NHS LINCOLNSHIRE in association with
UNITED LINCOLNSHIRE HOSPITALS TRUST AND LINCOLNSHIRE PARTNERSHIP FOUNDATION TRUST

SHARED CARE GUIDELINE: Methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine in the management of Attention Deficit Hyperactivity Disorder (ADHD)

The shared care protocol covers the initiation of treatment in children and adolescents. THIS PROTOCOL DOES NOT COVER THE INITIATION OF NEW TREATMENT IN ADULT PATIENTS. The protocol however can be extended to cover the ongoing therapy for existing patients once they have reached 18 years of age.

General Principles

Shared Care Responsibilities:

In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF*, 65, March 2013, p. 5)

Aims:

(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.

(2) Specific shared care guidance should be available for any high cost or high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.

(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.

(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies of any guideline in this series are available from members of the Greater East Midlands Commissioning Support Unit (GEMS) Prescribing & Medicines Optimisation Team.

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Lincolnshire East CCG
Lincolnshire West CCG
South Lincolnshire CCG
South West Lincolnshire CCG
Lincolnshire Partnership Foundation Trust
United Lincolnshire Hospitals Trust
Greater East Midlands Commissioning Support Unit

Introduction

In September 2008 the National Institute for Health and Clinical Excellence (NICE) published its clinical guideline 72 on diagnosis and management of Attention Deficit Hyperactivity Disorder (ADHD) in children, young people and adults.

The main conclusions from the guideline in relation to the pharmacological management of the condition are:

- Diagnosis should only be made by a specialist psychiatrist, paediatrician or other healthcare professional with training and expertise in the diagnosis of ADHD. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10.
- In pre-school age children – drug treatment is not recommended. Healthcare professionals should offer parents or carers of pre-school children with ADHD a referral to apparent-training/education programme as first-line treatment.
- In school age children with moderate ADHD and moderate impairment – drug treatment should be reserved for those with moderate impairment where non-drug interventions have been refused or where there are persisting significant impairment following parent-training/education programme or group psychological treatment.
- In school age children and young people with severe ADHD and severe impairment – offer drug treatment first line – also offer parents a group based training programme.
- Drug treatment should only be started by a healthcare professional with expertise in ADHD.
- Treatment should be based on comprehensive assessment.
- Drug treatment should always be part of comprehensive treatment plan that includes psychological, behavioural and educational advice and interventions.
- **GPs may continue prescribing and monitoring drug treatment under shared care arrangements**.
- Do not use antipsychotics for the management of ADHD in children and young people.
- Methylphenidate, atomoxetine and dexamfetamine are recommended, within their licensed indications, as options for the management of ADHD.
- Drug choice is the responsibility of the healthcare professional with expertise in ADHD and should be based on:
    - ❖ Co-morbidities e.g. tics, tourettes syndrome, epilepsy.
    - ❖ Different adverse effects of drug treatments
    - ❖ Potential problems with compliance e.g. arrangements for midday dose to be administered at school.
    - ❖ Potential risk of misuse
    - ❖ Preferences of child/young person and their parent/carer.
- NICE advises:
    - ❖ Consider methylphenidate for ADHD without significant co morbidity
    - ❖ Consider methylphenidate for ADHD with co morbid conduct disorder
    - ❖ Consider methylphenidate or atomoxetine in the presence of tics, Tourettes syndrome, anxiety disorder, and stimulant misuse or stimulant diversion.
    - ❖ Consider atomoxetine if methylphenidate has been tried and has been ineffective at the maximum tolerate dose or the child/young person is intolerant to low or moderate doses of methylphenidate.
    - ❖ If there is a choice of more than one drug use the drug with the lowest overall cost.

- Consider dexamfetamine when symptoms are unresponsive to the maximum tolerated dose of methylphenidate or atomoxetine.

