Effective Shared Care Agreement (ESCA)

Dexamfetamine (as Amfexa®▼)

Approved for Solihull locality only. **(from age 6 years) [unlicensed in adults]**

ESCA: For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of dexamfetamine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary.
2. Specialist assessment and confirmation of the diagnosis of attention deficit/hyperactivity disorder.
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
5. Do baseline monitoring prior to initiation of this agent: • weight, blood pressure, pulse and essential medical history, cardiovascular examination and ECG where indicated. • full mental health and social assessment, full history and physical examination, family history of cardiac disease and an ECG if there is past medical and/or family history of cardiac or cerebrovascular problems. • risk assessment for substance misuse and potential for drug diversion.
6. Initiate treatment and stabilise dose of Dexamfetamine (as Amfexa®).
7. Dexamfetamine is a Schedule 2 Controlled Drug (CD), therefore should be prescribed in line with the Misuse of Drug Regulations. Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 days per prescription.
8. Advise the patient on the importance of good adherence with the prescribed medication. Check adherence at each clinic appointment.
9. Review the patient's condition and response to treatment every 6 months. Advise patients, families/ carers to report any side effects and/ or concerns. At 6 monthly reviews (unless otherwise indicated): • Monitor efficacy of long term treatment and consider whether benefit can be gained from continued treatment. • Monitor height, weight, appetite, heart rate and BP and any psychiatric symptoms. • Request any further investigations that are clinically indicated such as ECG, blood investigations. • Assess progress with regards to psychological, behavioural, educational and occupational needs. • Assess ongoing need for medication. • Assess any side effects. • Consider the potential for drug diversion and potential for misuse.
10. Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
11. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
12. Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.
13. Advise GP on the management of side effects and raise awareness at which point these will be reviewed and/ or managed by the specialist.
14. Advise the GP when to stop treatment and on management of discontinuation if necessary.
15. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
16. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Ensure: • Patient/ family are clear who will be responsible for monitoring and what this will entail. • Patient/ family are aware of any significant adverse effects/ events, which should be urgently reported and who these should be reported to. (GP/ specialist).						
3. Prescribe dexamfetamine (as Amfexa®) at the dose recommended.						
4. Dexamfetamine is a Schedule 2 Controlled Drug (CD), therefore should be prescribed in line with the Misuse of Drug Regulations. Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 days per prescription.						
5. Adjust the dose as advised by the specialist.						
6. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
7. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist.						
8. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment.						
9. Refer back to specialist if condition deteriorates.						
10. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.						
11. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
12. Stop treatment on advice of specialist.						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment.
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with dexamfetamine (as Amfexa®) with the specialist, clinical nurse specialist or GP.
4. Report any adverse effects to the specialist or GP whilst taking dexamfetamine (as Amfexa®).
5. Attend regular outpatient appointments with the specialist.
6. Female patient: Inform the specialist, clinical nurse specialist or GP if she becomes or wishes to become pregnant.

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Indication	Dexamfetamine is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate			
Dosage and Administration	The recommended starting daily dose is 5mg once or twice daily (e.g. at breakfast and lunch), increasing if necessary by weekly increments of 5mg in the daily dose according to tolerability and degree of efficacy observed. In the treatment of hyperkinetic disorders / ADHD, the times at which the doses of dexamfetamine 5 mg tablets are administered should be selected to provide the best effect when it is most needed to combat school and social behavioural difficulties. Normally the first increasing dose is given in the morning. Dexamfetamine 5 mg tablets should not be taken too late after lunch time to avoid disturbances of sleep. The regimen that achieves satisfactory symptom control with the lowest total daily dose should be employed. The maximum daily dose in children and adolescent usually is 20 mg, although doses of 40 mg may in rare cases be necessary for optimum titration. The decision to give dexamfetamine once or twice daily should be based on the course of symptoms at different times of the day. *Use in Adults* Dexamfetamine (Amfexa®) Tablets are not licensed for use in adults. The safety and efficacy of dexamfetamine in adults have not been established.			
	Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary.			
Renal Impairment **Hepatic impairment**	There is no experience with the use of dexamfetamine in patients with renal or hepatic insufficiency. In these patients peak plasma levels could be higher and elimination could be prolonged. Thus, dexamfetamine should be used with special caution in this patient group by taking care of titration and dosage.			
Contra-indications / Special precautions Please refer to SPC for full list- link under references.	•Known hypersensitivity to the active substance or any of the excipients •Known hypersensitivity to sympathomimetic amines •Glaucoma •Phaeochromocytoma •Symptomatic cardiovascular disease, 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			
Side Effects	Very common	Insomnia, nervousness, decreased appetite, reduced weight gain and weight loss during prolonged use in children.		
	Common	Abdominal pain and cramps, nausea, vomiting, dry mouth, abnormal behaviour, aggression, excitation, anorexia, anxiety, depression, irritability, vertigo, dyskinesia, headache, hyperactivity, arrhythmia, palpitations, tachycardia, changes in blood pressure and heart rate (usually increases), arthralgia		
	Adverse effect		**Frequency**	**Action to be taken**
	Aggressive behaviour, anxiety, confusion, delirium, depression, euphoria, insomnia, irritability, tics, night terrors		Not stated	Reduce dose, ensure not given too near bedtime. Discontinue if tics develop. Refer back to consultant
	Paranoia, psychosis		Not stated	Withdraw drug. Refer back to consultant.
	Palpitations, tachycardia, change in blood pressure, cardiomyopathy, chest pain, death due to cardiovascular collapse		Not stated	Not stated. Check pulse after every dose change. Do an ECG if necessary
	Abdominal pain and cramps, nausea, vomiting, dry mouth		Common	These effects usually occur at the beginning of treatment and may be alleviated by concomitant food intake

