Essential Shared Care Agreement (South Staffordshire): Methylphenidate (immediate release and long acting), Lisdexamfetamine, and Atomoxetine for Attention Deficit Hyperactivity Disorder (ADHD) in Children & Adolescents

Please complete the following details:
Patient's name, address, date of birth, preparation, dose and date below:
Prescribing professional's contact details (p.3)
And send One copy to:
-the patient's GP
-put one copy in care plan
-give one copy to the patient

Patient's name:	
Patient's address:	
Patient's Date of Birth:	
Preparation & Dose:	
Date sent:	

Note:
Guidelines will only be written when it has been agreed that shared care is or maybe an appropriate option in individual cases, and will include a statement of Specialist Unit /GP responsibilities.

Shared Care Guidelines will ensure that all GPs have sufficient information to enable them to undertake responsibility for specialist therapies and other therapies which may affect/interact with specialist therapies.

It is not the intention to insist that GPs prescribe such a therapy and any doctor who does not wish to undertake the clinical and legal responsibility for a Shared Care Drug is not so obliged. Acceptance of the Shared Care Guidelines will be endorsed by the medicines management departments of the CCG

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The information contained in this guideline is issued on the understanding that it is the best available from the resources at our disposal at the time of issue. For further information please refer to the relevant Summary of Product Characteristics and NICE guidance or contact your local Specialist or Drug Information Centre.

Further copies of this guideline may be obtained from:

- South Staffordshire & Shropshire Healthcare Foundation NHS Trust
- South Staffordshire CCGs' Prescribing Advisers.

Produced: May 2016
Review date: May 2018
This ESCA replaces E034

SHARED CARE GUIDELINES FOR ADHD MEDICINES IN CHILDREN & ADOLESCENTS (Children of 6 years of age and older)

BACKGROUND

ADHD is a neuro-developmental condition which manifests as cognitive and behavioural deficits. It is characterised by the core symptoms of hyperactivity, impulsivity and inattention. ADHD is thought to be a persistent condition and a diagnosis of ADHD should only be made by specialist psychiatrist or appropriately qualified healthcare professional, in a multi-disciplinary setting, with training and expertise in the diagnosis of ADHD.
Drug treatments for ADHD should always form part of a comprehensive treatment programme that focuses on psychological, behavioural and educational needs.

SHARED CARE CRITERIA

- Prescribing responsibility will only be transferred when it is agreed by the prescribing professional and the General Practitioner (GP) that the patient's condition is reasonably predictable and the treatment regime has been specified.
- When initiation is by the Trust, the patient will receive supplies of ADHD medication (e.g. Methylphenidate, Lisdexamfetamine, Atomoxetine) on a hospital or community prescription form until shared care is agreed.
- The patient will have an individual care programme defined for them and the GP will receive a copy of this. A named key professional will have been organised and the appropriate health team input organised.

RESPONSIBILITIES

Specialist service's responsibilities

- Assess the patient, establish a diagnosis and determine a management strategy to include the establishment of a Care Programme Approach and where appropriate and accessible involvement of the CPN/community mental health teams/community paediatric teams.
- Initiate methylphenidate, lisdexamfetamine or atomoxetine after pre-treatment screening and stabilise patient on maintenance dose. Communicate to GP which brand of methylphenidate long acting is prescribed, as different brands are not interchangeable Prescribing must be in compliance with Trust formulary, unless a clear rationale is documented and later communicated with the GP.
- Discuss the benefits and side effects of treatment with the patient (including CSM advice in relation to hepatic disorders and suicidal ideation with atomoxetine).
- Send a letter to the GP suggesting that the patient's condition now seems appropriate for a shared care approach, and that shared care is assumed to be formally agreed for this patient, unless written refusal is received within two weeks. Confirm the reason for the use of a second-line medication (if Lisdexamfetamine or Atomoxetine) and that prescribing complies with NICE guidance.

- The patient will receive a sufficient supply of methylphenidate/ lisdexamfetamine/ atomoxetine from the hospital to allow the GP time to consider shared care.
- As appropriate, on-going monitoring, using centile and growth charts, monitor the patient's blood pressure, and pulse (e.g. before and after each dose change and 6-monthly, and growth parameters (height and weight, minimum 6 monthly) and psychiatric symptoms.
- Communicate promptly with the GP when treatment is changed, and ensure test results are communicated to GP.
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
- Agree a medication review date with the GP and give advice on stopping treatment or drug holidays.
- Report adverse events to the MHRA via Yellowcard located in BNF or online www.yellowcard.gov.uk and GP.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.
- Evaluation of adverse events reported by the GP, and identification of any specific monitoring required.

