SHARED CARE GUIDELINES FOR PRESCRIBING OF METHYLPHENIDATE IN ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN

INDICATION

Methylphenidate is generally regarded as a first line choice of treatment for hyperkinetic disorders such as Attention Deficit Disorder under the supervision of a physician specialising in child psychiatry as part of a comprehensive treatment programme when psychological, behavioural and educational approaches alone prove unsuccessful.
Methylphenidate is licensed for use in attention deficit hyperactivity disorder (ADHD) **under specialist supervision**.

The NICE clinical guideline for attention deficit hyperactivity disorder (CG no. 72) states that drug treatment:

- should only be started by a healthcare professional with expertise in ADHD
- be based on a comprehensive assessment
- always form part of a comprehensive treatment plan that includes psychological, behavioural and educational advice and interventions.
- may be prescribed and monitored by GPs under shared care arrangements

The NICE guideline states that a pre-drug treatment assessment should be completed, including:

- A full mental health and social assessment,
- A full history and physical examination, including:
    - Assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms,
    - Heart rate and blood pressure (plot on a centile chart)
    - Height and weight (plot on a growth chart)
    - Family history of cardiac disease and examination of the cardiovascular system
- An electrocardiogram (ECG) if there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on cardiac examination
- Risk assessment for substance misuse and drug diversion.

Where methylphenidate is the preferred drug of choice, consider:

- Modified release preparations for convenience, their pharmacokinetic profile, improving adherence, reducing stigma (because the drug does not need to be taken at school) and reducing problems of storing and administering controlled drugs in schools
- Immediate release preparations if more flexible dosing is required or during initial titration to determine correct dosing intervals.

If there is a choice of more than one drug, use the drug of lowest overall cost.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of methylphenidate can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Shared Care is only appropriate if it provides the optimum solution for the patient.

- Patients will only be referred to the GP once the GP has agreed in each individual case
- Arrangements to transfer treatment from secondary to primary care may be made between 4 weeks and 6 months from initiation of treatment, once the condition has been stabilised

Specialist Responsibilities	
1	To make a diagnosis based on timely, comprehensive assessment using appropriate validated questionnaires and including an assessment of child's cultural/social circumstances. To determine a comprehensive management strategy and discuss with the patient/carer the risks, benefits and alternatives of/for treatment.
2.	To initiate treatment and stabilise the dose, supplying at least the first 28 days treatment.
3.	To ask the GP whether he or she is willing to participate in shared care. Requests to GPs should be made in writing and must include appropriate information to allow an informed decision to be made.
4	On agreement from the GP, to provide the GP with appropriate information, including relevant clinical and physical assessment information to support the transfer of clinical responsibility.
5	To communicate promptly with the GP when treatment is changed, stopped or adjusted and to communicate changes in response to treatment or the condition itself.
6	Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
7	Ensure that clear backup arrangements exist for GPs to obtain advice and support.
8.	In accordance with the recommendations from NICE: o to undertake initial monitoring of heart rate and blood pressure and record on a centile chart before and after each dose change, and every 3 months (where measurements are required between outpatient appointments the consultant may request the GP to undertake the measurement and contact the consultant with the result); o To undertake initial height and weight measurements; measure height every 6 months, plot on a growth chart and weight three and six months after the start of treatment and every 6 months thereafter. In children and young people, plot weight on a growth chart, this should be reviewed by the healthcare professional responsible for treatment. o monitor general response to medication and progress at school and mood.
9.	Ensure that patients know what to do and who to contact if they experience adverse events or an exacerbation of their condition.
10.	To ensure the patient has sufficient supply of medication until such time as is appropriate for the GP to assume prescribing responsibility. This may include times to cover initial transfer of responsibility and/or after 6 month reviews
11.	To ensure the patient/ carer has given informed consent to their treatment.
12.	To provide the patient, carers/parents and teachers with comprehensive advice and information
13.	To be available for advice if the patient's condition changes, ensuring that procedures are in place for the rapid re-referral of the patient by the GP.
14.	To liaise with the GP on any suggested changes in prescribed therapy and to stop treatment where appropriate.
12	To refer to an adult psychiatrist where appropriate, including discussing the patient's

	case and transferring care to them.
13	Report adverse events to the CSM.

General Practitioner Responsibilities	
1.	Initially, to refer the patient and family for specialist advice.
2.	Reply to the request for shared care as soon as practicable.
3.	Where appropriate, to prescribe methylphenidate at doses agreed with the specialist
4.	Monitor heart rate and blood pressure when requested by the consultant if it is required between outpatient appointments and communicate the results back to the consultant. Height and weight should be carefully monitored in children as growth retardation may occur. Children who are not gaining weight as expected should be referred back to specialist care for interruption of treatment.
5.	To deal with general health issues of the patient.
6.	Refer patient to the specialist if the patient's condition deteriorates.
7.	Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
8.	To provide support to specialists if they are transferring patients to adult psychiatric services.
9.	Report adverse events to the specialist and CSM

Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate consultant and GP appointments
3	Share any concerns in relation to treatment with methylphenidate
4	Use written and other information on the medication.
5	Seek help urgently if it is suspected that methylphenidate is causing side effects, or if the patient is otherwise unwell.

