following medicines must not be prescribed without consultation with the specialist:

- Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect
- Clonidine – increased duration of action of Dexamfetamine, reduced antihypertensive action of **clonidine**

Other clinically significant interactions:

- Coumarin anticoagulants, anticonvulsants, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs): metabolism may be inhibited by dexamfetamine. Dose adjustment may be required when starting or stopping dexamfetamine.
- SSRIs (e.g. fluoxetine, paroxetine): may increase exposure to dexamfetamine. Risk of serotonin syndrome.
- Serotonergic drugs, bupropion, tapentadol, tramadol: Risk of serotonin syndrome
- TCAs and nabilone: may increase risk of cardiovascular adverse events.
- Anticonvulsants (e.g. phenobarbital, phenytoin, primidone): Metabolism may be inhibited and absorption may be delayed by dexamfetamine. Dose adjustment may be required when stopping or starting dexamfetamine.
- Antacids (e.g. sodium bicarbonate) and urinary alkalinizing agents (e.g. acetazolamide, some thiazides): may increase exposure to dexamfetamine
- Gastrointestinal acidifying agents (e.g. ascorbic acid, fruit juices) and urinary acidifying agents (e.g. ammonium chloride, sodium acid phosphate): may reduce exposure to dexamfetamine

- Antihistamines: sedative effect may be counteracted
- Antihypertensives, including guanethidine: effects may be reduced by dexamfetamine
- Beta-blockers (e.g. propranolol): risk of severe hypertonia. May reduce effects of dexamfetamine
- Lithium, phenothiazines, haloperidol: may reduce the effects of dexamfetamine
- Disulfiram: may inhibit metabolism and excretion of dexamfetamine
- Opioids: analgesic effects may be increased and the depressant effects (e.g. respiratory depression) may be decreased by dexamfetamine
- Halogenated anaesthetics: risk of sudden blood pressure increase during surgery. Avoid dexamfetamine on the day of planned surgery.
- Cytochrome P450 (CYP450) substrates, inducers or inhibitors: use with caution; role of CYP450 in Dexamfetamine metabolism is not known
- Alcohol: may exacerbate adverse CNS effects of dexamfetamine
- Apraclonidine: effects decreased by dexamfetamine
- Ritonavir, tipranavir: may increase exposure to dexamfetamine

5.10 Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)

Arrange for electrocardiogram (ECG) and cardiology opinion are recommended, only if the patient has any of the following:

- History of congenital heart disease or previous cardiac surgery
- 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
- Chest pain suggestive of cardiac origin
- Signs of heart failure, heart murmur or hypertension
- Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

5.11 Ongoing monitoring requirements to be undertaken by primary care

See section 5.13 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms Weight and appetite Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) Explore whether patient is experiencing any difficulties with sleep	Every 6 months for the first year, after any change of dose and annually thereafter. Note: patients require monitoring every 6 months so monitoring will alternate with the secondary care provider
Assessment of adherence, and for any indication of Dexamfetamine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

5.12 Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

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Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
New or worsening seizures	Stop dexamfetamine and discuss with specialist. Discontinuation may be indicated.
Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, depression, paranoia, anxiety and agitation. NB: psychosis may occur following consumption of very high doses.	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue dexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether dexamfetamine can be re-started.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

5.13 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 medicines.

The patient/carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania, and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.
- The patient/carer should be advised:
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Dexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including amfetamines, see drugs and driving: the law. People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving .
- Avoid alcohol while taking dexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, over-activity, extreme fatigue as well as changes in the EEG during sleep, abrupt withdrawal after a prolonged period of intake of high doses of dexamfetamine should be avoided. Patients wishing to reduce their dose or stop dexamfetamine treatment should discuss with their specialist before doing so.
- Dexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store dexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

5.14 Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Dexamfetamine is not recommended for use during pregnancy The limited data available shows a risk of premature birth and reduced birth weight. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. The specialist will reassume prescribing responsibility, ending the shared care agreement.

