

EFFECTIVE SHARED CARE AGREEMENT (ESCA)

DRUG NAME: **LICENSED MEDICATIONS FOR ADHD**
INDICATION/S COVERED: **Attention Deficit Hyperactivity Disorder
(ADHD) in Children**

Traffic Light system classification: Amber

N.B. The eligibility criteria included here apply to new patients commencing treatment under this agreement & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

NOTES to the primary care prescriber

Amber drugs: Prescribing to be initiated by a consultant / specialist but with the potential to transfer to primary care. The expectation is that this agreement should provide sufficient information to enable primary care prescribers to be confident to take clinical and legal responsibility for prescribing these drugs.

The questions below will help you confirm this:

- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this effective shared care agreement?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this ESCA), then it is appropriate for you to accept prescribing responsibility. Sign and return a copy of the final page to the requesting consultant / specialist. Until the requesting consultant / specialist has received a signed copy of the final page indicating that shared care has been agreed all care (including prescribing) remains with the consultant / specialist.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant / specialist within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, which will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your Medicines Management pharmacist will assist you in making decisions about shared care.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The patient's best interests are always paramount

The primary care prescriber has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant

Information

Methylphenidate, dexamfetamine and lisdexamfetamine are controlled drugs that need monitoring for potential abuse or diversion. Prescriptions should usually be restricted to 28 days.

This information sheet does not replace the Summary of Product Characteristics (SPC), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

1. Link to the relevant SPC website:

Methylphenidate:

Concerta XL:

<https://www.medicines.org.uk/emc/search?q=%22Concerta%22>

Matoride XL:

<https://www.medicines.org.uk/emc/search?q=%22Matoride%22>

Xaggitin XL

<https://www.medicines.org.uk/emc/product/2704>

Equasym XL:

<https://www.medicines.org.uk/emc/search?q=%22Equasym%22>

Medikinet Tablets:

<https://www.medicines.org.uk/emc/search?q=%22Medikinet%22>

Medikinet XL tablets

<https://www.medicines.org.uk/emc/search?q=%22Medikinet%22>

Ritalin:

<https://www.medicines.org.uk/emc/product/1035>

Dexamfetamine:

Immediate release:

<https://www.medicines.org.uk/emc/search?q=%22Dexamfetamine+%22>

Lisdexamfetamine:

<https://www.medicines.org.uk/emc/search?q=%22lisdexamfetamine+dimesylate%22>

Atomoxetine:

<https://www.medicines.org.uk/emc/search?q=%22atomoxetine+hydrochloride%22>

2. Background to use for the indication/s, including licence status

Methylphenidate, Dexamfetamine and Lisdexamfetamine:

Methylphenidate, dexamfetamine, and lisdexamfetamine are stimulant drugs used in the treatment of severe Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD) and Hyperkinetic Disorder (HKD) as part of a comprehensive treatment approach when remedial measures alone prove insufficient. Methylphenidate is licensed in children of 6 years old and over.

Lisdexamfetamine is licensed in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. Lisdexamfetamine therapy is indicated by Sussex Partnership Trust and Costal West Sussex Clinical Commissioning Group after the trial of at least two preparations of modified release methylphenidate, unless a previous adverse reaction to methylphenidate has ruled out further use.

Atomoxetine:

Atomoxetine is licensed for the treatment of attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over, and in adolescents as part of a comprehensive treatment plan.

(Comprehensive treatment programme – defined to include psychological, education & social measures).

3. Dose & administration

Methylphenidate:

Plain – Ritalin® and Medikinet®: Child over 6 years initially 5mg once or twice daily e.g. with or after breakfast and lunch, increasing if necessary in weekly intervals of 5-10mg up to a maximum of 60mg per day in 2 to 3 divided doses.

In some children rebound hyperactivity may occur if the effect of the drug wears off in the evening. An additional dose later in the day may eliminate this difficulty but may disturb sleep.

Matoride XL®, Xaggitin XL® & Concerta XL®: Child over 6 years initially 18mg once daily (in the morning), increasing if necessary in weekly increments of 18mg up to a maximum of 54mg once daily.

Note: Total daily dose of 15mg of standard release formulation is considered equivalent to Matoride XL[®], Xaggitin XL[®] Concerta XL[®] 18mg once daily. 60mg of Ritalin[®] or Medikinet[®] is the maximum licensed dose. The equivalent dose of Matoride XL[®], Xaggitin XL[®] and Concerta XL[®] is 72mg, which is above the maximum licensed dose.

