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WORKING IN PARTNERSHIP WITH

SHARED CARE PRESCRIBING GUIDELINE
Dexamfetamine (Dexedrine®) for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Childhood

Surrey PCT's Medicines Management Committee classification: Amber

NOTES to the GP

Amber drugs: Prescribing to be initiated by a specialist (or if appropriate by a GP with specialist interest) but with the potential to transfer to primary care. The expectation is that these guidelines should provide sufficient information to enable GPs 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 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. Sign and return a copy of page 9 to the requesting specialist. Until the requesting specialist has received a signed copy of page 9 indicating that shared care has been agreed all care (including prescribing) remains with the specialist.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the specialist 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 PCT 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 GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the specialist

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Background

Definition: Attention Deficit Hyperactivity Disorder (ADHD) is one of the most commonly diagnosed behavioural disorders of childhood, affecting 1-5% of school age children. Its basic symptoms include developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity. It causes problems at home, in school and with peer relationships and may have long term adverse effects on self-confidence, academic performance, vocational success and social development.

- It can be divided into three types, depending on whether inattention or hyperactivity is the predominant presentation
- It must have been present for at least six months and be maladaptive and inconsistent for the age of the child (although in the case of developmental delay the developmental age should be taken into account).
- There must be clear evidence of impairment in social and / or academic functioning
- Some impairment must be present in at least two settings
- The symptoms must be present in at least two settings
- The symptoms must be present before the age of seven
- The symptoms must not be accountable for by any other type of mental disorder or illness although they may occur in conjunction with some development disorders.

Its consequences are low self-esteem, emotional and social problems which may lead to further problems with drug abuse etc in the longer term. These children's academic achievements are often very low consequently often leading to employment problems.

Where drug treatment is considered appropriate, methylphenidate, atomoxetine and dexamfetamine are recommended, within their licensed indications, as options for the management of ADHD in children. The decision regarding which product to use should be based on the following[1]:

- The presence of co-morbid conditions (for example, tics disorders, Tourette's syndrome, epilepsy)
- The different adverse effects of the drugs
- Specific issues regarding compliance identified for the individual child, for example problems created by the need to administer a mid-day treatment dose at school
- The potential for drug diversion (where the medication is forwarded on to others for non-prescription uses) and/or misuse
- The preferences of the child and/or his or her parent or guardian.

If there is a choice of one or more appropriate drugs, the product with the lowest cost (taking into account the cost per dose and number of daily doses) should be prescribed[1].

Prescribing of methylphenidate, atomoxetine and dexamfetamine for ADHD by Specialists alone results in a significant pressure being put on acute Trusts and is an inconvenience to families. Shared care prescribing guidelines for ADHD allow parents to collect prescriptions from their local GP practice at their convenience, whilst ensuring continuous specialist care of the child through regular monitoring at clinic appointments. A number of resources and support is available to GPs to ensure that they feel confident to take on the prescribing of ADHD drugs (see list on pg 8).

Diagnosis

Should be made by a child / adolescent psychiatrist or paediatrician with a special interest in ADHD, involving the child, its carers and school. A multidisciplinary assessment including educational and clinical psychologists, social workers etc may be necessary in individual cases. **Almost 50% of children who have ADHD may have other co-morbid conditions which include autistic spectrum/Asperger's syndrome, dyslexia, dyspraxia and oppositional-defiant difficulties. Recognising these conditions is important to ensure comprehensive planning is made.**

Technology

- Dexamfetamine is a sympathomimetic amine with a central stimulant and anoretic activity. It is an alternative in children who do not respond to methylphenidate or atomoxetine.
- Onset of action is 60-90 minutes with peak serum concentration being reached within three hours of oral administration. Metabolised in the liver and excreted in the urine as unchanged drug and inactive metabolites.
- The drug will only work where hyperactivity and attention deficit are the presenting problems and not on behavioural problems such as oppositional defiant disorder (ODD) which may mimic ADHD. However if ODD and ADHD are co-morbid, treatment of ADHD would enable ODD to be treated more successfully.
- Treatment should be discontinued periodically, usually annually, by the specialist. The drug should be withdrawn slowly to avoid inducing depression or extreme fatigue. During this time the child will be kept under review by the specialist with close liaison with the parents and the school.