<table>
<tr><td rowspan="8">Monitoring</td><td>Pre-treatment assessment</td><td colspan="3">Prior to prescribing, it is necessary to conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart.</td></tr>
<tr><td>After commencing treatment</td><td colspan="3">Growth, psychiatric and cardiovascular status should be continuously monitored.
• Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months;
• Height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart;
• Development of de novo or worsening of pre-existing psychiatric disorders, including depression and aggressive behaviour, should be monitored at every adjustment of dose and then at least every 6 months and at every visit.
Patients should be monitored for the risk of diversion, misuse, and abuse of dexamfetamine</td></tr>
<tr><td colspan="4">Actions to be taken:</td></tr>
<tr><td>Parameter</td><td>Frequency of monitoring</td><td>Action</td><td>By Whom</td></tr>
<tr><td>Weight gain</td><td>3 – 6 monthly</td><td>Failure to gain weight appropriately - may require withdrawal.</td><td rowspan="3">Specialist at regular reviews. (If specialist review >6 monthly, GP may be requested to carry out monitoring) For some patients GP may be asked to carry out BP monitoring between appointments.</td></tr>
<tr><td>Blood pressure</td><td>3 – 6 monthly</td><td>Monitor whilst taking medication to ensure within published range for age of child.</td></tr>
<tr><td>Growth Development</td><td>3 – 6 monthly</td><td>If adversely affected consideration should be given to dose reduction or interrupting therapy in those on long-term treatment.</td></tr>
<tr><td>Full Blood Count</td><td>Only if blood dyscrasia suspected</td><td>Manufacturers recommend periodic blood tests to detect haematological abnormality, but we are aware of no evidence for this practice and think that the remote chance of benefit is usually outweighed by the unpleasantness for the child [Ref. Eur Child Adolesc Psychiatry 2004;13 Suppl 1:I7-30.]</td><td>Low threshold for investigation e.g. if recurrent infections or purpuric rash occur</td></tr>
<tr><td>Drug Interactions (significant interactions as outlined in BNF, please see BNF and SPC for more detail)</td><td colspan="4">Chlorpromazine - Dexamfetamine possibly antagonises antipsychotic effects of chlorpromazine Guanethidine - Dexamfetamine antagonises hypotensive effect of guanethidine
MAOIs - Risk of hypertensive crisis when dexamfetamine given with MAOIs, avoid dexamfetamine for at least 2 weeks after stopping MAOIs
Ritonavir - Plasma concentration of dexamfetamine possibly increased by ritonavir</td></tr>
</table>

References

1. NICE Quality Standard QS39; Attention Deficit Hyperactivity Disorder; July 2013.
2. NICE Clinical Guideline CG72: Attention deficit hyperactivity disorder: diagnosis and management; Sept 2008.
3. Summary of product characteristics for Dexamfetamine (Amfexa®) accessed 17/10/2016 via www.medicines.org.uk.
4. BNF for children
5. Worcester prescribing Committee. Shared Care Guidelines for Methylphenidate (immediate release and long acting), Dexamfetamine and Atomoxetine and Lisdexamfetamine for Attention Deficit Hyperactivity Disorder (ADHD) in Children, Adolescents and Adults. 2014
6. ADHD Institute; European guidelines. Eur Child Adolesc Psychiatry 2004; 13 Suppl 1:I7-30.
7. CurleyM. & Vaughan S. (1987) Assessment and resuscitation of the paediatric patient. Critical care nurse Vol7.No 3.pages 26-7,30-4,36

Appendix 1:

Effective Shared Care Agreement (ESCA)

Dexamfetamine (as Amfexa®▼)

(from age 6 years) [unlicensed in adults]

Approved for Solihull CCG only.

For the treatment of Attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate.

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Transitioning patients Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary	Adult service consultant to tick and sign please

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with dexamfetamine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care