Equasym XL[®]: Child over 6 years, initially 10mg once daily (in the morning before breakfast), increasing if necessary in weekly intervals to a maximum of 60mg daily.

Medikinet XL[®]: Child over 6 years, initially 10mg once daily (in the morning with breakfast), adjusted according to response at weekly intervals to a maximum of 60mg daily.

Dexamfetamine (Amfexa[®] & generic versions):

The usual starting dosage for children aged 3-5 years is 2.5mg a day, increased if necessary by 2.5mg a day at weekly intervals; for children aged 6 years and over, the usual starting dose is 2.5mg 2 to 3 times per day increasing if necessary by 5mg per day at weekly intervals. The usual upper limit is 20mg a day though some older children have needed 40mg or more for optimal response. Maintenance dose should be given in 2 to 4 divided doses.

Lisdexamfetamine (Elvanse[®]):

Lisdexamfetamine is a pro-drug formulation of dexamfetamine, which is converted to free dexamfetamine by enzymes present on red blood cells. The starting dose in children of 6 years and over is 30mg once daily taken in the morning, which can be increased in dose by 20mg increments at minimum intervals of one week up to a maximum of 70mg once daily.

Atomoxetine:

Atomoxetine is licensed in children from the age of 6 years.

Dosing in children/adolescents up to 70kg body weight:

Initially a total daily dose of approximately 0.5mg/kg per day. This should be maintained for a minimum of 7 days, before titrating upwards according to clinical response and tolerability. Maintenance dose is approximately 1.2mg/kg per day (depending on the patient's weight and available dosage strengths of atomoxetine).

No additional benefit has been demonstrated for doses higher than 1.2mg/kg/day. The safety of doses above 1.8mg/kg has not been systematically evaluated.

Dosing of children/adolescents over 70 kg body weight:

Initial dose of 40mg per day. This should be maintained for a minimum of 7 days, before titrating upwards according to clinical response and tolerability. Maintenance dose is 80mg per day.

Maximum licensed dose is 100mg/day; however no additional benefit has been demonstrated for doses higher than 80mg. The safety of single doses over 120mg and total daily doses above 150mg have not been systematically evaluated.

Notes:

- Atomoxetine should be administered as a single daily dose in the morning with or without food.
- For adolescents whose ADHD symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. However, start of treatment with atomoxetine in adults is not appropriate.

4. Cautions

Methylphenidate, Dexamfetamine, and Lisdexamfetamine:

Cardiovascular:

The use of stimulants of the central nervous system has been associated in reports of sudden death at usual doses in children, some of whom had structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone may carry an increased risk of sudden death, stimulant products are not recommended in children or adolescents with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant medicine.

If consideration is being given for a patient to commence stimulant therapy they should have a careful history (including assessment for a family history of sudden cardiac or unexplained death or malignant arrhythmia) and a physical examination to assess for the presence of cardiac disease. Such patients should receive further specialist cardiac evaluation if initial findings suggest such history or disease. If a patient develops symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other symptoms

suggestive of cardiac disease during stimulant treatment they should undergo a prompt specialist cardiac evaluation.

Stimulant clinical trial data analyses in children and adolescents with ADHD witnessed that patients using such medications may commonly experience changes in diastolic and systolic blood pressure of over 10 mmHg relative to controls. The clinical consequences of these cardiovascular effects in children and adolescents are not known.

Caution is advised in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate.

Cardiovascular status should be carefully monitored. Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months.

Psychiatric:

Stimulants should be used with caution in patients with history of tics, Tourette's syndrome and porphyria. In psychotic children, stimulants may exacerbate behavioural disturbances and thought disorder.

Treatment emergent psychotic or manic symptoms, e.g. hallucinations, delusional thinking or mania in children or adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant and discontinuation of treatment may be appropriate.

Patients with new onset suicidal ideation or behaviour during stimulant treatment for ADHD should be evaluated immediately by their physician. Consideration should be given to the exacerbation of an underlying psychiatric condition and to a possible causal role of stimulant therapy. Treatment of an underlying psychiatric condition may be necessary and consideration should be given to a possible discontinuation of the stimulant medication. Careful supervision is required during drug withdrawal since this may unmask depression as well as chronic overactivity

Development or worsening of psychiatric disorders should be monitored at every adjustment of dose, then at least every 6 months, and at every visit; discontinuation of treatment may be appropriate.