Healthcare professional information available from:
https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/

Breastfeeding:

Dexamfetamine is excreted in human milk, therefore a risk to infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from dexamfetamine, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. High doses may interfere with lactation, although this is not confirmed in practice. If breastfeeding does take place, infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect.

Healthcare professional information available from: https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

5.15 Specialist contact information

Name:

Role and speciality:

Daytime telephone:

Email address:

Alternative contact:

Out of hours contact details:

5.16 Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

6 Shared Care Protocol for Atomoxetine in Adult Services

6.1 Background

Atomoxetine is a sympathomimetic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It is an alternative treatment option in patients who cannot tolerate lisdexamfetamine or methylphenidate, or whose symptoms have not responded to separate 6-week trials of lisdexamfetamine or methylphenidate (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Atomoxetine is licensed for use in adults with ADHD of at least moderate severity. Adults should have ADHD symptoms pre-existing from childhood, which should ideally be confirmed by a third party.

Atomoxetine should be used as part of a comprehensive treatment programme, typically including psychological, educational, and social measures.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed.

Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. 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.

6.2 Indications

Licensed indication: attention deficit hyperactivity disorder (ADHD)

6.3 Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 6.2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 6.14), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 6.7) and interactions (see section 6.10).

- Conduct required baseline investigations and initial monitoring (see section 6.11).
- Initiate and optimise treatment as outlined in section 6.8. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 6.16).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 6.11 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 6.12 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

6.4 **Primary care responsibilities**

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 6.8, taking into any account potential drug interactions in section 6.10.
- Adjust the dose of atomoxetine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 6.12. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 6.13 and discuss with specialist team when required.
- Stop atomoxetine and make an urgent referral for appropriate care if cerebral ischaemia or new or worsening seizures occur.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

6.5 **Patient and carer responsibilities**

- Take atomoxetine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber and consider recording adverse effects by using checklist. Seek immediate medical attention if they develop any symptoms as detailed in section 6.14.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of atomoxetine with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if atomoxetine affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 6.14).

- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

6.6 Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF and SPC for comprehensive information.

Contraindications:

- Hypersensitivity to the active substance or to any of the excipients
- During treatment with monoamine oxidase inhibitors (MAOI), or within 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Narrow angle glaucoma
- Severe cardiovascular or cerebrovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, cerebral aneurysm, or stroke
- History of phaeochromocytoma

Cautions:

- Psychiatric and neuropsychiatric symptoms or disorders, including psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, and mania
- Known serious structural cardiac abnormalities; consultation with a cardiac specialist required before treatment
- Underlying medical conditions which could be worsened by increases in blood pressure and heart rate, including hypertension, tachycardia, or cardiovascular or cerebrovascular disease
- Prolonged QT interval (congenital or acquired, e.g. drug-induced) or family history of QT prolongation
- Any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes (risk of orthostatic hypotension)
- Concomitant medications that elevate blood pressure: assess for neurological signs and symptoms at every monitoring visit
- Other conditions that may precipitate or otherwise induce cerebrovascular conditions: assess for neurological signs and symptoms at every monitoring visit
- Hepatic insufficiency; dose adjustments required, see section 6.8.
- History of seizures
- Susceptibility to angle-closure glaucoma
- Age over 65 years; safety and efficacy has not been systematically evaluated
- Known CYP2D6 poor metaboliser genotype. Dose reduction required, see section 6.8.

6.7 Initiation and ongoing dose regimen

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.

