|  |  |  |
| --- | --- | --- |
| Lisdexamfetamine Shared Care Guideline: Prescribing Agreement for Attention Deficit Hyperactivity Disorder in Children & Young People (6-18 years) | | |
| **Section A: To be completed by the hospital specialist prescriber initiating the treatment** | | | |
| **GP Practice Details:**  Name: ………………………………………  Address: ……………………………………  Tel no: ………………………………………  Fax no: ………………………………………  NHS.net e-mail: …………………………… | | **Patient Details:**  Name: ………………………………………………  Address: ……………………………………………  DOB: ………………………………  Hospital number: …………………………………  NHS number (10 digits): ………………………… | |
| **Specialist name:** …………………………… **Clinic name:**………………………………….  **Contact details**: Address:........................................................................................................................  Tel no: ……………………………………… Fax no: ………………………………………  NHS.net e-mail: …………………………… | | | |
| **Diagnosis:** ……………………………………… | **Medication name, dose and frequency to be prescribed by GP:** ………………………………………………. | | |
| **Next hospital appointment:** | | | |
| Dear Dr. ……………………..,  Your patient was reviewed on *;* they started (insert medication name and dose) on  for the above diagnosis and in my view, their condition is now stable. I am requesting your agreement to sharing the care of this patient from  in accordance with the attached Shared Care Prescribing Guideline (approval date ). Please take particular note of the responsibilities for the specialist prescriber, GP and patient for this shared care arrangement are detailed.  Patient information has been given outlining potential aims and side effects of this treatment  The patient has given me consent to treatment possibly under a shared care prescribing agreement (with your agreement) and has agreed to comply with instructions and follow up requirements.  Report all adverse effect of **Lisdexamfetamine**, to the MHRA via the yellow card system.  The most recent investigations have been performed on  and are acceptable for shared care. Please monitor:  Blood pressure, pulse and weight every 6 months  For children 10 years and underweight every 3 months.  For children over 10 years weight at 3 and 6 months after starting treatment and every 6 months thereafter.  For diversion of methylphenidate.  Please re-refer the patient or seek specialist advice from the psychiatrist or paediatrician if there is deterioration in ADHD symptomatology, behaviour, evidence of suicidal ideation or adverse effects of medication.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Test** | **Baseline** | **Date** | **Current** | **Date** | | Blood pressure |  |  |  |  | | Pulse |  |  |  |  | | Weight (including centiles) |  |  |  |  | | Height (including centiles) |  |  |  |  |   Other relevant information: ………………………………………………………………………………………..  Specialist prescriber Signature: ………………………………………………Date: | | | |
| **Section B: To be completed by the GP and returned to the hospital specialist prescriber as detailed in Section A above [If returned via e-mail, use NHS.net email account ONLY]** | | | |
| Please sign and return your agreement to shared care within 14 days of receiving this request.  Tick which applies:  I accept sharing care as per shared care prescribing guideline and above instructions.  I would like further information. Please contact me on: ……………………….  I am not willing to undertake shared care for this patient for the following reason:  ……………………………………………………………………………………………………………….  GP name: ………………………………………….……….  GP signature: ………………………………………………Date: | | | |

**This Page is Intentionally Blank**

# Lisdexamfetamine Shared Care Guideline: Prescribing Agreement for Attention Deficit Hyperactivity Disorder in Children & Young People (6-18 years)

|  |
| --- |
| NOTES to the GP  The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing this medicine.  The questions below will help you confirm this:   * Is the patient’s condition predictable or stable? * Do you have the relevant knowledge, skills, and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline? * Have you been provided with relevant clinical details including monitoring data?   If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. Prescribe a maximum of 30 days at a time with a review date of every 6 months. Quantities should be supplied in line with pack size and local waste reduction program.  If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the specialist prescriber 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, who 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 CCG pharmacist will assist you in making decisions about shared care.  It would not normally be expected that a GP would decline to share prescribing on the basis of cost.  **The patient’s best interests are always paramount** |

Approved by: Integrated medicines committee (IMOC)

Approval date: 27th November 2024

Review Date: November 2026

|  |  |  |
| --- | --- | --- |
| **Lisdexamfetamine for attention deficit hyperactivity disorder (ADHD) in Children & Young People**  **(6-18 years)** | | |