Lisdexamfetamine

- Lisdexamfetamine was launched in the UK in 2013 licensed to be used as part of a comprehensive treatment programme for the treatment of attention deficit disorder in children aged over 6 years of age when response to previous methyphenidate treatment is considered to be clinically inadequate. Lisdexamfetsamine is a prodrug that is converted in the blood to dexamfetamine. Lincolnshire's Prescribing and Clinical Effectiveness Forum (PACEF) has approved lisdexamfetamine for use within its licensing authorisation as an option for treatment.

Drug Details

Approved generic name - **Methylphenidate**
Brand Name - Concerta XL, Equasym XL, Medikinet, Medikinet XL, Ritalin
Form and strength: standard release and modified release preparations

Approved generic name – Atomoxetine
Brand Name - Strattera
Form and strength: 10mg, 18mg, 25mg, 40mg, 60mg and 80mg capsules

Approved generic name - Dexamfetamine
Form and strength: 5mg tablets

Approved generic name - Lisdexamfetamine
Brand name – Elvanse
Form and strength: 30mg,50mg and 70mg capsules

Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Provide a comprehensive baseline physical assessment as stipulated in NICE guidance.
2. Interpret or arrange interpretation of electrocardiogram (ECG) if applicable.
3. Initiate therapy following full discussion with the patient/carer of different treatment options, benefits and risks. **The choice of initial drug treatment and any changes to the choice of treatment is the responsibility of the specialist service.**
4. Provide the child/young person/parent/carer with all necessary information on their condition and treatment.
5. Liaise with GP, School and any other agency involved with the child/young person, providing a comprehensive treatment programme for the child/young person. This must include frequency of specialist review following stabilisation and be aware of ongoing issues relating to prescribing when reaching young adulthood.
6. Titrate dose according to schedule adjusting dose as appropriate and undertake monitoring of clinical response and side effects. **In certain circumstances agreement may be reached**

between the specialist service and the GP for the GP to continue to titrate the dose according to response.

7. Send a letter to the GP, once a patient is stabilised on treatment suggesting that shared care should be considered for this patient. This letter should contain the following information.
    - Patient details including name, address date of birth and NHS number.
    - Details of treatment including drug name, dose, date treatment commenced and any further dose titration that is required (if applicable).
    - Details and the results of any investigations/ base line checks that have been carried out prior to commencement of treatment. This should include blood pressure, pulse rate, weight and height.
    - Date of patient's last clinic visit and date of next clinic visit.
    - Name and contact details of consultant, key worker (if appropriate) and main carer.

Appendix A is an example of the letter but format and content may vary depending on which specialist service is responsible for the treatment.

8. Review the patient a minimum of once every six months. The six monthly reviews should include routine monitoring of height, weight, blood pressure and heart rate. The review should also include monitoring of any drug related side effects, the need to continue with the medication and review of any co-existing conditions.
9. Issue a letter/clinic report to the GP after each review appointment providing a summary of review findings, confirmation of continuing treatment or treatment changes, confirmation that relevant monitoring has taken place or an explanation as to why it has been deemed necessary unnecessary, assessment of the child/young person's progress and confirmation that further prescriptions should be issued and the time of the next review.
10. Respond to any request from the GP to review the patient due to adverse effects of therapy.
11. Report any adverse effects of therapy to the Medicines and Health care products Regulatory Agency (MHRA)
12. Advise the GP on continuing or stopping the medication following medical review of the patient and associated drug therapy.
13. Notify the GP if the patient is failing to attend for appropriate monitoring and advise GP on appropriate action. If the patient and their family fail to attend on two consecutive occasions the specialist will contact the patient's GP and advise them not to issue any further prescriptions and the patient will be discharged from the specialist service.
14. For patients aged 17-18 years manage withdrawal of treatment prior to discharge or refer to appropriate adult services.
15. Will inform the patient's GP if the ongoing responsibility for patient care is to be transferred to another consultant/ specialist service and to ensure both parties are aware of this change

Methylphenidate and dexamfetamine are schedule 2 controlled drugs and therefore all controlled drug prescription writing legislation set down in the section of "Controlled Drugs and Drug dependence" in the British National Formulary (BNF) applies.
The legal status of Lisdexamfetamine is still under review by the Advisory Council on Misuse of Drugs. In the interim the Home Office and the Royal Pharmaceutical Society have advised that Lisdexamfetamine should be treated as a schedule 2 CD.