Growth:

Suppression of growth (weight gain and/or height) has been reported with long term use of stimulants in children, therefore careful monitoring is required.

Growth should be monitored during stimulant treatment with height, weight and appetite recorded on a centile chart at baseline, after every dose increase and at least every 6 months.

Seizures:

Caution should be exercised when prescribing stimulants in patients with epilepsy. Stimulants may lower the convulsive threshold. If seizure frequency increases or new-onset seizures occur, stimulant medication should be discontinued.

Abuse Potential:

Stimulants should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion. Patients should be carefully monitored for the risk of diversion, misuse and abuse of stimulant medication.

Specific administration instructions:

Patients should be informed that Concerta XL[®] must be swallowed whole and must not be chewed, divided or crushed. Equasym XL[®] and Medikinet XL[®] capsules can be opened and the contents sprinkled on to apple sauce if desired. The capsule contents should not be crushed or chewed.

Lisdexamfetamine (Elvanse[®]) may be swallowed whole, or the capsule opened and the entire contents dissolved in a glass of water. If the contents include any compacted powder, a spoon may be used to break apart the powder in the water. The contents should be stirred until completely dispersed. The patient should consume the full glass of water immediately; it should not be stored. The active ingredient dissolves completely once dispersed; however, a film containing the inactive ingredients may remain in the glass once the water is consumed.

Atomoxetine:**Cardiovascular:**

There have been reports of sudden death in children and adolescents who were taking atomoxetine at usual doses with existing structural cardiac abnormalities. Although some serious structural cardiac abnormalities alone carry an increased risk of sudden death, atomoxetine should only be used with caution in children or adolescents with known serious structural cardiac abnormalities and in consultation with a cardiac specialist.

Atomoxetine can affect heart rate and blood pressure. Most patients taking atomoxetine experience a modest increase in heart rate (mean <10 bpm) and/or increase in blood pressure (mean <5 mm Hg) that may not be clinically important.

MHRA advice in January 2012 states that atomoxetine causes clinically important increases in blood pressure or heart rate, or both, in a small proportion of patients. Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders. Thorough pretreatment screening and regular monitoring of cardiovascular status is recommended. Specialist cardiac evaluation and advice should be sought if pretreatment findings suggest cardiac disease or history, or if symptoms suggesting cardiac disease are found during treatment.

It is recommended that heart rate and blood pressure be measured and recorded on a centile chart before treatment is started and, during treatment, after each adjustment of dose and then at least every 6 months to detect possible clinically important increases.

Atomoxetine can cause prolongation of the QT interval and so should be used with caution in patients with congenital or acquired long QT or a family history of QT prolongation.

As orthostatic hypotension has also been reported, atomoxetine should be used with caution in any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes.

Psychiatric:

Suicide-related behaviour has been reported in patients treated with atomoxetine. Patients who are being treated for ADHD should be carefully monitored for the appearance or worsening of suicide-related behaviour.

Treatment-emergent psychotic or manic symptoms (e.g., hallucinations, delusional thinking, mania or agitation in children and adolescents without a prior history of psychotic illness or mania) have been reported following exposure to atomoxetine at usual doses. Atomoxetine may also exacerbate pre-existing psychotic or manic symptoms. If such symptoms occur, consideration should be given to a possible causal role of atomoxetine, and discontinuation of treatment should be considered.

Patients should be closely monitored for the appearance or worsening of aggressive behaviour, hostility or emotional lability. Hostility (predominantly aggression, oppositional behaviour and anger) and emotional lability were more frequently observed in clinical trials among children and adolescents treated with atomoxetine compared to placebo.

Patient/parents should be warned to report immediately the appearance or worsening of any of these behaviours or symptoms, being particularly vigilant when starting treatment and with increased doses.

Growth:

Growth and development should be monitored during treatment with atomoxetine. Height, weight and appetite should be recorded on a centile chart at baseline, after very dose change and at least at six monthly intervals. Patients requiring long-term therapy should be monitored and consideration should be given to dose reduction or interrupting therapy in patients who are not growing or gaining weight satisfactorily.