| **Specialist prescriber responsibilities**   * Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#Two_indications)) and communicated to primary care. * Use a shared decision-making approach; Discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#Eleven_advice_to_patients)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.   <https://www.choiceandmedication.org/swlstg-tr/printable-leaflets/patient-information-leaflets/75/ALL/>   * Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review * Assess for contraindications and cautions (see [section 4](#Four_cx_and_cautions)) and interactions (see [section 7](#Seven_interactions)). * Conduct required baseline investigations and initial monitoring (see [section 8](#Eight_specialist_monitoring)). * Initiate and optimise treatment as outlined in [section 5](#Five_dosing). Prescribe the maintenance treatment for at least 4 weeks and until optimised. * Prescribe in line with controlled drug prescription requirements (section 6). * Once treatment is optimised, complete the shared care documentation, and send to patient’s GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#Thirteen_specialist_contact)). * Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care. * Conduct scheduled reviews and monitoring in [section 8](#Eight_specialist_monitoring) and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD. * Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. Trial discontinuations should be managed by the specialist. · Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant. · Provide advice to primary care on the management of adverse effects if required. * Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant. * Provide advice to primary care on the management of adverse effects if required.   **Primary care responsibilities**   * Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible. * If accepted, prescribe ongoing treatment as detailed in the specialist’s request and as per [section 5](#Five_dosing)taking into account any potential drug interactions in [section 7](#Seven_interactions). * Prescribe in line with controlled drug prescription requirements (section 6). * Adjust the dose of Lisdexamfetamine prescribed as advised by the specialist. * Conduct the required monitoring as outlined in [section 9](#Nine_primary_care_monitoring). Communicate any abnormal results to the specialist. * Assess for possible interactions with Lisdexamfetamine when starting new medicines (see [section 7](#Seven_interactions).) * Manage adverse effects as detailed in [section 10](#Ten_ADRs_and_Management) and discuss with specialist team when required. * Stop Lisdexamfetamine and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected. * Refer the management back to the specialist if the patient becomes or plans to become pregnant. * Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.   **Patient and/or carer responsibilities**   * Take Lisdexamfetamine as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist. * Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend. * Report adverse effects to their GP. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#Eleven_advice_to_patients). * Report the use of any over the counter (OTC) medications to their primary care prescriber and be aware they should discuss the use of Lisdexamfetamine with their pharmacist before purchasing any OTC medicines. * Be aware that Lisdexamfetamine can affect cognitive function and, therefore patients must ensure their ability to drive is not impaired before driving. * Lisdexamfetamine is subject to drug driving laws. Not to drive, cycle or operate machines if Lisdexamfetamine affects their ability to do so safely, e.g. by causing dizziness, drowsiness and visual disturbances and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/adhd-and-driving> and [section 11](#Eleven_advice_to_patients). * Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs. * Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store Lisdexamfetamine safely and securely. It must not be shared with anyone else. * Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant. | | |
| **1. Background** [Back to top](#Responsibilities) | | |
| Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity. It is indicated as part of a comprehensive treatment programme for the treatment of attention deficit hyperactivity disorder (ADHD) when the response to a 6-week trial of methylphenidate treatment is considered clinically inadequate. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance [NG87 Attention deficit hyperactivity disorder: diagnosis and management](https://www.nice.org.uk/guidance/ng87/chapter/Recommendations)). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural, and occupational or educational needs.  Lisdexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. A maximum of 30 days’ supply for Lisdexamfetamine should be prescribed. See NICE Guidance [NG46 Controlled drugs: safe use and management](https://www.nice.org.uk/guidance/ng46/chapter/Recommendations).  Pharmacological treatment of ADHD may be needed for extended periods. When Lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly by a healthcare professional with expertise in ADHD, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy.  Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated. | | |
| **2. Indications** [Back to top](#Responsibilities) | | |
| Licensed for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate or not tolerated (2nd line treatment).  Use of Lisdexamfetamine is as well as a comprehensive treatment programme typically includes psychological, educational, and social measures. | | |
