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WORKING IN PARTNERSHIP WITH

SHARED CARE PRESCRIBING GUIDELINE
Methylphenidate 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 11 to the requesting specialist. Until the requesting specialist has received a signed copy of page 11 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 inappropriate 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 10).

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

- Methylphenidate is a short acting stimulant similar to amphetamines first used for hyperactive children in the USA in the 1960s.
- 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 is stopped immediately and 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 methylphenidate is given by the specialist for a trial period of one month.
2. If improvement of symptoms is not observed after appropriate dosage adjustment over the one month period, the drug should be discontinued by the specialist. The medication may be stopped abruptly; there is no tailing off necessary.
3. The drug may be discontinued periodically to assess the child's condition as advised by the specialist.
4. It is the specialist's responsibility for stopping methylphenidate or to agree aftercare when the patient reaches 18 years of age.
5. All children and families with a child taking methylphenidate 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.
6. 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.
7. Prescriptions should be written in accordance with the Misuse of Drugs Act
8. Some clinicians use methylphenidate 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(s) 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 methylphenidate for Attention Deficit / Hyperactivity disorder (ADHD) in childhood [2].

Dose / Licensing

- Methylphenidate is recommended in NICE guidelines as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children over 6 years of age[2].
- Methylphenidate is not licensed for children less than 6 years of age, but may be so used under certain circumstances by the specialist. It is often discontinued during adolescence although this practice is likely to change when adult psychiatry services are more developed.
- Methylphenidate 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.
- Patients may be initiated on either a standard release preparation or a modified release (m/r) preparation of methylphenidate. The dose of standard release methylphenidate initially starts at 5mg once or twice daily (morning and lunch time) and is then gradually titrated up to a usual maximum of 60mg daily in divided doses at intervals of 3-4 hours. The dose may be increased to 2.1mg/kg daily in divided doses (max 90mg daily) under the direction of a specialist. The dose should be titrated up by weekly increments of 5-10mg of the total daily dose. 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.
- The patient can be commenced on or changed to the m/r preparation, if appropriate, up to a usual maximum of 60mg once daily for Equasym XL® or Medikinet XL® or 54mg once daily for Concerta XL® (see Concerta XL® [3], Equasym XL® [4] or Medikinet XL® [5] SPCs for details). The dose may be increased to a maximum of 2.1mg/kg daily (max 90mg daily for Equasym XL® and Medikinet XL® or max 108mg daily for Concerta XL®) under the direction of a specialist.
- If improvement of symptoms is not observed after appropriate dosage adjustment over a one month period the drug should be discontinued by the specialist.

Characteristics of immediate and modified release forms of methylphenidate (SIGN [6])

Name	Product details	Strengths	Formulation	Release profile	Administration details	Cost (Mims Mar 2010)
Generic or branded methylphenidate eg: Ritalin® Equasym® Medikinet®	Immediate release 3-4 hours duration	5mg 10mg 20mg	Tablet	Peak plasma concentration in 1-2 hours.	Tablets can be halved	**Ritalin®** : 30 x 10mg tablets: £5.57 **Equasym®:** 30 x 5mg tablets: £2.67 30 x 10mg tablets: £4.99 30 x 20mg tablets: £9.59 **Medikinet®:** 30 x 5mg tablets: £2.78 30 x 10mg tablets: £4.99 30 x 20mg tablets: £9.98
Concerta XL®	Modified release 10-12 hours duration	18mg 27mg 36mg Dose equivalent: 18mg=5mg IR tds 36mg=10mg IR tds	Capsule shaped tablet containing two layers of drug separated by semi permeable membrane. Outer layer (overcoat) released first, followed by gradual release of drug from inner core. Empty tablet shell excreted.	22% IR: 78% MR Initial peak concentration in 1-2 hours. Second peak at 6-8 hours.	Tablet must be swallowed whole, not chewed, crushed or broken	30 x 18mg tablets: £31.19 30 x 27mg tablets: £36.81 30 x 36mg tablets: £42.45
Equasym XL®	Modified release up to 8 hours duration	10mg 20mg 30mg	Capsule containing two types of pellets/beads which allow immediate release of drug, followed by gradual release over the day.	30% IR: 70% MR Initial peak plasma concentration in 1-2 hours. Second peak at 4.5 hours.	Capsule may be opened and contents mixed with soft foods (*stability unknown*). Contents must be swallowed whole, not chewed, crushed or broken.	30 x 10mg capsules: £25.00 30 x 20mg capsules: £30.00 30 x 30mg capsules : £35.00
Medikinet XL®	Modified release up to 8 hours duration	10mg 20mg 30mg 40mg	Capsule containing two types of pellets/beads allowing immediate release of half the dose, followed by gradual release over the day.	50% IR:50% MR Initial peak plasma concentration in 1-2 hours. Second phase of drug release 3 hours later resulting in a 3-4 hour plateau.	Capsule may be opened and contents mixed with soft foods (*stability unknown*). Contents must be swallowed whole, not chewed, crushed or broken. Ingestion with high fat content food delays absorption by approximately 1.5 hours.	28 x 10mg capsules: £20.18 28 x 20mg capsules: £26.91 28 x 30mg capsules : £31.39 28 x 40mg capsules : £43.20