Seizures:

Atomoxetine can lower the seizure threshold. Atomoxetine should be introduced with caution in patients with a history of seizure. Discontinuation of atomoxetine should be considered in any patient developing a seizure or if there is an increase in seizure frequency where no other cause is identified.

Hepatotoxicity & allergy:

Atomoxetine should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted. Very rarely, liver toxicity, manifested by elevated hepatic enzymes and bilirubin with

jaundice, has been reported.

Allergic reactions have been reported in patients, although uncommon (including rash, oedema, and urticaria).

5. Contraindications

Methylphenidate, Dexamfetamine, and Lisdexamfetamine:

Known hypersensitivity to methylphenidate, dexamfetamine, lisdexamfetamine or any of the other product ingredients.

Marked anxiety and tension, hyperthyroidism/thyrotoxicosis, hyperexcitability or agitated states, family history or diagnosis of Tourette's syndrome, history of drug or alcohol abuse, glaucoma, pregnancy and breastfeeding.

Diagnosis or history of severe depression, anorexic disorders, suicidal tendencies, psychotic symptoms, mania, schizophrenia, severe mood disorders, psychopathic or borderline personality disorder

Stimulants should not be used in combination with monoamine oxidase inhibitors (MAOIs). Stimulant medication should not be used within two weeks after discontinuing therapy with a MAOI. Treatment with an MAOI should not be initiated within two weeks of discontinuing stimulant therapy.

Unless specialist cardiac advice has been obtained: in pre-existing cardiovascular disorders, including moderate to severe hypertension and advanced arteriosclerosis, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, phaeochromocytoma, potentially life-threatening arrhythmias, and dysfunction of cardiac ion channels

Atomoxetine:

Known hypersensitivity to atomoxetine or any of the other product ingredients.

Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOIs). Atomoxetine should not be used within two weeks after discontinuing therapy with a MAOI. Treatment with an MAOI should not be initiated within two weeks of discontinuing atomoxetine.

Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders whose condition would be expected to deteriorate if they experience clinically important increases in BP or heart rate

Phaeochromocytoma.

Atomoxetine should not be used in patients with narrow angle glaucoma.

If the patient develops jaundice and/or other signs of liver injury, then atomoxetine should be immediately discontinued and not restarted.

6. Side effects

Methylphenidate, dexamfetamine, and lisdexamfetamine:

Very Common (frequency estimate >10%) side effects include:

- Insomnia, nervousness and headache
- Decreased appetite and weight loss (lisdexamfetamine)

Common (frequency estimate 1% to 10%) side effects include:

- Abdominal pain, nausea, vomiting, diarrhoea, dry mouth, appetite suppression (usually transient), weight loss, anorexia
- Drowsiness, dizziness, dyskinesia
- Tachycardia, palpitations, arrhythmias, changes in BP and heart rate
- Rash, pruritis, urticaria, fever, alopecia, arthralgia and muscle tightness

Less Common (frequency estimate 0.1% to 1%) side effects include:

- Hypersensitivity reactions, constipation, tremor, blurred vision and dry eyes
- Psychotic symptoms, suicidal ideation and irritability
- Chest pain

Atomoxetine:

Very Common (frequency estimate >10%) side effects include:

- Decreased appetite (usually transient), headache, somnolence, abdominal pain, nausea and vomiting (usually transient).

Common (frequency estimate 1% to 10%) side effects include:

- Anorexia (loss of appetite), irritability, mood swings, insomnia, dizziness, constipation, dyspepsia, dermatitis, rash, fatigue, lethargy, weight loss (0.5kg average), greatest during initiation and at higher doses, increased blood pressure.

Less Common (frequency estimate 0.1% to 1%) side effects include:

- Early morning awakening, syncope, migraine, peripheral coldness, allergic reaction, palpitations and sinus tachycardia

Post marketing reports of psychosis, suicidal ideation, seizure, QT prolongation, abnormal liver function tests and hepatitis have all been reported.

