Prescribing Framework for Methylphenidate for Attention Deficit Hyperactive Disorder

Patient’s Name:………………………………………………………….. NHS Number: ……………

Patient’s Address:……………………………………………………………..(Use addressograph sticker)

GP’s Name:………………………………………………………………………

Communication

We agree to treat this patient within this Prescribing Framework.

Specialist Prescriber’s Name ……………………………………………………………………….

Specialist Prescriber’s Signature…………………………………………………………Date:…………

GP’s Signature……………………………………………………………………………..Date:…………

The front page of this form should be completed by the specialist and the form sent to the patient’s general practitioner.
The patient’s GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is unwilling to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist’s letter.

Full copy of framework can also be found at:
http://www.hey.nhs.uk/content/prescribingCommittee/amber.aspx

APPROVAL PROCESS

Written by: Jackie Stark, Medicines Management Pharmacist, HFT
Consultation process: HFT Drug Therapeutics Committee, Community Paediatrics, HEY?
Approved by: Include MMIG, LMC, HFT DTC
Ratified by: HERPC
Review date: 2 years

Prescribing framework for Methylphenidate for ADHD
Date approved by the HERPC:July 2012

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Review date: July 2014
1. Background

Attention-Deficit Hyperactivity Disorder (ADHD) is diagnosed if the three clinical features - inattention, over-activity and impulsiveness - have been present from an early age, persist in more than one situation (e.g. at home and in school) and impair function. The diagnosis must be made following a comprehensive assessment by an appropriate child psychiatrist and/or a paediatrician with special interest and training in this field. Drug therapy with methylphenidate is only one part of the package of care for children with ADHD which typically includes social, psychological, behavioural and educational interventions. In later adolescence and adult life, the range of possible impairment extends to educational and occupational underachievement, dangerous driving, difficulties in carrying out daily activities such as shopping and organising household tasks, in making and keeping friends, in intimate relationships (for example, excessive disagreement) and with childcare.

Treatment aims in ADHD are to reduce hyperactive behaviour, detect and treat any co-existing disorders, promote academic and social function and learning, improve emotional adjustment and self-esteem, and to relieve family distress.

Treatment of ADHD often needs to be continued into adolescence, and may need to be continued into adulthood. Initiating treatment in adulthood is unlicensed. Adults who present with symptoms of ADHD for the first time in primary care or general adult psychiatric services who do not have a childhood diagnosis of ADHD, should be referred for assessment by a mental health specialist trained in the diagnosis and treatment of ADHD.

These guidelines aim to provide a framework for the prescribing of methylphenidate by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

Methylphenidate is a Schedule 2 Controlled Drug (CD). Prescription requirements for prescribing CDs should therefore be observed.

The guidelines should be read in conjunction with
- The general guidance on prescribing matters given in EL (91) 127 “Responsibility for prescribing between hospitals and GPs”.
- NICE Clinical Guideline 72 Attention Deficit Hyperactivity Disorder

2. Indication

Methylphenidate (Ritalin/Equasym/Concerta XL®) is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older and in adolescents as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10

This shared care protocol applies to children 6 years and above, and adults. The drug is not licensed for children less than six years of age. Initiating treatment in adulthood is unlicensed. Methylphenidate is included in the BNF as treatment for adults (off-licence)
3. Dose

**CHILDREN and YOUNG PEOPLE 6–18 years:** 5mg once or twice daily and increase at weekly intervals by 5–10mg daily; usual max. 60mg daily in divided doses but may be increased to 2.1mg/kg daily (max. 90mg daily) by the specialist. If improvement is not observed after appropriate dosage adjustment the drug will be discontinued. In some patients, rebound hyperactivity may occur as the effect of the drug wears off in the evening. Dividing the doses to include an additional dose at bedtime may eliminate this difficulty. However, bedtime doses may cause sleep disturbance.