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

Initial stabilisation:

- Adults weighing 70 kg or above: 40 mg daily for at least 7 days,
- Adults weighing up to 70 kg: 500 micrograms/kilogram daily for at least 7 days

Then titrated according to clinical response and tolerability. Total daily dose may be given as a single dose in the morning or in two equally divided doses, with the last dose no later than the early evening. The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

- Adults weighing 70 kg or above: 80 mg to 100 mg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 100 mg. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.
- Adults weighing up to 70 kg: up to 1.2 mg/kg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 1.8 mg/kg daily. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment

Hepatic insufficiency:

- moderate hepatic insufficiency (Child-Pugh Class B) reduce starting and target doses to 50% of usual (reduce dose by half, i.e. starting dose should be 20mg daily, and total daily dose should not exceed 50mg daily)
- severe hepatic insufficiency (Child-Pugh Class C) reduce starting and target doses to 25% of usual (reduce dose by three quarters, i.e. starting dose should be 10mg daily, and total daily dose should not exceed 25mg daily)

Renal insufficiency:

No adjustment is necessary, but be aware that atomoxetine may exacerbate hypertension in patients with end stage renal disease.

Known CYP2D6 poor metaboliser genotype:

- Due to several-fold increase in atomoxetine exposure, consider a lower starting dose and slower up-titration.

6.8 **Pharmaceutical aspects**

Route of administration	Oral
Formulation	Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg Atomoxetine hydrochloride 4 mg/mL oral solution
Administration details	Atomoxetine can be taken with or without food. Capsules should not be opened for administration: risk of irritation. Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste. If a dose is missed then take it as soon as possible, but no later than the early evening. Do not take more than the usual total daily dose in any 24 hour period. **A double dose should NOT be taken to make up for a missed dose.**
Other important information:	The initiating specialist will decide the formulation on an individual basis as this will depend on the needs and preferences of the patient.

6.9 **Significant medicine interactions**

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- MAOIs: avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of adverse effects.
- CYP2D6 inhibitors: increased atomoxetine exposure. E.g. selective serotonin reuptake inhibitors (SSRIs), quinidine, terbinafine, bupropion, cinacalcet, dacomitinib, and panobinostat. Slower dose titration and lower final dose may be necessary. Clinical response and tolerability should be re-evaluated if a CYP2D6 inhibitor is started or stopped.
- Potent inhibitors of other cytochrome P450 isoforms in patients who are poor CYP2D6 metabolisers. It is not clear whether there is a clinically significant increase in atomoxetine exposure in this patient group.
- Beta-2 agonists, including salbutamol: high dose beta-2 agonists, such as salbutamol, may potentiate cardiovascular effects.
- Drugs which prolong the QT interval: risk of QT interval prolongation. E.g. antipsychotics, class IA and III anti arrhythmics, some antibiotics such as ciprofloxacin or erythromycin, methadone, mefloquine, tricyclic, antidepressants, lithium, and some selective serotonin reuptake inhibitors (SSRIs) such as citalopram.
- Drugs which cause electrolyte imbalance: risk of QT interval prolongation. E.g. thiazide diuretics.
- Drugs which lower the seizure threshold: risk of seizures. E.g. tricyclic antidepressants, SSRIs, antipsychotics, phenothiazines, mefloquine, chloroquine, bupropion, and tramadol. Use caution when stopping medications that may induce seizures on withdrawal, such as benzodiazepines.
- Anti-hypertensive drugs: effectiveness of anti-hypertensives may be decreased, monitoring is required.
- Drugs that increase blood pressure: possible additive effects, monitoring is required.

- Drugs that affect noradrenaline: possible additive or synergistic pharmacological effects. E.g. dexamfetamine, lisdexamfetamine, imipramine, venlafaxine, mirtazapine, pseudoephedrine, phenylephrine.

6.10 Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A full assessment, as recommended by NICE This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for atomoxetine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Appetite
- Blood pressure (BP) and heart rate

Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:

- history of congenital heart disease or previous cardiac surgery
- 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
- chest pain suggestive of cardiac origin
- signs of heart failure, heart murmur or hypertension current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- including development or worsening of tic and movement disorders
- Assessment of symptom improvement. Discontinue if no improvement is observed after 4-8 weeks.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 6.12 remains appropriate.