| **3. Locally agreed off-label use** [Back to top](#Responsibilities) | | |
| Not applicable | | |
| **4. Contraindications and cautions** [Back to top](#Responsibilities)  This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drug/ciclosporin.html) & [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for comprehensive information. | | |
| **Contraindications:**   * Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines. * Glaucoma. * Symptomatic cardiovascular disease. * Moderate or severe hypertension. * Advanced arteriosclerosis. * Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment. * Hyperthyroidism or thyrotoxicosis. * Agitated states.   **Cautions:**   * History of substance or alcohol abuse. * Cardiovascular disorders such as structural cardiac abnormalities, cardiomyopathy, arrhythmias, coronary artery disease, mild hypertension, recent myocardial infarction, or heart failure. * Family history of sudden cardiac or unexplained death, ventricular arrhythmia, tics or Tourette’s syndrome. * Underlying medical conditions or concomitant drugs which can increase the QT-interval or heart rate, or elevate blood pressure (e.g., cardiac disease, electrolyte disturbance). * History of seizure disorders (discontinue if seizures occur). * Susceptibility to angle-closure glaucoma. * Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour), tics, Tourette’s syndrome, anxiety, or bipolar disorder. * Depressive symptoms: patients should be screened for risk of bipolar disorder, including psychiatric and family histories. * Severe renal impairment; GFR 15-30mL/min/1.73m2 or CrCl less than 30mL/min. Dose reduction is required, see [section 5](file:///C:\Users\Esther-Njane\Downloads\B1621_v_lisdexamfetamine-for-patients-within-adult-services.docx#Five_dosing). * Hepatic insufficiency (due to lack of data). * Pregnancy or breast-feeding (see [section 12](file:///C:\Users\Esther-Njane\Downloads\B1621_v_lisdexamfetamine-for-patients-within-adult-services.docx#Twelve_pregnancy_paternity)). * Potential for abuse, misuse, or diversion. | | |
| **5. Initiation and ongoing dose regime** [Back to top](#Responsibilities)   * Transfer of monitoring and prescribing to primary care is after at least **12 weeks**, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 4 weeks. * The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. * All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. * Termination of treatment will bethe responsibility of the specialist. | | |
| **Initial stabilisation (must be prescribed by the initiating specialist):** The starting dose is 30 mg taken once daily in the morning. When in the judgment of the clinician a lower initial dose is appropriate, patients may begin treatment with 20 mg once daily in the morning. **Maintenance dose (following initial stabilisation):** The dose may be increased by 10 or 20 mg increments, at approximately weekly intervals. The maximum recommended dose is 70 mg/day; higher doses have not been studied. **The initial maintenance dose must be prescribed by the initiating specialist.**  **Conditions requiring dose adjustment:**  Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a 1-month period. If paradoxical aggravation of symptoms or other intolerable adverse events occur, the dosage should be reduced or discontinued  Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and GP of the outcome.  In severe renal impairment (GFR 15-30mL/min/1.73m2 or CrCl less than 30mL/min), the recommended maximum dose is 50 mg per day. | | |
| **6. Pharmaceutical aspects** [Back to top](#Responsibilities) | | |
| Route of administration: | Oral | |
| Formulation: | Formulation:  Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®). See [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for full details. | |
| Administration details: | The dose may be taken with or without food Lisdexamfetamine capsules may be swallowed whole, or the capsule opened, and the entire contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. See [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for further information.  If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. Afternoon doses should be avoided because of the potential for insomnia | |
| Other important information: | Lisdexamfetamine is a schedule 2 controlled drug and is subject to [legal prescription requirements](https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html). It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of Lisdexamfetamine.  Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations. | |
| **7. Significant medicine interactions** [Back to top](#Responsibilities)  The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drug/ciclosporin.html) or [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for comprehensive information and recommended management. | | |
