NHS South of Tyne and Wear

serving Gateshead Primary Care Trust, South Tyneside Primary Care Trust and Sunderland Teaching Primary Care Trust

SHARED CARE GUIDELINE

For

Methylphenidate for the Management of Attention Deficit Hyperactivity Disorder (ADHD) in children, young people and adults

Implementation Date: April 2012

Review Date: March 2014

This guidance has been prepared and approved for use within Gateshead, South Tyneside and Sunderland in consultation with Primary and Secondary Care Trusts and Local Medical Committees.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe these treatments within a shared care setting

Further copies are available from

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Approved by:

Committee	Date
Gateshead Medicines Management Committee	**April 2012**
South Tyneside Prescribing Committee	**March 2012**
Sunderland Primary Care Prescribing Group	**March 2012**
South of Tyne and Wear Medicines Management Committee	

Name of drug:	**Methylphenidate**	Form and strength:	Please refer to BNF for full listing preparations
Brand name:	Ritalin, Medikinet, Concerta XL, Medikinet XL	BNF Code:	4.4. CNS Stimulants and drugs used for Attention Deficit Hyperactivity Disorder (ADHD)
Conditions(s) to be treated **Methylphenidate is indicated for the treatment of ADHD as part of a multidisciplinary support package which considers the psychological, behavioural, educational or occupational needs of the patient.**		Aim of treatment **To improve the symptoms of ADHD, the essential features of which is a persistent pattern of inattention and/or hyperactivity – impulsivity that is more frequent and severe than is typically observed in individuals at a comparable level of development**	

Excluded patients	Currently methylphenidate is licensed for the use in children over the age of 6 years. Although it is occasionally prescribed off-label for the treatment of younger children with ADHD, it is recommended that GPs should not normally be asked to prescribe methylphenidate for children in this age group.
Eligibility criteria for shared care	Children aged 6 years or over, young people and adults who have been assessed by the specialist where: • The patient is stabilised on treatment and has then been supplied with a further month's treatment by the specialist to give time for shared care to be arranged. • In some circumstances it may be more appropriate for the GP to prescribe on the advice of the specialist during the initiation and titration phase. This must be done on a case by case basis by prior arrangement and all the necessary information for the GP to do this safely must be provided by the specialist. • A package of multi-disciplinary support which includes the psychological, behavioural and educational or occupational needs as appropriate will be considered before transfer of prescribing to the GP. • Both the specialist, and GP agree to the shared care arrangement (in accordance with Responsibilities of General Practitioners below)
Initiation	Initiation of treatment will take place in secondary care by a medical specialist in the care of people with ADHD
Duration of treatment	For as long as benefit is maintained. The specialist team will be responsible for reviewing clinical need, benefits and side effects. The specialist will supervise the discontinuation phase. Treatment should be considered for discontinuation in adolescence but it may need to be continued into adulthood if clinically indicated. Drug holidays are not routinely recommended; however, consideration should be given to the parent or carer and child or young person with ADHD working with their healthcare professional to find the best pattern of use, which may include periods without treatment. Spontaneous or accidental omission of doses (e.g. due to a compliance problem) can also provide useful information on the continued benefit of the treatment. If a trial discontinuation is considered, this is usually done when the patient is experiencing a stable routine i.e. avoid exam times, stressful periods at work etc).
Usual Maintenance Dose	***Standard Release*** - usually 5mg once or twice daily, increased if necessary by 5mg to 10mg at weekly intervals. Maximum licensed dosage 60mg daily in divided doses, though NICE recommends up to 90mg/day in children and young people and up to a maximum of 100mg/day in adults. Side effects should be