GP Responsibilities

The GP will:

1. Prior to referral to the specialist service determine the severity of behavioural and/ or inattention problems suggestive of ADHD and how they affect the child or young person and their parents or carers. If problems are having an adverse impact on development or family life and persist with at least moderate impairment following either a period of up to 10 weeks watchful waiting or referral into a parent training/education programme then refer to secondary care either a paediatrician, child psychiatrist or specialist from the Children & Adolescents Mental Health Service. CAMHS.
2. Refer directly to secondary care if the behavioural and /or inattention problems are associated with severe impairment.
3. Notify the consultant in writing, without undue delay whether or not they agree to share care.
4. Provide any information requested by the specialist in relation to previous history of QT prolongation or concurrent medication.
5. Prescribe the drug therapy as part of the shared care agreement once patient is stabilised. In certain circumstances the GP, following a request from the consultant specialist may agree to further titrate the dose according to the patient's response.
6. Monitor the patients overall health and well being.
7. Monitor patients heart rate, BP and weight as stipulated in monitoring section.
8. Monitor those patients prescribed atomoxetine for signs of depression,
9. Monitor patient's suicidal thoughts or behaviour. If warning signs are detected treatment should be discontinued and urgent advice sought from specialist.
10. Remain alert for the potential for misuse of methylphenidate and dexamfetamine, by observing the frequency and quantity of prescriptions issued and be alert to changes in family circumstances.
11. Report adverse effects of therapy to the consultant and the medicines and health care products Regulatory Agency (MHRA).
12. Act on advice provided by the consultant if patient does not attend for appropriate monitoring. If the patient and their family fail to attend on two consecutive occasions then the GP will be advised not to issue any further prescriptions.
13. Can re-refer patients and their families back to secondary care following discontinuation of treatment as outlines in point 11 if the family can show they are willing to engage with both the specialist service and the monitoring requirements for the proposed treatment.
14. Alert the specialist if there are any concerns about the patient's response to treatment or the ability of the patient to tolerate treatment.
15. Alert the specialist if there are any issues identified relating to poor concordance/compliance e.g. irregularities in the collection of repeat prescriptions.

Referral Criteria

The patients will be stabilised on a suitable dose of methylphenidate, atomoxetine, dexamfetamine or lisdexamfetamine before prescribing responsibility is transferred to the GP.
The specialist service will continue to supply treatment until the GP is prepared to accept responsibility for shared care.

Licensed Indications

Methylphenidate hydrochloride, atomoxetine, dexamfetamine and lisdexamfetamine are all licensed for the treatment of Attention Deficit Hyperactivity Disorders.
Their license states that treatment should be initiated by a specialist physician experienced in managing the condition or in the case of dexamfetamine use should be under specialist supervision.
There are licensing variations between the various substances and products. Refer to summary of product characteristics for further details. **Methylphenidate, dexamfetamine and lisdexamfetamine are not licensed for the management of ADHD in adults aged over 18 years.**
Atomoxetine, methylphenidate and lisdexamfetamine are not licensed for use in children under the age of 6 years of age.