SUPPORTING INFORMATION

Dosage and Administration

Children over 6 years: Initially 5mg once or twice daily (e.g. at breakfast and lunch), increasing the dose and frequency of administration if necessary by weekly increments of 5-10mg in the daily dose. Doses above 60mg daily are not recommended. The total daily dose should be administered in divided doses. Methylphenidate is not licensed in children less than 6 years of age.

If the effect of the drug wears off too early, disturbed behaviour and/or inability to go to sleep may recur. A small evening dose may help to solve this problem.

If no improvement of symptoms is achieved after appropriate dosage adjustment over a one-month period, the drug should be discontinued. It should also be discontinued periodically to assess the child's condition. Drug treatment is usually discontinued during or after puberty.

N.B. NICE CG72 states that if there is a poor response to treatment, following review and consultation with a tertiary or regional centre, consider increasing the dose of methylphenidate to 0.7mg/kg up to three times a day, or a total daily dose of 2.1mg/kg/day (up to a total maximum dose of 90mg/day for immediate release, or the equivalent modified-release dose). These doses are higher than recommended in the BNF. Monitor closely for side effects.

Contraindications

Contraindications included in the current Summary of Product Characteristics include:

• patients with hypersensitivity to methylphenidate or any of the excipients

• patients suffering marked anxiety, agitation or tension
• patients suffering depression, suicidal ideation or psychosis
• caution is advised in patients being treated with pressor agents and MAO inhibitors.
• hyperthyroidism, severe angina pectoris, cardiac arrhythmias, glaucoma.
• patients with a history of drug abuse or alcohol abuse.
• patients with hyperthyroidism, glaucoma, porphyria or hyperexcitability.
• patients with Gilles de la Tourette syndrome or similar dystonias or siblings with these features

Special Warnings

Methylphenidate may exacerbate psychotic conditions, behavioural and thought disorder. Psychotic or manic symptoms can be caused by stimulants at usual doses. Caution in family history of dystonias. If tics develop, discontinue treatment. Chronic abuse of Ritalin can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur, especially with parenteral abuse. Ritalin should be used with caution in patients with epilepsy as clinical experience has shown that it can cause an increase in seizure frequency in a small number of such patients. If seizure frequency increases, Ritalin should be discontinued

Females of child-bearing potential should not use methylphenidate unless clearly necessary.

Treatment should be stopped gradually since abrupt cessation may produce extreme fatigue and mental depression.

Side Effects
Headache, drowsiness, dizziness, dyskinesia, blurred vision, abdominal pain, nausea and vomiting, dry mouth, reduced weight gain and growth retardation (with long-term use). Skin rash, pruritis, urticaria, fever, arthralgia, hair loss, tachycardia, palpitations, arrhythmias, increases in blood pressure and heart rate. Very rare reports have been made of abnormal liver function.

The summary of product characteristics should be consulted for full information with respect to adverse effects and drug interactions.

Drug Interactions
Possibilities of interaction may occur with concurrent use of: coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), phenylbutazone and tricyclic antidepressants, guanethidine, caution is advised in patients being treated with pressor agents and MAO inhibitors.

At current prices (Drug Tariff, August 2009):
30 x methylphenidate 5mg tabs (non-proprietary) = £2.67
30 x methylphenidate 10mg tabs (non-proprietary) = £5.80
30 x methylphenidate 20mg tabs (non-proprietary) = £9.59

30 x methylphenidate 10mg (Ritalin®) = £5.57

Modified Release formulations:
30 x methylphenidate MR tabs 18mg (*Concerta XL*®) = £31.19
30 x methylphenidate MR tabs 27mg (*Concerta XL*®) = £36.81
30 x methylphenidate MR tabs 36mg (*Concerta XL*®) = £42.45
30 x methylphenidate MR caps 10mg (*Equasym XL*®) = £25.00
30 x methylphenidate MR caps 20mg (*Equasym XL*®) = £30.00
30 x methylphenidate MR caps 30mg (*Equasym XL*®) = £35.00
28 x methylphenidate MR caps 10mg (*Medikinet XL*®) = £21.00
28 x methylphenidate MR caps 20mg (*Medikinet XL*®) = £28.00

28 x methylphenidate MR caps 30mg (*Medikinet XL®*) = £33.72
28 x methylphenidate MR caps 30mg (*Medikinet XL®*) = £33.72
28 x methylphenidate MR caps 40mg (*Medikinet XL®*) = £44.95

References

1. NICE CG 72. Attention deficit Hyperactivity Disorder. Sept 2008
2. Ritalin Tablets (Methylphenidate) 10mg tabs (Novartis Pharmaceuticals UK Ltd) Summary of Product Characteristics. January 2009.
3. Bournemouth, Dorset and Poole Prescribing Forum Pharmacological Intervention in ADHD
4. *Ritalin®* (Methylphenidate) tabs 10mg (Novartis Pharmaceuticals Ltd) Summary of Product Characteristics January 2009
5. *Concerta XL®* 18mg/ 36mg prolonged-release tablets (Janssen-Cilag Ltd) Summary of Product Characteristics August 2008
6. Concerta XL® 27mg prolonged-release tablets (Janssen-Cilag Ltd) Summary of Product Characteristics September 2008
7. NICE TA98 Methylphenidate, atomoxetine and dexamfetamine for ADHD.

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Written By	**Mental Health Sub-group**	**August 2009**
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