<table>
<tr><td></td><td>closely monitored when higher than licensed doses are used.
Prolonged release[1] (Concerta XL) - 18mg once daily, increased if necessary by 18mg at weekly intervals. Maximum licensed dose is 54mg daily, though NICE recommends up to 108mg/day in children and adults with close monitoring of side effects.
(Medikinet XL) – Initially 10mg once daily, increased gradually if necessary. Maximum licensed dosage 60mg daily in divided doses, though NICE recommends up to 90mg/day in children and young people and up to a maximum of 100mg/day in adults. Side effects should be closely monitored when higher than licensed doses are used.</td></tr>
<tr><td>Usual Dose Range</td><td>See above</td></tr>
<tr><td>Maximum Dose</td><td>See above</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Preparations</td><td>Please refer to SPC, or latest version of the BNF.</td></tr>
<tr><td>Cost 30 days
(Drug Tariff)</td><td>
<table>
<tr><th></th><th>Secondary Care (inc VAT)</th><th>Primary Care</th></tr>
<tr><td>Methylphenidate 5-60mg / day – Ritalin / Medikinet</td><td>£1.44 - £10.67</td><td>£2.78 - £32.94</td></tr>
<tr><td>Methylphenidate 18–54mg / day Concerta XL</td><td>£38.45 - £81.84</td><td>£31.19 - £73.64</td></tr>
<tr><td>Methylphenidate 10–60mg / day Medikinet XL[2]</td><td>£28.73 -£80.50</td><td>£20.18 - £70.11</td></tr>
</table>
Notes
1. Due to the prolonged-release design of the tablet, CONCERTA® XL should only be used in patients who are able to swallow the tablet whole. Patients should be informed that CONCERTA® XL must be swallowed whole with the aid of liquids. The tablets must not be chewed, divided, or crushed. The tablet shell is eliminated from the body and the patient and parent should be informed.
2. The Contents of Medikinet capsules can be sprinkled on a tablespoon of apple sauce (then swallowed immediately without chewing) Drinking some fluids e.g.water should follow the intake of the sprinkles with apple sauce. The capsules and the capsule contents must not be crushed or chewed.</td></tr>
<tr><td>Adverse effects</td><td>
<table>
<tr><td>- Insomnia (common)
- Appetite suppression (common)
- Stomach-ache (often transient)
- Headache (often transient)</td><td>May be alleviated by adjusting the drug dose. Insomnia may also be alleviated by adjusting the timing of the doses.</td></tr>
<tr><td>- Raised blood pressure
- Increase in seizure frequency in patients with epilepsy
- Heart rhythm changes
- Blurred eyesight
- Evidence of blood disorders (rare)</td><td>Consider omission of dose until discussed with the specialist.</td></tr>
</table>
Blood disorders - If the child develops symptoms of anaemia (e.g. persistent paleness or tiredness), bruising or bleeding, a sore throat, or lesions on the skin, in the mouth or mucous membranes, or a serious infection, carry out a full blood count to exclude the possibility of a blood dyscrasia. Routine blood tests are not recommended unless there is a clinical indication.
There is little evidence to suggest long-term treatment suppresses height and weight gain. See the BNF and manufacturers' SPCs for a</td></tr>
</table>