6.11 **Ongoing monitoring requirements to be undertaken by primary care**

See section 6.13 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms. Weight and appetite. Assessment for new or worsening psychiatric and neurological signs or symptoms .	Every 6 months for the first year, after any change of dose and annually thereafter. Note: patients require monitoring every 6 months so monitoring will alternate with the secondary care provider
Assessment of adherence, and for any indication of atomoxetine abuse, misuse, or diversion.	As required, based on the patient's needs and individual circumstances
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD.	Annually

6.12 **Adverse effects and other management**

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	**Action for primary care**
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular	Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP
Hypertension	Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see section 6.10). If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice.

Gastrointestinal disorders Including abdominal pain, vomiting, nausea, constipation, dyspepsia	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally resolves.
Weight or BMI outside healthy range, including anorexia or weight loss	Recommend small, frequent meals and/or snacks, and high calorie foods of good nutritional value. Recommend taking atomoxetine with or after meals, and not before. Obtain dietary advice if required. Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medicine may be required.
Psychiatric disorders New or worsening psychiatric symptoms, e.g. suicide related behaviour, psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, or depression	Contact specialist team and refer for psychiatric assessment if appropriate. Refer for urgent psychiatric assessment if suicide related behaviour or ideation occurs. Discuss ongoing benefit of treatment with specialist team.
Hepatic effects Signs or symptoms of liver injury, e.g. abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine	Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team. Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist).
Nervous system disorders Somnolence or sedation	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in late afternoon or early evening). Generally resolves.
New onset of seizures, or increased seizure frequency	Discuss with specialist team. Discontinuation of atomoxetine should be considered.

6.13 **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 medicines.**

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections. If an erection persists for more than 2 hours go to A&E; this is an emergency.

- Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of angle closure glaucoma, seek immediate medical attention, ideally from an eye casualty unit or A&E.
- Symptoms suggestive of cardiac disease (e.g. palpitations, exertional chest pain, unexplained syncope, or dyspnoea).
- New or worsening psychiatric symptoms (e.g. psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania).
- Report suicidal thoughts or behaviour, and development or worsening of irritability, agitation, and depression.
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory).
- Risk of hepatic injury: report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistent abdominal pain.
- Symptoms of allergic or anaphylactic reactions (e.g. rash, angioedema, or urticaria).
- If they suspect they may be pregnant or are planning a pregnancy.

The patient should be advised:

- Not to drive or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or fatigue, and to inform the DVLA if their ability to drive safely is affected. See https://www.gov.uk/adhd-and-driving
- Not to stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.

Patient information:

Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

Patient information leaflets are also available from
https://www.medicines.org.uk/emc/search?q=atomoxetine

6.14 Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy

Atomoxetine is not recommended for use during pregnancy unless a clinical decision is made that the potential benefit outweighs the risk to the foetus.

Evidence on exposure to atomoxetine during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks, and additional monitoring should be considered on a case-by-case basis.

Patients who become pregnant while taking atomoxetine, or who plan a pregnancy, should be referred to the specialist team for review.

Breastfeeding

There is no published evidence on the safety of atomoxetine in breastfeeding. Decisions to use atomoxetine while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and the benefits of therapy. Long half-life in slow metabolisers increases risk of accumulation in some breastfed infants. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite or slow weight gain, sleep disturbances, gastrointestinal symptoms), although these may be difficult to detect.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/atomoxetine/

Paternal exposure

No evidence regarding adverse outcomes following paternal exposure was identified.