7. Interactions

Methylphenidate, dexamfetamine and lisdexamfetamine:

- Methylphenidate may possibly enhance anticoagulant effect of coumarins.
- Risk of hypertensive crisis when stimulants given with MAOIs and moclobemide. Amphetamine should not be administered during or within 14 days following the administration of monoamine oxidase inhibitors (MAOI) as it can increase the release of norepinephrine and other monoamines. This can cause severe headaches and other signs of hypertensive crisis. A variety of toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal outcomes.
- Methylphenidate possibly inhibits metabolism of SSRIs and tricyclics and so contribute to increase risk of side effects from these medications.
- Stimulants may decrease the effect of drugs used to treat hypertension.
- Because a predominant action of stimulants is to increase extracellular dopamine levels, caution is recommended when administering stimulants with dopaminergic drugs, including antipsychotics.
- Seizures are a potential risk with stimulant medication. Caution is advised with concomitant use of medicinal drugs which are known to lower the seizure threshold (such as antidepressants, neuroleptics, mefloquine, bupropion, or tramadol).
- QT interval prolongation is an increased risk when stimulants are administered with other QT prolonging drugs (such as antipsychotics, anti-arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants, lithium) and drugs that cause electrolyte imbalance (such as thiazide diuretics).
- Methylphenidate possibly increases plasma concentration of phenytoin, phenobarbital and primidone.
- Alcohol may exacerbate adverse CNS effects therefore it is advisable to abstain from alcohol during treatment.
- Ascorbic acid and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting) that acidify urine increase urinary excretion and decrease the half-life of amphetamine. Sodium bicarbonate and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis) that alkalinise urine decrease urinary excretion and extend the half-life of amphetamine.

Atomoxetine:

- Risk of hypertensive crisis when given with MAOIs and moclobemide
- Combining with potent cytochrome P450 inhibitors particularly CYP2D6 inhibitors (e.g., *fluoxetine, paroxetine, quinidine, terbinafine*): In patients receiving treatment with these drugs, atomoxetine exposure may be 6- to 8- fold increased as atomoxetine is primarily metabolised by CYP2D6. Slower titration and lower final dosage of atomoxetine may be necessary in those patients who are also taking CYP2D6 inhibitor drugs.
- Atomoxetine should be administered with caution to patients being treated with high dose nebulised or systemically administered salbutamol (or other beta₂ agonists) because the action of salbutamol on the cardiovascular system can be potentiated, increases in heart rate and blood pressure.
- QT interval prolongation is an increased risk when atomoxetine is administered with other QT prolonging drugs (such as antipsychotics, anti-arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants, lithium), drugs that cause electrolyte imbalance (such as thiazide diuretics) and drugs that inhibit CYP2D6.
- Seizures are a potential risk with atomoxetine. Caution is advised with concomitant use of medicinal drugs which are known to lower the seizure threshold (such as antidepressants, neuroleptics, mefloquine, bupropion, or tramadol).
- Because of possible effects on blood pressure, atomoxetine should be used cautiously with pressor agents.

- Drugs that affect noradrenaline should be used cautiously when co-administered with atomoxetine because of the potential for additive or synergistic pharmacological effects. Examples include antidepressants, such as imipramine, venlafaxine, and mirtazapine, or decongestant pseudoephedrine.

8. Criteria for use

Methylphenidate and dexamfetamine are stimulant drugs licensed in the treatment of severe Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD) and Hyperkinetic Disorder (HKD) part of a comprehensive treatment plan.

Lisdexamfetamine is licensed when response to previous methylphenidate treatment is considered clinically inadequate. Lisdexamfetamine therapy is indicated by Sussex Partnership Trust and Coastal Western Sussex Clinical Commissioning Group after the trial of at least two preparations of modified release methylphenidate, unless a previous adverse reaction to methylphenidate has ruled out further use of methylphenidate. Switching from one M/R formulation of methylphenidate to another can provide in some patients more effective symptom control due to the differing release parameters of the M/R forms of methylphenidate or minimise side-effects related to sleep disturbance or appetite suppression.

Atomoxetine is licensed for the treatment of attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over, and in adolescents as part of a comprehensive treatment plan.

(Comprehensive treatment programme – defined to include psychological, education & social measures).

9. Any further information (e.g. supporting therapies)

Methylphenidate, Dexamfetamine and Lisdexamfetamine:

If improvement of symptoms is not observed after the appropriate dosage adjustment over one month, it should be discontinued.

Following updated MHRA guidance on the use of methylphenidate in ADHD, issued in March 2009, treatment with stimulant medication should be interrupted at least once a year to determine whether continuation is needed (e.g. by stopping the drug for up to two weeks each year). Drug treatment should usually be discontinued by late adolescence.