| The following medicines must not be prescribed without consultation with the specialist:   * **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide**) – additive hypertensive effect. A two-week washout is required when switching to either medicine.   Other clinically significant interactions: -   * **Selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine, paroxetine**): may increase exposure to Lisdexamfetamine, risk of serotonin syndrome * **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome * **Tricyclic antidepressants (TCAs) and nabilone**: may increase risk of cardiovascular adverse events. * **Ascorbic acid and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis)** that acidify urine increase urinary excretion and decrease the half-life of amfetamine. * **Sodium bicarbonate and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting)** that alkalinise urine decrease urinary excretion and extend the half-life of Lisdexamfetamine. * **Antihypertensives**, including guanethidine: effects may be reduced by Lisdexamfetamine. * **Lithium, phenothiazines, haloperidol**: may reduce the effects of Lisdexamfetamine. * **Opioids** (including tapentadol and tramadol): analgesic effects may be increased by Lisdexamfetamine. * **Alcohol:** Limited data is available; therefore, caution is advised as alcohol may exacerbate the CNS side effects of Lisdexamfetamine. * Apraclonidine: effects decreased by Lisdexamfetamine. * **Ritonavir,** tipranavir: may increase exposure to Lisdexamfetamine. * **Safinamide:** predicted to increase the risk of severe hypertension when given with Lisdexamfetamine * **Atomoxetine**: increased risk of adverse effects. | | |
| **8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist prescriber**  Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care. [Back to top](#Responsibilities) | | |
| **Baseline investigations:**   * A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required. * A risk assessment for substance misuse and drug diversion * Height, weight, and body mass index (BMI) * Blood pressure (BP) and heart rate * Arrange for electrocardiogram (ECG), only if the patient has any of the following:   o History of congenital heart disease or previous cardiac surgery  o Sudden death in a first-degree relative under 40 years suggesting a cardiac disease  o Shortness of breath on exertion compared with peers  o Fainting on exertion or in response to fright or noise  o Palpitations  o Chest pain suggestive of cardiac origin  o Signs of heart failure, heart murmur or hypertension  o Current treatment with a medicine that may increase cardiac risk  **Initial monitoring:**   * Before every change of dose: assess heart rate, blood pressure, and weight. * After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring. * Monitor for aggressive behaviour or hostility. * Assessment of symptom improvement. Discontinue if no improvement is observed after one month.   **Ongoing monitoring:**   * Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why. * Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.   When a patient is reviewed, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. | | |
| **9. Ongoing monitoring (ADHD)**   * Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This in southwest London will be carried out by secondary care specialists, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why. * Review outcomes should be communicated to the primary care prescriber in writing with any changes.   [Back to top](#Responsibilities)  See [section 10](#Ten_ADRs_and_Management) for further guidance on management of adverse effects/responding to monitoring results. | | |
| **Monitoring** | | **Frequency** |
| * Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms. (Additional relevant investigations (e.g., ECG if family history of arrhythmias or sudden death or if the treatment may affect the QT interval). * Weight and appetite. * Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g., tics, anxiety, symptoms of bipolar disorder). * Explore whether patient is experiencing any difficulties with sleep. | | * Blood pressure & pulse every 6 months. * For children 10 years and underweight every 3 months. * For children over 10 years weight at 3 and 6 months after starting treatment and every 6 months thereafter * Height and weight should be plotted on a growth chart which are available through the RCPCH website <https://www.rcpch.ac.uk/resources/growth-charts> |
| Monitor clinical response and side effect burden within two weeks of dose change | | 2 weeks |
| Assessment of adherence, and for any indication of Lisdexamfetamine abuse, misuse, or diversion. | | As required, based on the patient’s needs and individual circumstances. |
| Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD | | Annually |
| **10. Adverse effects and other management** [Back to top](#Responsibilities)  **Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  For information on incidence of ADRs see relevant summaries of product characteristics | | |
| **Result** | | **Action for primary care** |
| **As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance** | | |
| **Cardiovascular**  Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP | | * In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management. * In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice. |
| **Weight or BMI outside healthy range**  Anorexia or weight loss, weight or BMI outside healthy range | | Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per [NICE NG87](https://www.nice.org.uk/guidance/ng87/):   * take medication with or after food, not before. * additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off * obtaining dietary advice * consuming high-calorie foods of good nutritional value   Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required. |