IR = Immediate release, MR = Modified release, tds = three times a day NB: Modified release preparations should be prescribed by brand as they are not interchangeable

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Cautions [3-5, 7-9]

- 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 methylphenidate: monitor height and weight.
- Hypertension, monitor blood pressure.
- Epilepsy, increased seizure frequency observed in a small number of patients, discontinue if seizure frequency increases. Incidence of ADHD is however increased in children with epilepsy.
- Pregnancy, lactation (**refer to individual SPCs**).
- Careful supervision is required during drug withdrawal since this may unmask depression as well as chronic over-activity.
- Concerta XL® must be swallowed whole with the aid of liquids and must not be chewed, divided or crushed. Equasym XL® and Medikinet XL® capsules may be opened and the contents sprinkled on soft food (NB: the contents must be swallowed whole, not chewed, crushed or broken).
- Motor tics, tics in siblings or a family history or diagnosis of Tourette's syndrome.
- Use caution where there is a history of drug or alcohol abuse. Alcohol may exacerbate the adverse CNS effect of psychoactive drugs including methylphenidate. It is therefore advisable for patients to abstain from alcohol during treatment.

Contra-indications [3-5, 7-9]

- Children with marked anxiety, agitation or tension.
- Hyperthyroidism, severe angina pectoris, cardiac arrhythmias, glaucoma, thyrotoxicosis.
- Known sensitivity to methylphenidate or excipients of the formulation.
- During or for 14 days after treatment with an MAOI (monoamine oxidase inhibitor).

Interactions [3-5, 7-9]

- Methylphenidate may inhibit the metabolism of coumarin anticoagulants, some anticonvulsants (phenobarbitone, phenytoin and primidone), phenylbutazone and tricyclic antidepressants. The dosage of these drugs may have to be reduced.
- MAOIs. Because of possible hypertensive crisis, methylphenidate is contra-indicated in patients being treated (currently or within preceding 2 weeks) with non-selective irreversible MAOIs.
- Alcohol may exacerbate the adverse CNS effect of methylphenidate. Patients should be advised to abstain from alcohol during treatment.
- Pseudoephedrine, phenylpropanolamine (both found in OTC cough and cold remedies). Patients should be warned when buying cough and cold medicines.

Side effects [3-5, 7-9]

Frequency	Side effect
Very Common: >10%	• Nervousness and insomnia at onset of treatment – reduce the dosage and / or omit the afternoon or evening dose (if severe can be helped by adding melatonin 3-9mg at night (to be initiated by specialist only). Alternatively, clonidine can be given but additional monitoring is required with ECGs etc, initiated by specialist only).
Common: >1% to <10%	• Decreased appetite - may be transient. Give medication with or just after eating. If the child has difficulty settling to sleep, give bedtime snack which helps sleep as the effect of afternoon dose should be wearing off. • Headache, drowsiness, dizziness and dyskinesia – paracetamol helps • Abdominal pain, nausea and vomiting. Usually occur at beginning of treatment and often eased by taking with food • Dry mouth • Tachycardia, palpitations, arrhythmias, changes in blood pressure (usually upwards) • Rash, pruritis, urticaria, fever, arthralgia and hair loss
Rare: <1%	• Blurred vision and difficulties in visual accommodation • Angina pectoris • Reduced weight gain and slight growth retardation with prolonged use
Very Rare: <0.01%	• Hyperactivity, convulsion, muscle cramps, tics etc see drug SPC • Abnormal liver function ranging from raised transaminase to hepatic coma • Thrombocytopenic purpura, exfoliative dermatitis and erthema multiforme • Leucopenia, thrombocytopenia and anaemia.

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 methylphenidate 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 methylphenidate and the parents at this stage are instructed to communicate directly with the clinic.
5. Set the review interval and criteria. The Specialist must ensure contact four weeks after initiation of treatment to assess if being effective. 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 methylphenidate 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 methylphenidate. 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 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, Concerta XL® – www.medicines.org.uk (accessed 8 December 2009).
4. Product specification, Equasym XL®– www.medicines.org.uk (accessed 8 December 2009).
5. Product specification, Medikinet XL® – www.medicines.org.uk (accessed 8 December 2009).
6. SIGN clinical guideline 112 October 2009: Management of attention deficit and hyperkinetic disorders in children and young people.
7. Product specification, Ritalin® –www.medicines.org.uk (accessed 8 December 2009).
8. Product specification, Equasym®– www.medicines.org.uk (accessed 8 December 2009).
9. Product specification, Medikinet® – www.medicines.org.uk (accessed 8 December 2009).

Other references used:

- Ashford and St Peter's Hospital NHS Trust Shared Care Protocol for the use of Methylphenidate (Ritalin®, Equasym®, Concerta XL®) 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
Methylphenidate 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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