	full list of potential adverse effects.
Contra-indications	Cardiovascular disease (including moderate to severe hypertension) hyper excitability or agitated states, hyperthyroidism, history of drug or alcohol abuse, glaucoma, pregnancy and breastfeeding.
Special Precautions / Warnings	Careful consideration should be given by the specialist when prescribing for patients with a predisposition to tics or Tourette syndrome. This is an off label use of methylphenidate, but still appropriate for shared care. If tics develop, or worsen, the GP should contact the specialist and there should be a review to decide if treatment continues. History of drug or alcohol abuse – see potential problems and their management.
Potential Problems and their management	**Methylphenidate dependence is not a problem in the treatment of** ADHD. The presence of alcohol or cannabis consumption is not a contraindication to prescribing methylphenidate, though concomitant cannabis and methylphenidate use should be closely monitored in those with a family history or past history of psychosis. Drug treatment for people who misuse substances such as cocaine or heroin should only be prescribed by healthcare professionals with expertise in managing both ADHD and substance misuse. For adults with ADHD and drug or alcohol disorders, there should be close liaison between the professional treating the ADHD and an addiction specialist
Renal impairment and liver disease	There is little experience with use in patients with renal insufficiency. However, since renal clearance is not an important route of methylphenidate clearance, renal insufficiency is expected to have little effect on the pharmacokinetics of methylphenidate. There is no experience with use in patients with hepatic insufficiency.
Pregnancy and breast feeding	Methylphenidate is contra-indicated in pregnancy and breast feeding
Monitoring	See below
Consultant Responsibilities	The specialist team will: • Undertake review of relevant medical history and relevant physical examination, including: assessment of history of exercise syncope, undue breathlessness and other cardiovascular disease symptoms • Exclude family history of serious cardiac disease and perform examination of the cardiovascular system. In this context, family history of serious cardiac disease includes congenital heart disease, premature sudden death[b] or ventricular arrhythmias. As a minimum, this should be applied to first degree relatives ([b]premature sudden death is defined as less than 55 years in men, less than 65 years in women) • arrange an electrocardiogram (ECG), if not carried out by the GP, if there is past medical or family history of serious cardiac disease (defined as above), a history of sudden death in young family members or abnormal findings on cardiac examination **Usually this information will be available to the specialist. If not, the specialist will work in collaboration with the GP to obtain this. If sufficient information is not available, the specialist should not prescribe methylphenidate, nor make a recommendation to the GP to prescribe.** • Carry out a pre-drug treatment assessment, including a full mental health and social assessment, risk assessment for substance misuse and drug diversion,

	baseline heart rate and blood pressure, height and weight. **Children and Young People** • Review 6 monthly in children and young people. Include in the review: – Clinical need, benefits and side effects – The views of the person with ADHD, and those of the parents, carers and teachers, or close friend as appropriate – The effect of missed doses, planned dose reductions and any period of no treatment – The preferred pattern of drug use – Co-existing conditions; treat or refer if necessary – The need for psychological, social and occupational support for the person and their parents or carers – Monitor heart rate and blood pressure and record on a centile chart at baseline, before and after each dose change and then every 6 months, unless more frequent monitoring is clinically indicated. Sustained resting tachycardia, arrhythmia or systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on two occasions should prompt dose reduction and referral to a paediatrician or physician. This information should be communicated to the GP within 24 hours. – Monitor weight at baseline then 3 and 6 months after the start of treatment and every 6 months thereafter and plot weight on a growth chart. – Monitor Height at baseline then every 6 months and plot on a centile chart **Adult patients** Adult patients will be receive an annual review covering: • Clinical need, benefits and side effects. • The views of the person with ADHD, carers, a spouse or close friend as appropriate. • The effect of missed doses, planned dose reductions and any period of no treatment. • The preferred pattern of drug use. • Co-existing conditions; treat or refer if necessary. • The need for psychological, social and occupational support for the person or their carers. For adult patients, heart rate, blood pressure and weight will be monitored by the GP
GP Responsibilities	If the patient is to be referred to secondary care to consider the diagnosis of ADHD, the GP should work in collaboration with the specialist to provide a full history and physical examination, including: • assessment of history of exercise syncope, undue breathlessness and other cardiovascular disease symptoms • heart rate and blood pressure • height and weight • family history of serious cardiac disease and examination of the cardiovascular system. In this context, family history of serious cardiac

