

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

INTRODUCTION

The NICE clinical guideline no.72, Attention Deficit Hyperactivity Disorder makes recommendations for the diagnosis and management of attention deficit hyperactivity disorder (ADHD) in children, young people and adults. They describe ADHD as a heterogeneous behavioural syndrome characterised by the core symptoms of hyperactivity, impulsivity and inattention. In general, ADHD is a persisting disorder. Of the young people with a sustained diagnosis, most will go on to have significant difficulties in adulthood, which may include continuing ADHD, personality disorders, emotional and social difficulties, substance misuse, unemployment and involvement in crime.

The guideline states that “drug treatment is the first-line treatment for adults with ADHD with either moderate or severe levels of impairment. Methylphenidate is the first-line drug. If methylphenidate is ineffective or unacceptable, atomoxetine or dexamfetamine can be tried. Where there may be concern about the potential for drug misuse and diversion (for example, in prison services), atomoxetine may be considered as the first-line drug treatment for ADHD in adults. The drug treatment for adults with ADHD should always form part of a comprehensive treatment programme that addresses psychological, behavioural and educational or occupational needs.”

Methylphenidate is licensed for use in attention deficit hyperactivity disorder (ADHD) under specialist supervision. However at the time of publication of the NICE clinical guideline (September 2008), methylphenidate, atomoxetine and dexamfetamine did not have UK marketing authorisation for the treatment of adults with ADHD. NICE recommends that **“prescribers should advise people with ADHD and their parents or carers of the implications of prescribing unlicensed or ‘off-label’ drugs. Informed consent should be obtained and documented.”**

Drug treatment for adults with ADHD who also misuse substances should only be prescribed by an appropriately qualified healthcare professional with expertise in managing both ADHD and substance misuse. For adults with ADHD and drug or alcohol addiction disorders there should be close liaison between the professional treating the person’s ADHD and an addiction specialist. These patients will not be considered for shared care.

Young people with ADHD receiving treatment and care from CAMHS or paediatric services should normally be transferred to adult services if they continue to have significant symptoms of ADHD or other coexisting conditions that require treatment. Transition should be planned in advance by both referring and receiving services. If needs are severe and/or complex, use of the care programme approach should be considered.

Drug treatment for adults with ADHD should be started only under the guidance of a psychiatrist, nurse prescriber specialising in ADHD, or other clinical prescriber with training in the diagnosis and management of ADHD. As a general principle the NICE guideline states that following titration and dose stabilisation, prescribing and monitoring should be carried out under locally agreed shared care arrangements with primary care

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)
 - Weight

- 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.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of methylphenidate in adults (**off-label use**) 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 8 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 the person'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 titrate the dose against symptoms and side effects (up to a maximum of 100mg/day), supplying at least the first 8 weeks 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: <ul style="list-style-type: none"> ● 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 specialist with the result.) ● To undertake initial weight measurements and monitor 6-monthly,

	<ul style="list-style-type: none"> • monitor general response to medication 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 reviews
11.	To ensure the patient/ carer has given informed consent to their treatment.
12.	To provide the patient/ carer 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 review the patient at least annually, liaise with the GP on any suggested changes in prescribed therapy and to stop treatment where appropriate.
15.	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 specialist if it is required between outpatient appointments and communicate the results back to the specialist.
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.	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

Adult over 18 years of age (unlicensed use), 5mg three times daily increased if necessary according to response, max 100mg/day.⁹

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.

Contraindications

Contraindications 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, thyrotoxicosis
- 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 methylphenidate can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur, especially with parenteral abuse. Methylphenidate 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, methylphenidate 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, rarely reduced weight gain and slight growth retardation. Skin rash, pruritis, urticaria, fever, arthralgia, hair loss, tachycardia, palpitations, arrhythmias, changes 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.

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.
8. British National Formulary 58. September 2009

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	February 2010
Approved By	Bournemouth, Dorset and Poole Prescribing Forum	March 2010

Review Date	April 2011 or before in the light of new evidence and/or recommendations
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