6.15 Specialist contact information

Name:

Role and speciality:

Daytime telephone:

Email address:

Alternative contact:

Out of hours contact details:

6.16 Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

7 Shared Care Protocol for Guanfacine in Adult Services

Please note Guanfacine is non-formulary for ADULTS in Hertfordshire and West Essex ICB

7.1 Background

Guanfacine is a centrally-acting adrenergic medicine indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents. Use in adults is off-label, and should only be considered on the advice of a tertiary ADHD service. It may be recommended for people who have not responded to one or more stimulants, and one non-stimulant (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people

with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Guanfacine should be used as part of a comprehensive treatment programme, typically including psychological, educational and social measures.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed.

Long-term usefulness of guanfacine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. 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.

7.2 **Indications**

Attention-deficit hyperactivity disorder ǂ

ǂ Off-label indications – not licensed in adults. See section 7.1 for circumstances where NICE recommend use in adults.

7.3 **Specialist responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 7.2) and communicated to primary care.
- Prior to prescribing guanfacine, obtain advice from a tertiary service on the suitability for the patient.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 7.14), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 7.7) and interactions (see section 7.10).
- Conduct required baseline investigations and initial monitoring (see section 7.11).
- Initiate and optimise treatment as outlined in section 7.8. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 7.14).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 7.11 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 7.12 remains appropriate. Trial discontinuations should be managed by the specialist.

- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

7.4 Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 7.8, taking into any account potential drug interactions in section 7.10.
- Adjust the dose of guanfacine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 7.12. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 7.13 and discuss with specialist team when required.
- Make an urgent referral for appropriate care if suicidal behaviour or ideation, syncope, or other signs or symptoms of cardiovascular adverse effects occur.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

7.5 Patient and carer responsibilities

- Take guanfacine as prescribed and avoid abrupt withdrawal unless advised by their prescriber. Stopping guanfacine suddenly increases the risk of withdrawal effects, so it is important to gradually reduce the dose under medical supervision.
- Attend all monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 7.14.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of guanfacine with their pharmacist before purchasing any OTC medicines.
- Avoid alcohol and grapefruit juice while taking guanfacine, and drink plenty of other fluids.
- Not to drive, cycle, or operate heavy machinery if guanfacine affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 7.14).
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

7.6 Locally agreed off-label use

To be agreed by local ICBs.

7.7 Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to guanfacine or to any of the excipients
- Hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Cautions:

- Risk factors for torsades de pointes: bradycardia, heart block, hypokalaemia, history of QT interval prolongation, concomitant use of other medicines which may prolong the QT interval.
- History of cardiovascular disease, hypotension, orthostatic hypotension, or syncope.
- Family history of cardiac or unexplained death.
- Dehydration (may increase risk of syncope).
- Alcohol consumption (not recommended during treatment).
- Concomitant treatment with centrally acting depressants or antihypertensive (see section 7.10).
- Suicidal ideation or behaviour.
- Prescribing in the elderly is potentially inappropriate. See BNF information on prescribing in the elderly.

7.8 Initiation and ongoing dose regimen

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation

1 mg once daily, adjusted in increments of not more than 1 mg every week, if necessary and tolerated.

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation)

0.05-0.12 mg/kg/day. Maximum dose 7 mg daily.

The initial maintenance dose must be prescribed by the initiating specialist.

Adults who have shown clear benefit from guanfacine in childhood or adolescence may continue treatment into adulthood at the same daily dose.

Conditions requiring dose adjustment

Hepatic or renal insufficiency:

Dose reduction may be required in patients with hepatic impairment, severe renal impairment (GFR 29-15 mL/min), end stage renal disease (GFR <15 mL/min) or in patients requiring dialysis.

Patients taking CYP3A inhibitors or inducers:

A 50% reduction in guanfacine dose is recommended, and further dose titration may be required.