Lisdexamfetamine at oral doses up to 100mg has been shown in one abuse liability study to have less 'drug liking effects' than immediate release dexamfetamine 40mg. However oral doses of 150mg and above had comparable 'drug liking effects' to immediate release dexamfetamine 40mg. Another study on IV administration witnessed doses of up to 50mg producing drug liking effects greater than placebo, but less than IV administration of immediate release dexamfetamine 20mg.

All children and families with a child taking stimulant medication should be considered for psychosocial interventions, which may help to reduce the need for medication.

Explanations given to the family about the medication are important and this might include leaflets for parents and suitable discussion with the child emphasising the benefits of drug treatment on schoolwork.

Prescriptions should be written in accordance with the Misuse of Drugs Act.

Clinicians may prescribe stimulant medication on schooldays only where the effect sought relates mainly to education. This is recognised practice.

Atomoxetine:

ADHD symptoms can show an improvement by the first week of commencing atomoxetine and the maximum therapeutic effect can be seen from four weeks.

In response to adverse affects, atomoxetine can be discontinued without titrating down the dose otherwise it should be tapered off over a suitable time period.

If improvement of symptoms is not observed after appropriate dosage adjustment over a 10-week period, the drug should be discontinued by the CAMHS / ADHD specialist.

Consideration should be given to periodically discontinuing atomoxetine in order to assess child's condition and ongoing need for medication.

Following updated MHRA guidance on the use of atomoxetine in ADHD, issued in January 2012, patients taking atomoxetine for extended periods (i.e. >1 year) should have their treatment reviewed at least once a

year by a specialist to determine whether continuation is needed.

Drug treatment should usually be discontinued by late adolescence.

If a treatment break is deemed appropriate, consideration should be given to the length of any break. It may take up to five days for atomoxetine to be eliminated. Following any treatment break it may take four weeks before the full benefit from atomoxetine is again observed.

10. References

- Strattera 10mg, 18mg, 25mg, 40mg, 60mg, 80mg or 100mg hard capsules [atomoxetine – Eli Lilly]. *Electronic Medicines Compendium*. (8 June 2015). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Ritalin [methylphenidate – Novartis Pharmaceuticals]. *Electronic Medicines Compendium*. (28th March 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018)¹
- Equasym XL 10mg, 20mg or 30mg Capsules [methylphenidate – Shire Pharmaceuticals]. *Electronic Medicines Compendium*. (10th March 2014). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Medikinet Tablets 5mg, 10mg & 20mg tablets [methylphenidate – Flynn Pharma]. *Electronic Medicines Compendium*. (20th March 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Medikinet XL 5mg, 10mg, 30mg, 40mg, 50mg or 60mg capsules [methylphenidate – Flynn Pharma]. *Electronic Medicines Compendium*. (20th March 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Concerta XL 18, 27mg, 36mg & 54mg Prolonged-Release Tablets [methylphenidate – Janssen-Cilag]. *Electronic Medicines Compendium*. (20th March 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Matoride XL 18mg, 36mg & 54mg prolonged-release tablets methylphenidate [methylphenidate - Sandoz Pharma] *Electronic Medicines Compendium*. (20th March 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Xaggitin XL 18mg, 27mg, 36mg & 54mg Prolonged-Release Tablets [methylphenidate – Etypharm]. *Electronic Medicines Compendium*. (28th June 2017). Available from: <http://www.emc.medicines.org.uk> (accessed 2nd March 2018)
- Amfexa 5mg, 10mg & 20mg tablets [dexamfetamine – Flynn Pharma]. *Electronic Medicines Compendium*. (3rd October 2016). Available from: <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- Elvanse 20mg 30mg, 40mg, 50mg, 60mg or 70mg hard capsules [lisdexamfetamine – Shire]. *Electronic Medicines Compendium* (3rd November 2016). Available from <http://www.emc.medicines.org.uk> (accessed 8th January 2018).
- NICE Guidelines: Attention Deficit Hyperactivity Disorder (CG72). September 2008. Available from: <http://guidance.nice.org.uk/CG72> (accessed 8th January 2018).
- British National Formulary. 74th Edition. London: BMJ Publishing Group Ltd and RPS Publishing; 2017.
- Drug Safety Update. Volume 5, Issue 6 (January 2012). Available from <http://www.mhra.gov.uk/index.htm> (accessed 8th January 2018)
- Drug Safety Update. Volume 2, Issue 8 (March 2009). Available from <http://www.mhra.gov.uk/index.htm> (accessed 8th January 2018)
- Duff G. Strattera (atomoxetine) – conclusion of risk: benefit review (16th February 2006). Medicines and Healthcare products Regulatory Agency (MHRA). Available from: <http://www.mhra.gov.uk/index.htm> (accessed 8th January 2018)