Recommended Dosage and Administration

Methylphenidate

Standard formulations e.g. generic methylphenidate or branded products Ritalin or Medikinet require careful dose titration.
Child 6-18 years. - The recommended starting dose is 5mg daily or twice daily increasing as necessary in weekly increments of 5-10mg to an effective dose. Usual maximum recommended dose is 60mg in two or three divided doses. Dose may be increased beyond the licensed daily dose of 0.7mg/kg up to 2.1mg/kg daily in 2-3 divided doses (up to a maximum of 90mg daily), under the direction of a specialist.
At higher doses monitor carefully for adverse effects.
Adults over 18 years – unlicensed use. 5mg three times daily increased if necessary at weekly intervals according to response. Maximum dose 100mg daily in 2-3 divided doses.
Modified release formulations – vary in the ration of immediate release to extended release methylphenidate that they contain, and also have differing pharmacokinetic profiles resulting in some delivering higher levels of methylphenidate at the start of the day and some provide a therapeutic effect lasting that of a school day 8 hours where others provide an effect lasting up to 12 hours.
Concerta XL – The formulation is 22% immediate release and 78% extended release. For those patients who have not previously taken methylphenidate the starting dose is 18mg once daily. Dose should be carefully titrated in increments of 18mg once a week to a maximum daily dose of 54mg/day taken as a single daily dose in the morning. If patients have previously taken methylphenidate Concerta XL please refer to manufactures information for equivalent doses.
Equasym XL - This contains immediate release and extended release methylphenidate in the ratio 30:70. . For those patients who have not taken methylphenidate before the starting dose is 10mg once daily in the morning increasing gradually if required. For those patients currently on immediate release methyphenidate careful dose titration will be required when switching to a modified release formulation.
Medikinet XL - This formulation consists of 50% extended release and 50% immediate release methylphenidate. In those patients not currently taking methylphenidate the starting dose is 10mg once daily in the morning with or after breakfast increasing gradually if required. For those patients currently on immediate release methyphenidate careful dose titration will be required when switching to a modified release formulation.

Atomoxetine

Child over 6 years of age and adolescent with body weight up to 70kg, initially 500micrograms/kg daily for seven days then increased according to response to usual maintenance dose of 1.2mg/kg daily.

Child and adolescent with body weight over 70kg, initially 40mg daily for seven days then increased according to response to usual maintenance dose of 80mg daily ; but may be increased to 1.8mg/kg/day up to a maximum dose of 120mg daily (unlicensed) under the direction of a specialist. These higher doses should only be used after review of poor response to drug treatment and in consultation with a tertiary or regional centre. At higher does monitor carefully for adverse effects. Total daily dose can be given either a single dose in the morning or in two divided doses with the last dose given no later then early evening.

Dexamfetamine

Children less than 6 years of age initially 2.5mg daily titrated gradually to a maximum of 20mg daily in divided doses.

Children aged 6 years or more initially 5-10mg daily titrated gradually to a maximum of 40mg daily in divided doses.

Lisdexamfetamine dimesylate

Children aged 6 years or older initially 30mg once daily in the morning. The lowest effective dose should be used. The dose can be increased by 20mg increments at approximately weekly intervals to a maximum recommended daily dose of 70mg. Treatment should be stopped if the symptoms do not improve after appropriate dosage adjustment over a one month period.

Background Pharmacology

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most commonly diagnosed behavioural disorders of childhood, affecting 1-5% of school aged children. Its basic symptoms include developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity. It causes problems in at home, in school, with peer relationships and may have long term adverse effects on self confidence, academic performance, vocational success and social development. Drugs licensed for the treatment of this disorder should be used as part of a comprehensive treatment programme.

Drugs used can be divided into two groups.

Central Nervous Stimulants

Methylphenidate – is a central nervous stimulant.

Dexamfetamine - is a sympathomimetic amine with a central stimulant and anorectic activity. On set of action is 60-90 minutes with peak serum concentration being reached 3 hours after oral administration.

Lisdexamfetamine dimesylate is a pharmacologically inactive prodrug of dexamfetamine. After oral administration lisdexamfetamine is rapidly absorbed from the gastrointestinal tract and hydrolysed primarily by red blood cells to dexamfetamine.