Criteria for Use

1. The diagnosis of ADHD is made by a Child Psychiatrist or a Specialist Paediatrician after a comprehensive assessment which includes the completion of questionnaires by carers and teachers, such as the Conner's questionnaires. If there is significant co-morbidity such as learning difficulties or other mental health problems, a full multidisciplinary assessment is advised. If medication is indicated as part of the treatment package, an initial prescription for dexamfetamine is given by the specialist for a trial period of one month.
2. Dexamfetamine is considered third line treatment for ADHD after methylphenidate and atomoxetine.
3. If improvement of symptoms is not observed after appropriate dosage adjustment over the one month period, the drug should be discontinued by the specialist. Treatment should be stopped gradually since abrupt cessation may produce extreme fatigue and mental depression.
4. The drug may be discontinued periodically to assess the child's condition as advised by the specialist.
5. It is the specialist's responsibility for stopping dexamfetamine or to agree aftercare when the patient reaches 18 years of age.
6. All children and families with a child taking dexamfetamine should receive psychological and / or educational interventions with a view to improving the symptoms of ADHD and allowing children to reduce their need for medication. The extent of these interventions and the level of need will be assessed and agreed with the individual clinician and family.
7. Explanations given to the family about medication are important. For example children should not be told that the medication is the only thing that can control their behaviour. Explanations should always seek to foster healthy development trajectories for children.
8. Prescriptions should be written in accordance with the Misuse of Drugs Act
9. Some clinicians use dexamfetamine on school days only where the effect sought may relate mainly to education and this is recognised practice.

Information

This does not replace the 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 for children.

This guideline follows the recommendations of NICE guidance 72 on the use of dexamfetamine for Attention Deficit / Hyperactivity disorder (ADHD) in childhood [2].

Dose / Licensing

- Dexamfetamine is indicated for use as part of a comprehensive treatment programme, where remedial behavioural methods alone have failed. Various trials show that the most effective treatments are those combining treatments with medication, but the resource implications of this means that many children would receive no care and medication alone does show significant gains.
- Dexamfetamine is considered third line treatment for ADHD after methylphenidate and atomoxetine.
- Dexamfetamine is not licensed for children under three years old and is often discontinued during adolescence although this practice is likely to change when adult psychiatry services are more developed.
- Dexamfetamine is a controlled drug subject to safe custody and handwriting regulations on prescriptions where total quantity to be supplied must be specified in both words and figures.
- For children <6 years: the dose starts at 2.5mg a day and is gradually titrated up if necessary by weekly increments of 2.5mg of the total daily dose to a maximum of 20mg daily. For children >6 years: the dose starts at 5-10mg a day and is gradually titrated up if necessary by weekly increments of 5mg of the total daily dose to a maximum of 40mg daily. The maintenance dose should be given as divided doses (usually 2-3 times daily).
- Twice daily doses are usually given in the morning and at lunchtime, however if the effect of the drug wears off too early in the evening disturbed behaviour and or inability to sleep may recur. A small evening dose may help to solve this problem.
- If improvement of symptoms is not observed after appropriate dosage adjustment over a one month period the drug should be discontinued by the specialist.

Cost

Drug	Dose	Cost (Mims 2010)
Dexedrine®	Children <6 years initially 2.5mg daily titrated gradually to a maximum of 20mg daily in divided doses. Children >6 years initially 5-10mg daily titrated gradually to a maximum of 40mg daily in divided doses.	28 x 5mg tablets: £3.00

Cautions[3]

- Must only be used under the supervision of a specialist in childhood behavioural disorders
- Moderately reduced weight gain and slight growth retardation have been reported with the long-term use of dexamfetamine: monitor height and weight
- Mild hypertension (contraindicated if moderate or severe), monitor blood pressure
- Motor tics, tics in siblings or a family history or diagnosis of Tourette's syndrome
- Psychosis, emotional instability
- Careful supervision is required during drug withdrawal. Treatment should be stopped gradually as abrupt cessation may produce extreme fatigue and mental depression.

Contra-indications[3]

- Children with marked anxiety, agitation or tension.
- Hyperthyroidism, glaucoma, porphyria or hyperexcitability.
- Symptomatic cardiovascular disease including moderate to severe hypertension.
- Pregnancy and lactation.
- Known hypersensitivity to dexamfetamine or other amphetamine derivatives or excipients of the formulation.
- During or for 14 days after treatment with an MAOI (monoamine oxidase inhibitor).
- Patients with a history of drug or alcohol abuse.