	disease includes congenital heart disease, premature sudden death[b] or ventricular arrhythmias. As a minimum, this should be applied to first degree relatives ([b] premature sudden death is defined as less than 55 years in men, less than 65 years in women) • an electrocardiogram (ECG) if there is past medical or family history of serious cardiac disease (defined as above), a history of sudden death in young family members or abnormal findings on cardiac examination • Routine blood tests are not recommended unless there is a clinical indication. A full blood count **should** be considered immediately if a child has prolonged or severe infection whilst on methylphenidate in order to exclude blood dyscrasia (very rarely reported). All of the relevant results should be copied to the specialist. • Monitor and liaise with the specialist regarding any adverse effects that arise during treatment including the reporting of serious adverse drug reactions to the MHRA. • Prescribe methylphenidate following stabilisation of the patient by the specialist. It is strongly recommended that prescriptions are issued for a maximum treatment duration of **one month**, in line with good practice guidance for controlled drug prescribing. Check/act upon any results communicated by the specialist and act upon requests for additional monitoring as agreed with the specialist. **For Adult patients, the following monitoring will be carried out by the GP** Monitor and record heart rate and blood pressure before and after each dose change and then every 6 months, unless more frequent monitoring is clinically indicated. Clinically significant sustained resting tachycardia, or systolic blood pressure, measured on three occasions, should be discussed with the specialist and the course of action documented. Any arrhythmias should prompt dose reduction and referral to a cardiologist. This information should be communicated to the specialist within 24 hours. Monitor weight 3 and 6 months after the start of treatment and every 6 months thereafter.
Communications - Consultant	• Contact the GP at the appropriate time after initiating methylphenidate and seek formal agreement for the sharing of patient care. • Provide the patient's GP with information on the dose and formulation of methylphenidate used, and arrangements for review (at least 6 monthly in children and young people, and annually in adults). • Ensure that the parent/carer understands the proposed treatment including information contained within the patient information leaflet, problems that may be encountered and how to avoid/minimise them. Particular attention is drawn to the section on actions to be taken in the event of the rare occurrence of anaemia or prolonged/serious infection. • Ensure any 'verbal' communication, e.g. dosage changes discussed directly with the patient / carer, are confirmed in writing to the GP as soon as possible (preferably faxed). • Advise the GP when methylphenidate treatment should be discontinued. The specialist will supervise the discontinuation phase.

	• Provide written guidance e.g. dosage regimen information for parents/teachers/guardians regarding drug treatment, where it is considered appropriate. • Liaise with the GP if any other additional tests/monitoring is required between appointments. • Monitor and liaise with the GP regarding any adverse effects, which occur during treatment, including reporting of all serious adverse drug reactions to the MHRA. • Notify GPs of patients who fail to attend reviews within 1 month, plus specific information on the planned course of action.
Communications - GP	• Notify the specialist promptly if he/she is unwilling to participate in the shared care arrangement. • Notify the specialist of any family/social circumstances, which may preclude treatment with methylphenidate (including current/past use of illicit drugs). • To contact the specialist if concerned about any aspects of the patient's treatment.
Drug Interactions	• Methylphenidate increases plasma concentrations of phenytoin and delays intestinal absorption of phenytoin, phenobarbitone and ethosuximide. • Methylphenidate inhibits metabolism of tricyclic antidepressants, primidone and warfarin. • Methylphenidate should be used with caution in patients receiving MAOIs - risk of hypertensive crisis. • Carbamazepine may reduce the efficacy of methylphenidate due to induction of the cP450 3A4 enzyme.

Contact details	Consultant:
Agreed Date	**Expiry date as per front sheet**

For full prescribing information on methylphenidate, please refer to the Summary of Product Characteristics available from the electronic medicines compendium at: www.medicines.org.uk

Appendix 2 Shared Care Request Form

- **Consultant to complete FIRST SECTION of form**
- **GP to complete SECOND section and RETURN to SECONDARY CARE TRUST CLINICIAN TEAM if transfer declined.**

Section 1

Consultant	
Hospital address	
Contact Phone Number	

Patient's name	
Address	
This patient is stabilised on	
Dose	
Prescription for 28 days supply given on	

Compliance aid YES/NO

Monitored by

Designated community pharmacy

Their treatment has been explained to them and a review has been arranged for

…… ……..

Appointments to continue every …… months

Section 2

Patient's name	
Address	

I do **NOT ACCEPT** the proposed Shared-Care Agreement for this patient

My reasons for not accepting: Please complete this section

Signed ……date……..

Please return to the Secondary Care Trust Clinician team at :

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