**ADULT:** over 18 years [unlicensed use], 5mg two to three times daily increased if necessary according to response, max. 100mg daily

Methylphenidate m/r (Concerta XL) may be used once daily in the morning, as indicated above, swallowed whole and must NOT be chewed, divided or crushed. Patients can be converted from standard methylphenidate preparations as described in the Summary of Product Characteristics. The dosage can be adjusted in 18mg increments to a maximum of 54mg once daily in the morning.

Once the patient has been stabilised a further 4-week supply will be prescribed by the psychiatrist/paediatrician to allow adequate time for information to be passed to their General Practitioner.

4. Duration of treatment

Advice will be given to the GP by the secondary care Specialist on duration of treatment and dose changes for each individual patient.

3. Contraindications and cautions

- Cardiovascular disease including heart failure, cardiomyopathy, severe hypertension and arrhythmias, structural cardiac abnormalities,
- Phaeochromocytoma
- Vasculitis
- Cerebrovascular disorders
- Hyperthyroidism
- History of drug or alcohol abuse
- Angle closure glaucoma
- Pregnancy and breast-feeding
- Monitor for psychiatric disorders
- Marked anxiety disorders or agitation
- Psychosis, uncontrolled bipolar disorder,
- Hyperthyroidism
- Contra-indicated in severe depression or those with suicidal ideation
- Caution in patients with tics or family history or diagnosis of Tourette’s Syndrome
- Caution in epilepsy
- Abrupt withdrawal should be avoided
Methylphenidate m/r (Concerta XL®) should not be used in patients with severe gastrointestinal tract narrowing or dysphagia or significant difficulty with swallowing tablets because medication in methylphenidate m/r (Concerta XL®) is contained within a non-deformable, non-absorbable shell which is eliminated unchanged from the body in the patient’s stool.

4. Adverse effects

The following have been reported:

- Decreased appetite and moderately reduced weight gain and growth retardation have been reported with the long-term use of methylphenidate in children (monitor height and weight)
- Occasional abdominal pain, nausea and vomiting (alleviated with concomitant food intake)
- Diarrhoea, dyspepsia, dry mouth, constipation
- Headaches
- Emotional lability
- Abnormal dreams, confusion, suicidal ideation
- Tachycardia, palpitation, arrhythmias, changes in blood pressure, myocardial infarction, angina; supraventricular tachycardia, bradycardia
- Cough, nasopharyngitis
- Tics (very rarely Tourette syndrome), movement disorders, insomnia, nervousness, asthenia, depression, irritability, aggression
- Headache, drowsiness, dizziness, visual disturbances; fever; arthralgia;
- Rash, pruritus, alopecia; growth restriction, sweating, exfoliative dermatitis and erythema multiforme
- Dyspnoea
- Urinary frequency, haematuria
- Muscle cramps, epistaxis;
- Hepatic dysfunction
- Cerebral arteritis, psychosis, neuroleptic malignant syndrome
- Tolerance and dependence
- Blood disorders including leucopenia and thrombocytopenia
- Angle-closure glaucoma, and convulsions

5. Interactions

Methylphenidate has been reported to interact with the following

- Warfarin - may increase the anticoagulant effect
- Anticonvulsants – may increase levels of phenytoin and phenobarbitone
- Tricyclic antidepressants and SSRIs- may increase plasma levels
- Risperidone to increase side effects of risperidone
- MAOIs- risk of hypertensive crisis when methylphenidate given with MAOIs , some manufacturers advise avoid methylphenidate for at least 2 weeks after stopping MAOIs
- Clonidine- serious adverse events reported with concomitant use of methylphenidate and clonidine (causality not established)
- General anaesthetics- increased risk of hypertension when methylphenidate given with volatile liquid general anaesthetics
- Methylphenidate antagonises hypotensive effect of adrenergic neurone blockers

Alcohol can increase the CNS effects of methylphenidate.
There are no known interactions with antibiotics, simple analgesics and antihistamines

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF [www.bnf.org.uk](http://www.bnf.org.uk) or SPC ([www.medicines.org.uk](http://www.medicines.org.uk)).