Interactions[3]

- Adrenoreceptor blocking agents (e.g. propranolol) and lithium may antagonise the effects of dexamfetamine.
- The concurrent use of tricyclic antidepressants may increase the risk of cardiovascular side effects.
- Concurrent use of MAOIs or use within the preceding 14 days may precipitate a hypertensive crisis.
- Concurrent use of beta-blockers may result in severe hypertension.
- Amphetamines may delay the absorption of ethosuximide, phenobarbitone and phenytoin.
- Acute dystonia has been noted with concurrent administration of haloperidol.
- Phenothiazines may inhibit the actions of dexamfetamine.
- Alcohol may exacerbate the adverse CNS effect of dexamfetamine. Patients should be advised to abstain from alcohol during treatment.

Side effects[3]

- Insomnia, restlessness, irritability, euphoria, tremor, dizziness, headache and other symptoms of over-stimulation have been reported. Also dry mouth, unwanted anorexia and other gastro-intestinal symptoms, sweating, 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 precipitated by the hypertensive effect and possibly associated with pre-existing vascular malformation.
- Rhabdomyolysis and renal damage.
- The following adverse effects have been noted: psychosis/psychotic reactions, night tremors, nervousness, abdominal cramps, decreased blood pressure, altered libido and impotence, growth retardation, hyperpyrexia, mydriasis, hyperflexia, chest pain, confusion, panic states, aggressive behaviour, delirium, visual disturbance, tics and Tourettes syndrome in pre-disposed individuals.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. To assess the patient and establish a diagnosis of attention-deficit hyperactivity disorder, to determine a management strategy and communicate this to the family and GP. The diagnosis must clearly be demonstrated through a detailed report outlining the current problems, developmental history and presence of "core signs" of ADHD. These must meet the diagnostic criteria of the DSM-IV. Almost 50% of children who have ADHD may have other co-morbid conditions which include autistic spectrum/Asperger's syndrome, dyslexia, dyspraxia and oppositional-defiant difficulties. Recognising these conditions is important to ensure comprehensive planning is made.
2. Consider and discuss dexamfetamine treatment with the parents / responsible adult for the children who meet the criteria laid down in NICE guidance. This should include a discussion of the reasons for treatment, the possible side effects and the lack of information in relation to longer term outcomes including effectiveness and adverse effects.
3. Ensure baseline monitoring of height, weight, BP, pulse rate have been performed plus any additional relevant investigations such as ECG in case of family history of arrhythmia or sudden death.
4. Initiation and stabilisation of drug treatment. The GP is not expected to enter into a shared care agreement until the patient is stabilised on dexamfetamine and the parents at this stage are instructed to communicate directly with the clinic. As dexamfetamine is not considered first line treatment a GP might have agreed shared care previously with another drug. If the decision to switch treatment due to side effects/ poor response is made by the specialist then another shared care agreement should be made between the specialist and the GP once the patient has stabilised on dexamfetamine.
5. Set the review interval and criteria. The Specialist must ensure contact four weeks after initiation of treatment to assess effectiveness. An appointment should be arranged three months after initiation of treatment to undertake necessary monitoring (see point 6 below). Once a child's treatment is stabilised, six monthly review appointments are offered by the Specialist. Specialist ADHD nurses, junior doctors and other staff are closely involved with the monitoring of the patients. When junior / middle grade doctors are helping the Specialists in the clinic, changes should be made after discussion with the Specialist only, and should be clearly stated in a letter to the GP.
6. Undertake any necessary monitoring at clinic appointments (initially three monthly, then six monthly in the long term): blood pressure, pulse rate, weight and height (including centiles). Unless the child has symptoms routine monitoring of full and differential blood counts are not carried out.
7. Supply the medication until the dose is stabilised. Prescribing may be transferred to the GP under shared care once the patient is stabilised on medication. The GP will not be asked to prescribe the drug outside its licensed indications.
8. Maintain good communication with the GP. A written letter should be sent to the GP after each clinic visit notifying the GP of changes in the medication regime, adverse effects and results of the patient's routine monitoring. The GP must be notified of non-attendance at clinic.
9. Keep the GP fully informed about the patient's condition and medication. The specialist will be available to answer queries from the GP and carers.
10. Stop or modify the dosage as appropriate.
11. Advise the GP when the treatment is being discontinued. The specialist will provide necessary supervision and support during the drug discontinuation phase.
12. Liaison with other members of the multidisciplinary team responsible for the child's development and education. The parents and class teachers should be given information about dexamfetamine in particular the monitoring and side effects.
13. Evaluate adverse drug reactions reported by the GP or carer.
14. The appropriateness of medication into adulthood should be carefully reviewed. If the drug is to be continued beyond the age of 18, the specialist will seek to make appropriate arrangements.
15. Continue supply of medication for children under six years.
16. Explain to the patient / carer their roles