RESPONSIBILITIES and ROLES

Consultant / Specialist responsibilities	
1	Confirmation of diagnosis and identification of suitable patients following full assessment
2	Request agreement of shared care with primary care prescriber
3	Initiation of appropriate therapy
4	Discussion of risks and benefits with patients, outline possible side effects and explain their roles
5	To undertake a complete history, documenting: concomitant medicines; past and present medical and psychiatric disorders or symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia; and accurate pre-treatment height, weight and appetite on a growth chart.
6	To undertake a physical examination for the presence of heart disease.
7	To assess baseline cardiovascular status, including blood pressure and heart rate before prescribing and get specialist cardiac advice if appropriate.
8	To review the patient and monitor the following (if relevant to specific drug) usually on a six monthly basis (though well established adolescents may be seen annually. A move to annual monitoring must be communicated to the primary care prescriber), act on the results appropriately and communicate these results to the primary care prescriber: <ul style="list-style-type: none"> • Height, weight and appetite, recorded at baseline, following dosage adjustments and 6 monthly. Recorded on a growth centile chart. • Blood pressure and pulse, recorded at baseline, following dosage adjustments and 6 monthly. Record on a centile chart. • Blood and platelet counts at discretion of supervising clinician(s) (e.g. if recurrent nose bleeds, bruising or infections occur. Baseline, then when clinically indicated. • As stimulant medications are controlled drugs, the specialist or parents should inform the school concerning any medication for these indications. In order to assess the effects of the drug on the child's emotional, physical or behavioural states the specialist should request further information from the school about the child's behaviour. • To refer patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease for prompt specialist cardiac evaluation. • The development of new or worsening of pre-existing, psychiatric symptoms (also following dose adjustments and at every visit).
9	When prescribing stimulant medication to 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.
10	If prescribing modified release methylphenidate this must be by 'Brand' to avoid the risk of the wrong formulation being dispensed.
11	To advise and support parents and teachers.
12	To liaise with the child's school as appropriate.
13	Issuing initial prescription(s) until the patient is stabilised (minimum of one month) and until ESCA is in place
14	Ensure that all newly treated patients (and/or their carers) receive appropriate education and advice regarding their drug therapy and shared care arrangements. This should include written information where appropriate.
15	Providing primary care prescriber with clinic letter stating planned introduction and reviews
16	Provide outpatient reviews, monitor effectiveness/side effects
17	Notify the GP of the patient's failure to attend for clinical review or drug monitoring and give advice on stopping the medication.
18	To liaise and advise primary care prescriber to interrupt treatment at least annually and to assess ongoing need for medication.
19	To take responsibility for stopping the drug or to agree aftercare when the patient reaches 18 years of age.

Primary care prescriber responsibilities	
1	Initial referral to secondary care with a full history of any diagnosis or history where caution is needed or the ADHD medication is contraindicated.
2	To inform the consultant if unwilling to enter into shared-care arrangements.
3	To provide repeat prescriptions of the ADHD medication at the dose recommended once ESCA is agreed and in place and the patient is stabilised (not before initial one month stabilisation period). A demonstrable system should be in place to ensure that prescribing is reviewed by the primary care prescriber if there is no record of the fact that monitoring has taken place within the agreed time scales. Prescriptions for stimulants should be restricted to 30 days supply and are only valid for 28 days from the date of signature as stimulant medications are controlled drugs subject to safe custody and specific regulations for prescribing.
4	To record any changes in therapy in the prescribing record on receipt of such communication from secondary care and to act upon these.
5	To monitor prescribing rate of ADHD medications for individual patients.
6	To contact consultant / specialist if deterioration in behaviour.
7	To report adverse drug reactions or interactions to consultant / specialist.