7.9 Pharmaceutical aspects

Route of administration	Oral
Formulation	Guanfacine hydrochloride (Intuniv®▼) Prolonged-release tablets: 1 mg, 2 mg, 3 mg, 4 mg
Administration details	Guanfacine can be taken with or without food, but should not be given with high fat meals due to increased exposure. Tablets should be swallowed whole and not split, crushed or chewed. Guanfacine should be taken once daily in the morning or evening. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. If two or more consecutive doses are missed, re-titration is recommended, a lower starting dose may be required based on the patient's tolerance to guanfacine. Discuss with the specialist team or HCP with expertise in ADHD who conducts the annual review for advice on re-titrating guanfacine.
Other important information	Grapefruit juice should be avoided during treatment with guanfacine. Due to risk of blood pressure increase upon discontinuation, guanfacine should be gradually tapered at a rate of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when discontinuing treatment. Discontinuation should be managed by the specialist team or HCP with expertise in ADHD who conducts the annual review.

7.10 Significant medicine interactions

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Drugs which prolong the QT interval. Concomitant use with guanfacine is not recommended.
- CYP3A4 and CYP3A5 inhibitors, e.g. ketoconazole, clarithromycin, erythromycin, ciprofloxacin, diltiazem, fluconazole, verapamil, grapefruit juice, ritonavir: increased exposure to guanfacine.

Dose reduction may be required, see section 7.8.

- CYP3A4 inducers, e.g. carbamazepine, modafinil, phenytoin, rifampicin, St John's wort: reduced exposure to guanfacine. Dose increase may be required.
- Valproic acid: concomitant use may increase concentrations of valproic acid
- Antihypertensive medicines: risk of additive effects, e.g. hypotension, syncope
- CNS depressants, e.g. alcohol, sedatives, hypnotics, benzodiazepines, barbiturates, antipsychotics: risk of additive effects, e.g. sedation, somnolence

- Administration with high fat meals: increased exposure to guanfacine.

7.11 Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A full assessment, as recommended by NICE guidance for ADHD. This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for guanfacine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
- Height, weight, and body mass index (BMI).
- Blood pressure (BP) and heart rate.

Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:

- history of congenital heart disease or previous cardiac surgery
- 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
- chest pain suggestive of cardiac origin
- signs of heart failure, heart murmur or hypertension
- ECG is recommended if the patient has a co-existing condition treated with a medicine that may increase cardiac risk.

Initial monitoring:

- Weekly monitoring for signs and symptoms of somnolence, sedation, hypotension and bradycardia during dose titration and stabilisation.
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring:

- Before and after every change of dose: assess heart rate and blood pressure.
- Monitoring for signs and symptoms of somnolence, sedation during any dose adjustments or discontinuation.

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 7.12 remains appropriate.

7.12 **Ongoing monitoring requirements to be undertaken by primary care**

See section 7.13 for further guidance on management of adverse effects/responding to monitoring results

Monitoring	Frequency
Blood pressure and heart rate Somnolence and sedation Weight and appetite Signs or symptoms of cardiovascular adverse effects, e.g. syncope, bradycardia Suicidal ideation or behaviour	Every 3 months for the first year, and annually thereafter. Note: patients require monitoring every 6 months so monitoring will alternate with the secondary care provider More frequent monitoring is recommended following dose adjustment, which may be done in primary care if directions have been discussed and agreed with the specialist service.
Assessment of adherence	As required, based on the patient's needs and individual circumstances
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

7.13 **Adverse effects and other management**

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics.

Result	**Action for primary care**
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular	
Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation
Marked decrease from baseline in heart rate	Discuss with specialist team; dose reduction or cardiac evaluation may be required
Hypotension or orthostatic hypotension	Give lifestyle advice (e.g. drinking plenty of fluids, getting up slowly from standing or sitting) and repeat monitoring.