General Practitioner responsibilities
1. Some GPs may feel able to make diagnosis of ADHD. Psychoeducation and parent training can take place in primary care for children who have mild or moderate ADHD. Other GPs will initiate referral to a specialist on suspicion of ADHD. 2. GPs should be aware that almost 50% of children who have ADHD may have other co-morbid conditions which include autistic spectrum/Asperger's syndrome, dyslexia, dyspraxia and oppositional-defiant difficulties. Recognising these conditions is important to ensure comprehensive planning is made. 3. Children who are severely affected by ADHD should be referred to secondary care without delay. These children will require medication early as part of the treatment package. 4. Monitor patient's overall health and well being. 5. Continued prescription of treatment, once patient is stabilised on medication and shared care is agreed, at the appropriate intervals given the nature of the drug and the family involved. As it is not necessary for a doctor to see the child more than every 3-6 months, unless there are specific indications, repeat prescriptions can be issued without necessarily seeing the child on each occasion. 6. To check that the patient is attending their six monthly specialist ADHD clinics and thus continued prescription is required. 7. Although the responsibility for carrying out monitoring lies with the specialist, the GP must ensure results are acceptable before generating further prescriptions. 8. Symptomatic management of minor adverse effects. 9. Report any adverse effects to the consultant and Medicine and Healthcare Products Regulatory Agency (MHRA) where appropriate. 10. As this is a Controlled Drug, if the GP has information about previous misuse of drugs by family members, they should alert the relevant Child Psychiatrist or Paediatrician to this. 11. Referral back to specialist if any problems arise.

Patient's / Carer's role
1 Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment. 2 Share any concerns in relation to treatment with dexamfetamine. 3 Tell the specialist or GP of any other medication being taken, including over-the-counter products. 4 Read the patient information leaflet included with the medication and report any side effects or concerns they have to the specialist or GP

Audit / **Survey** (To be carried out by specialist clinic)

- Total number of patients assessed
- Number referred to Specialist
- Number of patients receiving treatment
- Are they being monitored correctly according to shared care protocol?
- Length of time drug used
- Evidence of benefit: increase in quality of life
- Length of treatment, number discontinued and reason for discontinuation

BACK-UP ADVICE AND SUPPORT

Hospital / clinic contacts:

Please see details on the referral letter.

Specialist support / resources available to GP - including patient information

1. Contact with relevant specialist / specialist nurse
2. Information in British National Formulary for children
3. References
4. ADHD support groups www.ADDISS.co.uk
5. Diagnostic and statistical manual of mental disorders, DSM IV, published by the American Psychiatric Association
6. Principles of Treatment for Hyperkinetic Disorder: Practice Approaches for the UK. Overmeyer S and Taylor E.
7. ADDmire (ADD multi-agency information resource) – a group of professionals and parents involved in the care of children with Attention-deficit hyperactivity disorder (also known as ADD or ADHD) www.addmire.org.uk. Site managed by Ashford and St Peter's Hospital's NHS Trust.

References:

1. NICE technology Appraisal Guidance No 98 March 2006: Methylphenidate, atomoxetine and dexamphetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents.
2. NICE clinical guideline 72 September 2008: Attention deficit hyperactivity disorder, Diagnosis and management of ADHD in children, young people and adults.
3. Product specification, Dexedrine® –www.medicines.org.uk (accessed 23 March 2010).

Other references used:

- SIGN clinical guideline 112 October 2009: Management of attention deficit and hyperkinetic disorders in children and young people.
- Ashford and St Peter's Hospital NHS Trust Shared Care Protocol for the use of Dexamfetamine (Dexedrine®) in Attention Deficit Hyperactivity Disorder in Childhood, August 2004.
- Blackwater valley and Hart, & North Hampshire Primary Care Trusts Treatment Plan and Shared Care Agreement Methylphenidate (Ritalin®, Equasym®, Concerta XL®), Atomoxetine (Strattera®) and Dexamphetamine (Dexedrine®) for attention deficit hyperactivity disorder (ADHD) in children and adolescents Dec 2005.

Shared Care Prescribing Guideline
Dexamfetamine (Dexedrine®) for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Childhood

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 6 months

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

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

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