Both methylphenidate and dexamfetamine are controlled drugs and subject to the requirements of the misuse of drugs regulations. As a prodrug of dexamfetamine it is expected that lisdexamfetamine will also be classed as a schedule 2 controlled drug. In the interim the Home Office and the Royal Pharmaceutical Society have advised that Lisdexamfetamine should be treated as a schedule 2 CD

All three drugs potentially have a resale value as drugs of abuse. These are all amphetamine related substances and are effective in increasing attention and concentration and reducing impulsive and restless behaviours. Secondary effects include increased school performance, improved peer relations and reduced aggression

Noradrenalin uptake inhibitor.

Atomoxetine is a highly selective and potent noradrenaline reuptake inhibitor, although the precise mechanism by which it works on ADHD is unknown. It is not a psychostimulant and is not an amphetamine derivative.

It is effective in increasing attention and concentration and reducing impulsive and restless behaviours. It may also improve sleep and have an effect on early morning behaviours. It provided 24 hour control of ADHD symptoms.

Adverse Effects

Methylphenidate

Insomnia, decreased appetite, occasional abdominal pain, nausea and vomiting, headaches, emotional lability, temporary growth retardation (may occur during prolonged use, changes in blood pressure and heart rate.

Atomoxetine

Headache, abdominal pain, decreased appetite, nausea and vomiting, dry mouth, insomnia (usually transient at start of treatment) increase in blood pressure, increase in heart rate, temporary growth retardation may occur hence requirement to monitor height and weight.

Signs and symptoms of liver disease (pruritus, jaundice, dark urine, right sided abdominal tenderness and unexplained “flu-like symptoms”).

Increase risk of emotional lability and suicidal thoughts or behaviour.

Development of seizures.

Prolongation of QT interval.

Dexamfetamine

Insomnia, restlessness, irritability, euphoria, tremor, dizziness, headache and other symptoms of over stimulation, have been reported. Also dry mouth, decreased appetite, occasional abdominal pain, nausea and vomiting, convulsions and cardiovascular effects such as tachycardia, palpitations and minor increases in blood pressure.

There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

Intracranial haemorrhages have been reported, presumably caused by the hypertensive effect and possibly associated with pre-existing vascular malformation.

Rhabdomyolysis and renal damage.

The following adverse effects have also been noted: psychosis/psychotic reactions night tremors, nervousness, decreased blood pressure, altered libido and impotence, growth retardation, hyperpyrexia, mydriasis, hyperfexia, chest pain, confusion, panic states, aggressive behaviour, delirium, visual disturbances, tics and Tourettes syndrome in pre-disposed individuals.

Lisdexamfetamine

Anorexia, insomnia, headache, gastrointestinal upset, weight loss, tics, emotional lability, psychomotor hyperactivity, aggression, dizziness, somnolence, mydriasis, rash, irritability, fatigue, pyrexia, tremor, tachycardia, palpitations, dyspnoea, dry mouth, raised blood pressure. Reports of cardiomyopathy and visual disturbances. As a black triangle drug all adverse reactions should be reported through the yellow card system accessible online at www.mhra.gov.uk/yellowcard.

Drug Interactions

Methylphenidate

Monoamine Oxidase Inhibitors (MAOIs)
Warfarin – may increase the anticoagulant effect
Anticonvulsants – may increase plasma levels of phenobarbitone, primidone.
Alcohol – may increase CNS effects of methylphenidate.

Atomoxetine

Monoamine Oxidase Inhibitors (MAOIs) Atomoxetine should not be used in combination with a MAOI. It should not be used within a minimum of two weeks after discontinuing therapy with a MAOI and treatment with an MAOI should not be initiated within two weeks after discontinuing treatment with atomoxetine.
Increases risk of ventricular arrhythmias with tricyclic antidepressants, methadone, amiodarone, disopyramide, parenteral erythromycin, moxifloxacin, and mefloquine, antipsychotics that increase the QT interval, sotalol and diuretics.
Use with caution in patients on concomitant drugs that may lower the seizure threshold e.g. antidepressants, mefloquine, bupropion, tramadol and neuroleptics.