| **Gastrointestinal disorders**  Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics | | Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required |
| **Psychiatric disorders**  New or worsening psychiatric or neuropsychiatric symptoms, e.g., mania, depression, paranoia, anxiety and agitation | | Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present |
| Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction | | Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required |
| New or worsening seizures | | Stop treatment and discuss with specialist. Discontinuation may be indicated. |
| Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea | | Discontinue Lisdexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary.  Discuss with specialist team to determine whether Lisdexamfetamine can be re-started. |
| Suspicion of abuse, misuse, or diversion | | Discuss with specialist team |
| **11. Advice to patients and carers** [Back to top](#Responsibilities)  The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines. | | |
| **The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**   * Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania and suicidal ideation * Palpitations, chest pain or syncope * Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory * Abdominal pain, malaise, jaundice or darkening of urine. * Skin rashes, or bruising easily. * Any visual changes such as difficulty with accommodation or blurring of vision. * If they suspect, they may be pregnant or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception and take a pregnancy test if they think there is a possibility, they could be pregnant.   **The patient should be advised:**   * Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments. * That Lisdexamfetamine can affect cognitive function and, therefore patients must ensure their ability to drive is not impaired before driving. * Lisdexamfetamine is subject to drug driving laws. Not to drive, cycle or operate machines if lisdexamfetamine affects their ability to do so safely, e.g. by causing dizziness, drowsiness and visual disturbances and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/adhd-and-driving> and [section 11](#Eleven_advice_to_patients). * Avoid alcohol while taking Lisdexamfetamine, as it may make some side effects worse. Avoid recreational drugs. * Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store Lisdexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see <https://www.gov.uk/guidance/controlled-drugs-personal-licences>. * Due to the risks of severe depression, and fatigue, abrupt withdrawal after a prolonged period of intake of high doses of Lisdexamfetamine should be avoided. Patients wishing to reduce their dose or stop Lisdexamfetamine treatment should discuss with their specialist before doing so.   **Patient and carers information:**   * NHS – attention deficit hyperactivity disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/> * [» Attention Deficit Hyperactivity Disorder (choiceandmedication.org)](https://www.choiceandmedication.org/swlstg-tr/condition/attention-deficit-hyperactivity-disorder/) * [ADHD and Mental Health | Signs and Symptoms of ADHD | YoungMinds](https://www.youngminds.org.uk/young-person/mental-health-conditions/adhd-and-mental-health/) * Patient information leaflets are also available from [Search Results - (emc) (medicines.org.uk)](https://www.medicines.org.uk/emc/search?q=%22Methylphenidate%22) * ADHD support groups [Support Groups | The UK ADHD Partnership](https://www.ukadhd.com/support-groups.htm) * [Patient leaflets | BMJ Best Practice](https://bestpractice.bmj.com/patient-leaflets?) * [ADHD and hyperkinetic disorder for parents | Royal College of Psychiatrists (rcpsych.ac.uk)](https://www.rcpsych.ac.uk/mental-health/parents-and-young-people/information-for-parents-and-carers/ADHD-and-hyperkinetic-disorder-information-for-parents)   **ADHD resources for children and young people, parents/carers and primary care professionals**  Working with the ADHD Foundation, we have launched new set of booklets for children, teenagers and their parents and carers. There are three separate booklets, each of which has a different focus:  • The children’s booklet is an interactive guide with 20 fun activities for children to help them focus, manage their emotions, and succeed  • The teenager’s booklet is a guide and workbook with information and activities to support teenagers living with ADHD  • The parents/carers booklet is an information and resource guide for parents and carers of children and young people with ADHD and may also be useful for health professionals including those working in primary care.  All three booklets are available to share and download on the website: <https://www.transformationpartnersinhealthandcare.nhs.uk/cyp-adhd-resources> | | |
| **12. Pregnancy, paternal exposure and breast feeding** [Back to top](#Responsibilities)  It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist. | | |