	If blood pressure decreases markedly from baseline, reduce dose by 1mg and discuss with specialist team.
Sedation and somnolence	Sedation and somnolence typically occur during the start of treatment and with dose increases. Review timing of dose; guanfacine may be taken in the morning or evening. Review lifestyle factors, and reinforce that alcohol should be avoided. Seek specialist advice if sedation persists. Dose reduction or discontinuation may be indicated.
Weight or BMI outside healthy range	Provide appropriate support on multicomponent interventions to increase physical activity levels, improve eating behaviour and quality of diet. Discuss with specialist if difficulty persists; dose reduction, or treatment break, or change of medicine may be required.
Psychiatric disorders Suicidal ideation or behaviour	Review patient and exclude other causes. Refer urgently for psychiatric assessment and notify the ADHD specialist team. Consider discontinuing guanfacine.

7.14 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 medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- New or worsening psychiatric symptoms, such as suicidal ideation or behaviour
- Signs and symptoms of bradycardia or hypotension, e.g. fatigue, dizziness, palpitations, feeling faint or fainting

The patient should be advised:

- To drink plenty of fluids; dehydration can increase the risk of falls or fainting.
- Not to drive, cycle, or operate machines if guanfacine affects their ability to do so safely, e.g. by causing dizziness or drowsiness, and to inform the DVLA if their ability to drive safely is affected. See https://www.gov.uk/adhd-and-driving .
- Avoid alcohol while taking guanfacine, as it may make side effects worse.
- Avoid grapefruit juice while taking guanfacine.
- Not to stop taking guanfacine without talking to their doctor. Due to risk of side effects, it is important to gradually reduce the dose of guanfacine under medical supervision.
- To ensure they visit their GP at the required interval

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Patient information

Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=guanfacine

7.15 Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy

Guanfacine is not recommended for use during pregnancy. There are no or limited data from the use of guanfacine in pregnant women, and animal studies have shown reproductive toxicity.

Patients who become pregnant while taking guanfacine, or who plan a pregnancy, should be referred to the specialist team for review.

Breastfeeding

There is no published evidence on the safety of guanfacine in breastfeeding. Decisions on whether to use while breastfeeding should be made on a case-by-case basis with specialist input e.g. UKTIS, taking into account the risks to the infant and benefits of therapy. The long half-life increases the risk of accumulation in breastfed infants. It may interfere with lactation, as guanfacine decreases prolactin levels in the mother. Infants should be monitored for decreased appetite/weight gain, sleep disturbances, gastrointestinal symptoms (e.g. pain, vomiting, constipation), although some of these may be difficult to detect.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/guanfacine/

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

7.16 Specialist contact information

Name:

Role and speciality:

Daytime telephone:

Email address:

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Alternative contact:

Out of hours contact details:

7.17 **Additional information**

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

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8 Appendices

8.1 Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear Click or tap here to enter text.

Patient name:

Date of birth:

NHS Number:

Diagnosis

As per agreed Click or tap here to enter text.shared care protocol for Click or tap here to enter text. for the treatment of Click or tap here to enter text., this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and a I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment

Specialist to complete	Yes	No
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time	☐	☐
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	☐	☐
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	☐	☐
The risks and benefits of treatment have been explained to the patient	☐	☐
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	☐	☐
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	☐	☐
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	☐	☐
I have included with the letter copies of the information the patient has received	☐	☐
I have provided the patient with sufficient medication to last until: Date:……....	☐	☐
I have arranged a follow up with this patient in the following timescale:	☐	☐

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Date:……		

Treatment was started on Click or tap here to enter text. And the current medication is Click or tap here to enter text.

Medicine	Route	Dose & frequency

If you are in agreement, please undertake monitoring and treatment from Click or tap here to enter text.

NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on Click or tap here to enter text. and should be continued in line with the share care guideline.

Please respond to this request for shared care, in writing, within 14days of the request being made where possible.

Yours sincerely

[Name], [Job title],

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8.2 Appendix 2: Shared Care Agreement letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear Click or tap here to enter text.

Patient Click or tap here to enter text.

NHS Number Click or tap here to enter text.

Identifier Click or tap here to enter text.

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from Click or tap here to enter text., and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____ Date: _____

Primary Care Prescriber address/practice stamp

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8.3 Appendix 3: Shared Care Refusal letter (Primary Care Prescriber to Specialist)

Re:

Patient Click or tap here to enter text.