Dexamfetamine

Tricyclic antidepressants may increase risk of cardiovascular adverse effect.
Beta-blockers used concurrently may result in severe hypertension.
Lithium may antagonise effects of dexamfetamine.
Concurrent use of MAOIs or use within the preceding fourteen days may precipitate a hypertensive crisis.
Antihistamines may delay absorption of ethosuximide, phenobarbitone and phenytoin.
Acute dystonia has been noted with concurrent administration of haloperidol.
Phenothiazines may inhibit the actions of dexamfetamine.
Alcohol can increase CNS effects of dexamfetamine and patients should be advised to abstain from alcohol during treatment.

Lisdexamfetamine

Ascorbic acid can acidifly urine , increase urinary excretion of lisdexamfetamine and reducing its half-life.
Sodium bicarbonate and other agents that alkalise the urine decrease urinary excretion and can prolong the half life.
Monamine oxidase inhibitors (MAOI's) should not be administered during or within 14 days of MAOI's as can increase the release of norepinephrine and other monoamines leading to severe headaches and other signs of hypertensive crisis.
Antihypertensives – may decrease effectiveness of guanethidine and other antihypertensive medications.
Could potentiate the analgesic effect of narcotic analgesics.
Chlorpromazine and haloperidol inhibit central stimulant effects of amphetamines.
Lithium may block anorectic and stimulatory effects of amphetamines.
May elevate plasma corticosteroid levels.

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Precautions

Methylphenidate

Should be used with caution in patients with history of epilepsy (discontinue or seek specialist advice if increased seizure frequency), psychotic disorders anxiety or agitation, tics or a family history of Tourette sundrome, susceptibility to angle-closure glaucoma; avoid abrupt withdrawal.

Atomoxetine

Should be used with caution in patients with cardiovascular disease including hypertension and tachycardia, or structural cardiac abnormalities. Atomoxetine should only be used with caution in those with congenital or acquired long QT or a family history of QT prolongation. The risk increases if atomoxetine is used concomitantly with other drugs that produce QT prolongation, drugs that cause electrolyte disturbances and those that inhibit cytochrome P450 2D6.

Patients should be monitored for the appearance of, or worsening of suicide related behaviour, hostility, psychotic or manic symptoms and emotional lability.

Seizures are a potential risk therefore atomoxetine should be introduced with caution in patients with a history of seizure. Discontinuation should be considered in any patient developing seizure or if thee is an increase in seizure frequency.

Should be discontinued in patients with jaundice or laboratory evidence of liver injury and should not be restarted. Patients and carers should be advised of risk of hepatic disorders and told how to recognise symptoms.

Dexamfetamine

Use with caution in patients with a history of epilepsy, impaired kidney function, family history of dystonias and in patients with a tic disorder.

Use with care where there is a history of drug or alcohol abuse.

Lisdexamfetamine

Use with caution in those with mild hypertension, heart failure, recent MI and ventricular arrhythmia. Evaluate cardiovascular status before starting treatment.

Use with caution in those with risk factors for seizures, psychotic disorders, bipolar disorder. Patients should be monitored for changes in psychiatric status including evaluation of tics and Tourette syndrome, the development or worsening of aggression or hostility. Consider discontinuation in case of psychotic or manic symptoms or if new-onset or worsening seizures.

Substance abuse or dependence. Monitor for signs of diversion, misuse or abuse.

Depression

Pregnancy – should only be used if the potential benefit justifies the potential risk to the foetus.

Renal impairment.

Contraindications

Methylphenidate –

Not to be used in patients with severe depression, suicidal ideation, anorexia nervosa, drug or alcohol dependence, psychosis, uncontrolled bipolar disorder, hyperthyroidism, cardiovascular disease (including heart failure, cardiomyopathy, severe hypertension and arrhythmias), structural cardiac abnormalities, phaeochromocytoma, vasculitis, cerebrovascular disorders.

Hypersensitivity or intolerance to methylphenidate or excipients

Atomoxetine –

Do not use in patients with narrow angle glaucoma

Should not be used if patient concurrently taking monoamine oxidase inhibitors (MAOIs).