| **Pregnancy:**  The active metabolite of Lisdexamfetamine, dexamfetamine, is thought to cross the placenta. The limited data available shows an increased risk of premature birth and preeclampsia. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.  If a patient becomes pregnant or is planning a pregnancy during treatment, they should discuss treatment options with their specialist. The specialist will reassume prescribing responsibility, ending the shared care agreement. Lisdexamfetamine should only be used during pregnancy if the potential benefit outweighs the risks.  Healthcare professional information available from [USE OF AMFETAMINES IN PREGNANCY (medicinesinpregnancy.org)](https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/)  **Breastfeeding:**  There is no published evidence for safety of Lisdexamfetamine in breastfeeding. The manufacturers recommend against use, and the UK Drugs in Lactation Service recommend caution (see link below). Lisdexamfetamine metabolites, including dexamfetamine, are excreted in human milk, therefore a risk to infants cannot be excluded. An individual risk assessment must be made, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Healthcare professional information available from: <https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/>  **Paternal exposure:**  No evidence regarding adverse outcomes following paternal exposure was identified. | | |
| **13. Specialist prescriber contact information** [Back to top](#Responsibilities) | | |
| Name: *insert name*  Role and specialty: *insert role and speciality*  Daytime telephone number: *insert daytime telephone number*  Email address: *insert email address*  Alternative contact: *insert contact information, e.g. for clinic or specialist nurse*  Out of hours contact details: *insert contact information, e.g. for duty doctor* | | |
| **14. Additional information** [Back to top](#Responsibilities) | | |
| Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. | | |
| **15. References** [Back to top](#Responsibilities) | | |
| * NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <https://www.nice.org.uk/guidance/ng87/> on 24/11/22 * eBNFc. Lisdexamfetamine, version last updated 11/11/2022. Accessed via [Lisdexamfetamine mesilate | Drugs | BNFC | NICE](https://bnfc.nice.org.uk/drugs/lisdexamfetamine-mesilate/) on 28/11/2022 * Lisdexamfetamine dimesylate 20 mg hard capsules (Elvanse®). Date of revision of the text: 11/01/21. Accessed via [Elvanse 20mg Hard Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)](https://www.medicines.org.uk/emc/product/14091/smpc)on 24/11/22 * NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <https://www.nice.org.uk/guidance/ng87/> on 21/11/2022. * NICE NG43: Transition from children to adults’ services for young people using health or social care services. Last updated February 2016. Accessed via <https://www.nice.org.uk/guidance/ng43/> on 21/11/2022. * Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via <https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/> on 21/11/2022. * NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Methylphenidate. Updated October 2022. Accessed via [Amfetamines | Prescribing information | Attention deficit hyperactivity disorder | CKS | NICE](https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/) on 21/11/2022. * Home Office. Guidance: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation. Last updated 8th August 2022. Accessed via [Controlled drugs list - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/controlled-drugs-list--2) on 24/11/2022 * Gov.uk: Drugs and driving: the lawGov.uk. Drugs and driving: the law. Accessed via [https://www.gov.uk/drug-driving-law on 13/05/21](https://www.gov.uk/drug-driving-law%20on%2013/05/21) * Young minds, ADHD and mental health Accessed via [ADHD and Mental Health | Signs and Symptoms of ADHD | YoungMinds](https://www.youngminds.org.uk/young-person/mental-health-conditions/adhd-and-mental-health/) on 24/11/22 * Shared care protocols guanfacine accessed via [NHS England » Shared Care Protocols](https://www.england.nhs.uk/medicines-2/regional-medicines-optimisation-committees-advice/shared-care-protocols/#list) on 21/11/2022 | | |
| **16. Other relevant national guidance** | | |
| * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/> * NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/> * General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care> * NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>. | | |
| **17. Local arrangements for referral** [Back to top](#Responsibilities)  Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. | | |
| Shared care from hospital to primary care  Primary care to hospital – Urgent referrals mental health crisis line or A&E out of hours. For routine/non-urgent referrals contact local CAMHs team. | | |
| **18. Communication**  Please note that the clinical letter received from the specialist prescriber/team should have the relevant contact details. If this is not provided you may find the following contact details useful.  **Medicines Information Services**   * South West London and St Georges Mental Health Hospital: Tel. 020 3513 6829 * South London and Maudsley (SLAM): Tel. 020 3228 2317 * Georges Hospital medicines helpline: Tel. 020 872 51033 * Kingston Hospital medicines helpline: Tel. 020 85467711 ext.2092   Epsom and St Helier Trust medicines helpline: Tel.020 872 51033 | | |