8	To refer patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease for prompt specialist cardiac evaluation.
9	To monitor patients overall health and well-being.
10	Liaise with consultant / specialist if any cause for concern or drug discontinued.
11	To provide a copy of this ESCA to the patient to ensure that they are familiar with all roles and responsibilities
12	If prescribing modified release methylphenidate this must be by 'Brand' to avoid the risk of the wrong formulation being dispensed.
13	When prescribing stimulant medication to 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.
14	To interrupt treatment at least annually on the recommendation of the specialist.
15	To ensure all relevant staff within the practice are aware of the shared care guidelines.
16	Ensure that if care of the patient is transferred to another prescriber that the new prescriber is made aware of the ESCA.

Patient's / Carer's role	
1	Ask the consultant / specialist or primary care prescriber for information, if he or she does not have a clear understanding of the treatment.
2	Share any concerns in relation to treatment with any medication covered by this agreement
3	Tell the consultant / specialist or primary care prescriber of any other medication being taken, including over-the-counter products.
4	Read the patient information leaflet included with your medication and report any side effects or concerns you have to the consultant / specialist or primary care prescriber.
5	To attend appointments.
6	Arrange blood tests as per consultant / specialist request
7	To be aware of side effects and report to their consultant / specialist or primary care prescriber any relevant symptoms such as: palpitations, exertional chest pain, unexplained fainting, shortness of breath, development of new or worsening of pre-existing psychiatric symptoms.

BACK-UP ADVICE AND SUPPORT

	Name / position	Telephone	Email
Specialist / Consultant:	Dr. Ann-Marie Skarstam (Lead Medical Clinician)	See below	See below
Alternative specialist (e.g. departmental contact):	Crawley & Horsham CAMHS Mid Sussex CAMHS	01403 223200 01444 472670	N/A
Hospital Pharmacy:	Worthing Hospital St Richards Hospital	01903 205 111, ext 85698 01243 788 122, ext	pharmacy@wsht.nhs.uk
Out of hours (e.g. medical team on call):	On call physicians	N/A	N/A

Version History

Document Name:		Effective Shared Care Agreement (ESCA) for Licensed Medications for Attention Deficit Hyperactivity Disorder (ADHD) in Children	
Document Type:		Effective Shared Care Agreement	
Relevant to:		All primary care prescribers working within Crawley, Horsham & Mid Sussex and all relevant clinicians at Sussex Partnership NHS Foundation Trust	
Version No.	Date	Author of original development or review	Details of document development
1	11/12	Graham Brown, Lead Pharmacist, CAMHS & Early Intervention	Original development
2	07/13	Graham Brown, Lead Pharmacist, CAMHS & Early Intervention	Updated to include Lisdexamfetamine
3	01/18	Graham Brown, Lead CAMHS Pharmacist,	General review
Approval for organisational use			
ESCA authorised for use in Crawley, Horsham & Mid Sussex by		Specialist/consultant: Dr Ann-Marie Skarstam, Lead Medical Clinician, Sussex CAMHS, 08/01/18	
		CPMAP: February 2018	

EFFECTIVE SHARED CARE AGREEMENT (ESCA)

DRUG NAME: <insert>

INDICATION: **Attention Deficit Hyperactivity Disorder (ADHD) in Children**

Agreement for transfer of prescribing to PRIMARY CARE PRESCRIBER

Patient details:

Name:

Address:

DoB:

NHS No:

Hospital No:

Drug name and dose: <insert>

The following tests and investigations have been carried out:

<insert details of tests>

Date treatment initiated:

At the last patient review the drug appeared to be effectively controlling symptoms / providing benefit:
Yes/No

The patients has now been stabilised on a dose of:

I will arrange to review this patient regularly. Date of next clinic appointment:

<Insert title of specialist>: <insert name>

Address: <insert relevant department>
<insert relevant hospital address>

Contact Number: <insert telephone number and extension>

Primary care prescriber:

Address:

Contact Number:

Main Carer:

Contact Number:

Key worker if appropriate:

Contact Number:

Agreement to shared care, to be signed by primary care prescriber and consultant/specialist.

Consultant/specialist signature:

Date:

Primary care prescriber signature:

Date:

If shared care is agreed and the primary care prescriber has signed above please return a copy of this page to the requesting consultant or alternatively fax to: <insert>