Hypersensitivity or intolerance to atomoxetine or excipients

Dexamfetamine –

Not to be used in patients with marked anxiety disorders, psychosis, cardiovascular disease (including hypertension), hyperthyroidism, glaucoma and in pregnancy (especially during first trimester) and breast feeding.

Contra-indicated in Tourettes syndrome but is used with caution by specialists. Any prescribing in this situation is unlicensed.

Hypersensitivity or intolerance to dexamfetamine or excipients.

Lisdexamfetamine-

Not to be used in those with hyperthyroidism, thyrotoxicosis, agitation, glaucoma, serious structural cardiac or heart rhythm abnormalities, cardiomyopathy, coronary artery disease or other serious cardiac disorders, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension.

Not to be used if breast feeding.

Monitoring

Responsibility of specialist service prior to commencement of treatment

Children and young people with ADHD should have a full pre-treatment assessment which should include:

Full mental health and social assessment

Full history and physical examination including:

- assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms
- - heart rate and blood pressure (plotted on centile chart)
- Height and weight (plotted on growth chart)
- Family history of cardiac disease and examination of the cardiovascular system.
- An ECG if there is a past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on cardiac examination.
- Risk assessment for substance abuse and drug diversion
- Enquiry about history of seizures or tics.

Monitoring required during drug treatment – Specialist responsibilities.

Blood pressure and heart rate should be monitored before and after each dose change, and every six months. **If sustained tachycardia, arrhythmia or systolic BP greater than 95th centile (or a clinically significant increase) is measured on 2 occasions contact paediatrician for advice and consider dose reduction.**

Height should be monitored every 6 months.

Weight should be measured at 3 & 6 months after treatment started and then 6 monthly thereafter.

Both height and weight measurements should be plotted on growth centile chart and should be regularly reviewed by the specialist responsible for treatment.

Monitoring during treatment - GP responsibilities.

Monitor child/adolescents B.P and heart rate every three months between specialist six monthly reviews or at intervals agreed with the responsible consultant/ specialist and alert them immediately if there are any concerns.

Monitor patient's weight during the first three months following initiation of treatment and alert responsible consultant/specialist if there is any weight loss.

Monitor for tics and notify the specialist service if they occur.

During treatment NICE states that people taking methylphenidate do not need routine blood tests and ECGs unless there is a clinical need

Reference values for blood pressure measurements

The Journal of hypertension 27(9):1719-1742 September 2009 contains reference blood pressure charts for children and adolescents. This can be accessed via The British Hypertension Society website following the link below:

http://www.bhsoc.org/resources/children-young-people/

Alternatively the Trent Medical Information Centre based at Leicester Universities Hospital recommend using reference algorithims from "Blood Pressures Centiles in Great Britain" by Lisa V Jackson et al. Published in Archives of Diseases in Childhood 2007;92;293-303.Archives of Diseases in Children which is also easy to use and readily available at:

http://www.ucl.ac.uk/paediatric-epidemiology/pdfs/blood_pressure_centiles.pdf

Management of adverse effects.

Atomoxetine

At normal doses atomoxetine can be associated with treatment emergent psychotic or manic symptoms e.g. hallucinations, delusional thinking, mania or agitation) in children or adolescents without a previous history. If such symptoms occur contact consultant medical team urgently for advice and consider discontinuing or withdrawing treatment.

Patients and their carers should be informed of risk of suicidal thoughts/behaviour and advised to contact the specialist team for urgent advice if these occur or if there is worsening of irritability, agitation or depression.

Development of seizures. Discontinue treatment and seek urgent advice from specialist.

Hepatic disorders. Be alert to possibility of jaundice or laboratory evidence of liver injury. If either occurs discontinue treatment and seek urgent specialist advice. In these circumstances treatment must not be restarted. Patients and carers should be advised of risk of liver damage and be told how to recognise symptoms. Prompt medical attention should be sought in case of abdominal pain, unexplained nausea, malaise, darkening of the urine or jaundice.