General Practitioner (GP)

- Reply to the request for shared care as soon as practicable by faxing back the signed agreement at Annex A.
- Monitor the patient's overall health and well-being.
- Prescribe methylphenidate/ lisdexamfetamine or atomoxetine at the dose recommended.
- Adjust the dose as advised by the specialist.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to the specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Look out for signs of diversion (transfer of the medicine from the individual for whom it was prescribed to one for whom it is not prescribed), misuse, and abuse of methylphenidate/ lisdexamfetamine.
- Adverse drug reaction/interaction monitoring. Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease during methylphenidate/ lisdexamfetamine treatment should undergo prompt specialist cardiac evaluation
- Report adverse events to the specialist and CSM.
- Keep the key worker/mental health team informed of progress.
- Inform specialist of all relevant medical information regarding the patient and any changes to the patient's medication irrespective of indication.
- Report adverse events to the prescribing professional and the MHRA/ CSM via Yellowcard located in BNF or online www.yellowcard.gov.uk.
- Communicate any test results to prescribing professional.

Patient

- Report to the prescribing professional or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with methylphenidate, lisdexamfetamine and atomoxetine.
- Inform prescribing professional or GP of any other medication being taken, including over-the-counter products.
- Report any adverse effects or warning symptoms to the prescribing professional or GP whilst taking methylphenidate, lisdexamfetamine and atomoxetine.

Back-up advice on the above is available at all times:
South Staffordshire & Shropshire Healthcare Foundation NHS Trust – Contact Details

Contact	Speciality	Available	☎	Out of Hours
		Mon-Fri 8.30 – 5.00		

LICENSED INDICATIONS

Methylphenidate, Lisdexamfetamine and Atomoxetine are indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age or over, but lisdexamfetamine is only indicated when response to previous methylphenidate treatment is considered clinically inadequate. Both Lisdexamfetamine and atomoxetine are second line to Methylphenidate on the Trust formulary. **Methylphenidate** is a schedule 2 **controlled drug (CD**) and Lisdexamfetamine is expected to be classified as a **Schedule 2 controlled drug**. Thus both should be treated as subject to prescription requirements. Hence prescriptions may be hand written with indelible ink, signed and dated by the prescriber with their address and must always state in the prescriber's own handwriting: name and address of patient; form and strength of preparation (e.g. 20mg capsules); the dose (e.g. 20mg TDS) and total quantity or number of dose units in words **AND** figures (e.g. 420mg = Four Hundred and Twenty milligrams or Twenty One (21) capsules). Alternatively where computer generated prescriptions for controlled drugs are issued, only the signature has to be in the prescriber's own handwriting. A prescription can be given for a maximum of 28 days.

DOSE AND ADMINSTRATION

Refer to most current BNF (section 4.4)

ADVERSE EFFECTS

For a full list see manufacturer's Summary of Product Characteristics (SPC) www.medicines.org.uk and also current BNF www.bnf.org/bnf.

Adverse Effect	**Frequency**	**Management**
Methylphenidate		
Nervousness and insomnia	>10%	Review dose and/or omit afternoon/
Decreased appetite	1-10%	Usually transient. Try taking medicine
Headache, drowsiness, dizziness	1-10%	
Abdominal pain, nausea & vomiting, dry mouth	1-10%	Occurs at initiation. May be alleviated by concomitant food intake.
Tachycardia, palpitations, increased blood pressure	1-10%	Discontinue if significant. Refer back to prescribing professional
Tic, aggression, anxiety, irritability	1-10%	Discontinue if significant (N.B dose titration should be slower if tics/seizures are already present). Refer back
Drug induced psychosis (e.g hallucinations, restlessness), depression, mood swings	<1%	Discontinue. Refer back to prescribing professional
Lisdexamfetamine		
Adverse Effect	**Frequency**	**Management**