6. Monitoring

Patients requiring long-term therapy should be carefully monitored. The patient’s response to the drug should be assessed by the prescriber at each clinical meeting. For children: parents and teachers should be advised to report on levels of activity, concentration, and other factors. These reports should be compared before and after treatment, and be used to facilitate the decision to increase the dose or to stop treatment.

For children and young people, height should be measured every 6 months. For all patients, weight and blood pressure should be measured 3 months after starting treatment and thereafter every 6 months. Methylphenidate has been shown to cause leucopenia, thrombocytopenia and anaemia (12 reports since 1964). A full blood count should be done every 12 months.

A young person with ADHD receiving treatment and care from Child and Adolescent Mental Health Services (CAMHS) or paediatric services should be reassessed at school-leaving age to establish the need for continuing treatment into adulthood. If continued treatment is necessary, arrangements should be made for a smooth transition to adult services with details of the anticipated treatment and services that the young person will require. Precise timing of arrangements may vary but should usually be completed by the time the young person is 18 years.

During the transition to adult services, a formal meeting involving CAMHS and/or paediatrics and adult psychiatric services should be considered, and full information provided to the young person about adult services. For young people aged 16 years and older, the care programme approach (CPA) should be used as an aid to transfer between services. The young person, and when appropriate the parent or carer, should be involved in the planning.

After transition to adult services, adult healthcare professionals should carry out a comprehensive assessment of the person with ADHD that includes personal, educational, occupational and social functioning, and assessment of any coexisting conditions, especially drug misuse, personality disorders, emotional problems and learning difficulties.

7. Information to patient

- Reporting of side-effects and adverse events to GP or Specialist
- Ensure they have a clear understanding of the treatment
### 8. Responsibilities of clinicians involved

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<tr>
<th>Stage of Treatment</th>
<th>Hospital Specialist</th>
<th>General Practitioner</th>
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| **Initiation**     | • Assessment and diagnosis of ADHD  
                    • Initiation of methylphenidate therapy, including conversion to methylphenidate m/r (e.g. Concerta XL) if required  
                    • Provision of written guidance and questionnaire’s for parents and teachers, regarding drug treatment, at specialists discretion  
                    • Reporting adverse events to CHM  
                    • Ensure baseline full blood count has been performed if indicated  
                    • Monitor height weight and blood pressure as indicated  
                    • Liaise and seek advice from the specialist team, when appropriate  
                    • Take over prescribing of medication 4 weeks after the patient has been stabilised on treatment and provide on-going clinical care |
| **Maintenance**    | • Monitor height weight and blood pressure as indicated until patient is stabilised.  
                    • Assess continued need for treatment annually including appropriate interruption of treatment with medication  
                    • Review treatment as requested by the GP.  
                    • Review the need for continuation with treatment and give advice on continuing dose  
                    • For young people, if Methylphenidate is continued beyond age 18 then care should be transferred from Paediatric to Young Persons and to Adult Psychiatric Services as appropriate.  
                    • Reporting adverse events to CHM  
                    • Advising the GP when methylphenidate should be discontinued for patients receiving the drug long-term.  
                    • Provide necessary supervision and support during discontinuation phase  
                    • Prescribing methylphenidate once the patient is stabilised  
                    • Liaison with the Paediatrician or Psychiatrists regarding any complications of treatment.  
                    • Reporting of adverse events to Specialist and CHM  
                    • Review treatment every 6 months  
                    • For children and young people, monitor height, weight and blood pressure every 6 months  
                    • For adults monitor weight and blood pressure every 6 months  
                    • Annual full blood count  
                    • Reporting to and seeking advice from the Specialists on any aspect of patient care which is of concern to the GP and may affect treatment  
                    • Co-operating with the Specialist during the discontinuation phase |