Indication of Likely Cost of Therapy in Primary Care

Approximate annual cost at licensed dose.

Methylphenidate

Methylphenidate 5-60mg in one to two divided doses £37 -£394
Medikinet 5-60mg in one to two divided doses £37 - £394
Ritalin -5-60mg in one to two divided doses £34-£402
Concerta XL 18-54mg once daily £375-£884
Equasym XL 10-60mg once daily £300-£840
Medikinet XL 10-60mg once daily £289 - £808

Atomoxetine

Strattera 10/18/25/40/60mg one tablet daily £812

Dexamfetamine

Dexedrine 2.5mg-40mg daily, £123-£1,966
Lisdexamfetamine 30-70mg daily £757 - £1,081

Prices from June 2013 edition of MIMS and June 2013 edition of Drug Tariff

Contact details

Lincolnshire Partnership Trust

Boston
Dr J Radomski
Archway Centre
Tel 01205 355739

Gainsborough
Dr Nadkarni
John Coupland Hospital
Tel 01427 816562

Grantham
Dr S Nazir
Child and Adolescent Unit
St Catherine's Road
Tel 01476 560759

Sleaford
Dr S Hakim & Dr S Timimi
Ashvilla Unit
Tel No 01529 488061

United Lincolnshire Hospitals Trust Community Paediatric Services

Boston
Dr E Ikhena
Boston Health Centre
Tel 01205 360880 ext 208

Grantham
Dr J Clarke
Grantham Hospital
Tel 01476 464500

Lincoln
Dr F Johnson
Lincoln County Hospital
Tel 01522 5125512 Ext 3177

For advice regarding medication

Specialist Mental Health Pharmacy Service
Unit 12 A
Oak House
Witham Park
Waterside South
Lincoln
LN5 7FB
Tel No 01522 839587

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6.Leicestershire Medicines Strategy Group- Shared care agreement for methylphenidate, dexamfetamine and atomoxetine for use in Attention Deficit Hyperactivity Disorder in children and adolescents.
7.Shared care protocol Dexamfetamine for treatment of ADHD. NHS Lothian. June 2009.
8.Summary of product characteristics. Elvanse 30mg,50mg & 70mg hard capsules. Shire Pharmaceuticals Limited. Updated 28th February 2013.

Compiled on behalf of Lincolnshire Partnership Trust Medicines Management Committee, United Lincolnshire Hospitals Community Paediatric Service and NHS Lincolnshire by:

Cathy Johnson
Interface Lead Pharmacist
NHS Lincolnshire

Updated June 2013

Appendix A Invitation to shared care.

Shared Care Protocol for treatment of Attention Deficit Hyperactivity Disorder in Childhood

Section 1: Agreement for transfer of prescribing to GP

Patient details/addressograph

Name ……
Address ……
……
DOB …… Hospital No ……

Drug name and dose:

The following tests, investigations have been carried out:

Blood pressure: Date:
Pulse: Date:
Weight: (including centiles) Date:
Height: (including centiles) Date:
Diagnosis of ADHD made on (date):
Medication started on (date):
Patient stabilised on (drug/dose):
Patient's last clinic visit on (date):
Patient's next clinic visit on: then every months

Consultant: Address: Contact Number:	**Agreement to shared care, to be signed by GP and Consultant before transfer of care to GP.** **Consultant Signature:** …… **Date:**
GP Address: Contact Number:	
Main Carer / parent / guardian: Contact Number:	**GP Signature:** …… **Date:**
Key worker if appropriate: Contact Number:	

The GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant. The GP should then discuss alternative arrangements with the responsible consultant.

Lincolnshire East CCG
Lincolnshire West CCG
South Lincolnshire CCG
South West Lincolnshire CCG
Lincolnshire Partnership Foundation Trust
United Lincolnshire Hospitals Trust
Greater East Midlands Commissioning Support Unit