Decreased appetite, insomnia, headache, dry mouth (adult), upper abdominal pain (6-12 yr), weight decreased (6-17 yr	≥10%	Refer back to prescribing professional
Anorexia, tic (6-12 yr), affect lability (6-17yr), psychomotor hyperactivity (6-12yr), aggression (6-12yr), dizziness, tremor (13-17yr), somnolence (6-12yr), mydriasis (6-12yr), tachycardia (13-17yr), palpitation (13-17 yr), dyspnoea (13-17yr), dry mouth (6-17yr), diarrhoea, upper abdominal pain (13-17yr), nausea, vomiting, (6-17yr), rash (6-12yr), irritability, fatigue, pyrexia (6-12yr), increased blood pressure (13-17yr). See full SPC for list of side effects which are uncommon/rare or where the frequency was not known.	≥ 1%	Reduce dose, ensure not given too near bedtime. Discontinue if tics develop. Withdraw drug. Refer back to prescribing professional Check pulse after every dose change. Do an ECG if necessary

Atomoxetine		
Appetite decreased, dry mouth, nausea	>10%	Usually settles after 1st month of
Insomnia	>10%	
Abdominal pain, constipation, dyspepsia, flatulence,	1-10%	
Weight decrease	1-10%	Usually settles after initial weight loss
Palpitations, tachycardia,	1-10%	
Libido decreased, sleep disorder, dizziness, sinus headache, tremor, fatigue, lethargy	1-10%	
Dysuria, urinary hesitation, urinary retention	1-10%	
Dysmenorrhoea, ejaculation disorder, erectile dysfunction, irregular menstruation, male genital pain,	1-10%	
Blood pressure increased	0.1-1%	Monitor. Discontinue if clinically indicated
Liver toxicity	0.001-0.1%	Discontinue drug. Refer back to
Post-Marketing Experience Spontaneous Reports (Atomoxetine)		
Suicide-related events, aggression, hostility and emotional lability, psychosis (including hallucinations),agitation, Seizure, QT interval prolongation, Abnormal liver function tests, jaundice, hepatitis	Not stated	

CAUTIONS

Methylphenidate: Psychiatric disorders, anxiety or agitation, tics or family historyof Tourette syndrome, drug or alcohol dependence, epilepsy or history of seizures, avoid abrupt withdrawal.

Lisdexamfetamine: Anorexia, history of cardiovascular disease or abnormalaties, psychosis or bipolar disorder, A history of substance abuse or dependence, may lower seizure threshold, tics and Tourette syndrome, Avoid abrupt withdrawal, acute porphria

Atomoxetine: Cardiovascular disease, including hypertension and tachycardia, structural cardiac abnormalities, QT interval prolongation, psychosis/mania, history of seizures, aggressive behaviour/hostility/emotional lability, hepatic impairment,

CONTRAINDICATIONS

Methylphenidate: Severe depression,suicidal ideation, anorexia nervosa, psychosis, uncontrolled bipolar disorder, hyperthyroidism, cardiovascular disease including heart failure, cardiomyopathy, severe hypertension, and arrhythmias, structural cardiac abnormalities, phaeochromocytoma, vasculitis, cerebrovascular disorders, During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs

Lisdexamfetamine: hypersensitivity to sympathomimetic amines or any of the excipients: concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days after MAOI treatment, hyperthyroidism or thyrotoxicosis, agitated states, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension, glaucoma.

Atomoxetine: Concomitant use or use within 2 weeks of MAOI, phaeochromocytoma.

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To be done in accordance with NICE recommendations:

Appetite, Weight & Height: Appetite, weight and height to be measures at baseline, and then after each dose adjustment or as a minimum at 3rd and 6th month after initiation and six monthly thereafter.

Heart rate and Blood pressure: Chart before and after each dose change and routinely every six months. Sustained resting tachycardia, arrhythmia or clinically significant high systolic blood pressure after two measurements, consider dose reduction and referral.

Sexual dysfunction: Erectile and ejaculatory dysfunction also dysmenorrhoea should be monitored as potential side effects of atomoxetine.

Psychiatric: Monitor for suicidal thoughts and behaviour, irritability, aggressive or hostile behaviour, agitation or depression

REFERENCES

1. NICE Clinical guideline 72; Attention Deficit Hyperactivity Disorder; Sep 2008
2. BNF – September 2015- March 2016.
3. http://www.medicines.org.uk

Annex A

South Staffordshire and Shropshire Healthcare NHS
NHS Foundation Trust
A Keele University Teaching Trust

Shared Care Agreement for ADHD in Children and Adolescents

Name of Prescriber:

Specialist Area:

Telephone Number:

Fax Number:……

Signature: Date:

Patient's Name:

Address:

Drug and dose:

Name of GP:

Signature: Date:

Practice Address