Patient Click or tap here to enter text.

Identifier Click or tap here to enter text.

Thank you for your request for me to accept prescribing responsibility in this patient.

In the interest of patient safely Click or tap here to enter text., in conjunction with local acute trusts have classified Click or tap here to enter text. as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take responsibility due to the following:

		Tick which apply
1	The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because [insert reason]. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.	☐
2	The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you	☐
3	A minimum duration of supply by the initiating clinician As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the	☐

	patient as soon as possible in order to provide them with the medication that you have recommended. Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.	
4	Initiation and optimisation by the initiating specialist As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.	☐
5	Shared Care Protocol not received As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.	☐
6	Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)	☐

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England Responsibility for prescribing between Primary & Secondary/Tertiary Care guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs”. In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Yours sincerely

Primary Care Prescriber signature: _____ Date: _____

9 References

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10 Appendix Policy Team admin to complete ref number: Initial Equality Impact Assessment analysis

This assessment relates to: ADHD Shared Care Version 1.0

(Please tick all that apply)

Link to Full Equality Impact Assessment can be found in InPut Here:

Does this Policy/Service/Function effect one group less or more favourably than another on the basis of:	Yes / No	What / where is the evidence / reasoning to suggest this?
Race, Ethnic Origins, Nationality (including traveling communities)	No	
Sex (Based on Biological Sex; Male, Female or Intersex)	No	
Age	No	
Sexual Orientation Including the LGBTQ+ Community	No	
People who are Married or are in a Civil Partnership	No	
People who are Pregnant or are on Maternity / Paternity Leave	No	

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Does this Policy/Service/Function effect one group less or more favourably than another on the basis of:	Yes / No	What / where is the evidence / reasoning to suggest this?
People who are Transgender / who have had gender reassignment treatments As well as gender minority groups	No	
Religion, Belief or Culture Including an absence of belief	No	
Disability / Mental, Neurological or Physical health conditions Including Learning Disabilities	No	
Other Marginalised or Minority Groups Carers, Low Income Families, people without a fixed abode or currently living in sheltered accommodation.	No	

Guidance on Completing this Document

This screening tool asks for evidence to ensure that these considerations are done in collaboration with groups that may be affected. Listed below are the ways that this evidence can be gathered to support this decision:

- Reviews with Staff who may be impacted by these changes
- Service User / Carer feedback or focus groups
- Guidance from national organisations (CQC / NHS Employers)
- The Equality and Inclusion Hub (on the Staff Intranet)
- Input from Staff Equality Networks or the Equality Advisor
- Reviewing this against good practice in other NHS Trust

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Initial Screening Question	Response
If you have identified no negative impacts, then please explain how you reached that decision. please provide / attach reference to any reasoning or evidence that supports this: (Nature of policy, service or function, reviews, surveys, feedback, service user or staff data)	No impact on any particular group.
Is there a need for additional consultation? (Such as with external organisations, operational leads, patients, carers or voluntary sector)	Not applicable
Can we reduce any negative impacts by taking different actions or by making accommodations to this proposed Policy / Service / Function?	Not applicable
Is there any way any positive impacts to certain communities could be built upon or improved to benefit all protected characteristic groups?	Not applicable
If you have identified any negative impacts, are there reasons why these are valid, legal and/or justifiable?	Not applicable

Please complete this document and send a copy to EPUT's Compliance, Assurance & Risk Assistant / Trust Policy Controller) at **epunft.risk@nhs.net** as part of the Approval Process, if this proposal / policy etc. has no positive or negative impacts on protected characteristic groups, a Full Equality Impact Assessment will not need to be completed

To be completed by the Trust Policy Controller		
Is a Full Equality Impact Assessment Required for this Policy, Service or Function?	Yes	No
Name:		
Date:		

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