SHARED CARE GUIDELINE

Pennine Care NHS
NHS Foundation Trust

Title: METHYLPHENIDATE and ATOMOXETINE FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS

Scope: Pennine Care NHS Foundation Trust NHS Bury NHS Oldham NHS Heywood, Middleton and Rochdale NHS Stockport NHS Tameside & Glossop	**Version:** Version 2

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To be read in conjunction with the following documents:	British National Formulary (BNF) Summaries of Product Characteristics (SPC) Patient Information Leaflets (PIL) NICE Guideline CG 72 September 2008 MHRA Drug Safety Update Vol 5 Issue 6 Jan 2012
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1. Introduction

ADHD is a neuropsychological /developmental condition which is defined by core symptoms of inattention, hyperactivity and impulsiveness. For a diagnosis of ADHD to be made, the symptoms should be pervasive, not accounted for by any other psychiatric or developmental disorder, and normally present before the age of 7.

Of those diagnosed in childhood, approximately 65% carry the disorder into adulthood. This represents 15% who retain the full symptoms of ADHD by the age of 25, and a further 50% may be considered to be in partial remission, displaying reduced levels of impairment due to symptoms.

In addition, adults may present to adult mental health services showing the symptoms of ADHD, which have persisted since childhood, but have never been diagnosed. Adults with ADHD may be significantly functionally and occupationally impaired, and experience other concomitant mental health problems (for example self harm, substance misuse, anxiety).

NICE Guideline CG72 recommends that drug treatment should be the first-ine approach in adult ADHD. Methylphenidate, atomoxetine and dexamfetamine are the drug treatments available to treat Adult ADHD but only atomoxetine is licensed in this indication. However NICE supports the first line use of methylphenidate in adults (despite the lack of licence). This SCG therefore only includes the use of atomoxetine and methylphenidate.

2. Scope

Pennine Care NHS Foundation Trust, associated Primary Care Trusts, Acute Trust Service Level Agreement partners.

3. Drug Treatment – General Information

- Drug treatment should be initiated only under the guidance of a consultant psychiatrist, or by a specialist team, where commissioned. It should always form part of a comprehensive treatment programme that addresses psychological, behavioural and occupational needs.

- Following the initial assessment, the consultant may advise the general practitioner (GP) of the treatment options, after which the GP may initiate and continue prescribing, in collaboration with the specialist team.

- Before commencing drug treatment a full assessment should be completed, which should include
    a. Full mental health and social assessment
    b. Full history and physical examination, including:
        i. Assessment if history of exercise syncope, undue breathlessness and other cardiovascular symptoms
        ii. Heart rate and blood pressure (plotted on centile chart)
        iii. Weight
        iv. Family history of cardiac disease and examination of cardiovascular system
    c. An 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.
    d. Risk assessment for substance misuse and/or drug diversion
    e. Baseline weight, pulse, blood pressure and psychiatric assessments.

- Initially, the dose should be gradually titrated upwards over 4-6 weeks, until there is no further symptom reduction, and the side effects are

tolerable. During the titration phase, symptoms and side effects should be recorded at each dose change, after discussion with the patient.

- The following should be monitored regularly for all patients
    a. Weight (every 6 months)
    b. Heart rate and blood pressure (every 3 months)
    c. Psychiatric symptoms, e.g. anxiety, panic, agitation, irritability, psychosis.

(Please also see information on individual drugs)

4. Product information and treatment regimen to be used

Methylphenidate, atomoxetine and dexamfetamine are the drug treatments available to treat Adult ADHD. Only atomoxetine is licensed in this indication but NICE supports the first line use of methylphenidate in adults (despite the lack of licence). This SCG therefore only includes the use of atomoxetine and methylphenidate.

Methylphenidate

Methylphenidate should be the **first drug** to be tried.

Methylphenidate is classed as a Schedule 2 **Controlled Drug** under the Misuse of Drugs Act 1971. Prescriptions must therefore conform to the Misuse of Drugs Regulations 2001 and include

- The name and address of the patient
- The name, form (including immediate- or modified-release) and strength of the preparation.
- Total quantity to be supplied, in words and figures
- The dose to be taken, and the frequency.
- Prescriber's signature, address and the date. (Prescriptions for Sch 2 Controlled Drugs are valid for 28 days from the date stated thereon.)

Caution should be exercised when prescribing methylphenidate to those likely to be at risk from stimulant misuse or diversion.

Methylphenidate is **not licensed** for the treatment of adult ADHD, however NICE Guideline CG 72 and the BNF make the following **dosage** recommendations-

5mg three times daily up to a maximum of 100mg daily

Methylphenidate is **available** as immediate- or modified –release tablets. Immediate release preparations may be prescribed up to four times a day. Modified release preparations are taken once a day. See Table 1 for dose equivalents (mg)

The effectiveness and side-effect profile is similar, between the two preparations. Factors favouring use of modified-release preparations include concerns about fluctuating control or adherence, perceived stigma, and patient preference.

Table 1 Dose equivalents of methylphenidate preparations

Immediate release methylphenidate	Concerta-XL	Equasym-XL	Medikinet-XL
10	-	10	10
15	18	-	-
20	-	20	20
30	36	30	30
-	-	-	40
45	54	-	-
60	72	60	-

Side effects – People treated with methylphenidate should be monitored for **weight loss, sustained tachycardia, arrhythmia, increased systolic blood pressure, tics, psychotic symptoms, anxiety, panic**. These may respond to dose reduction, or require a switch to atomoxetine. Cardiovascular changes may require referral to specialist services.

Atomoxetine

Atomoxetine may be considered where adequate trials of methylphenidate (or dexamfetamine) have proved unsatisfactory, or where there is likely to be risk from stimulant misuse or diversion.

Atomoxetine is **licensed** for the treatment of adult ADHD. NICE Guideline and BNF make the following **dosage** recommendations-

Adults up to 70 kg body weight – starting dose = approximately 0.5mg/kg body weight; increase after seven days to approximately 1.2 mg/kg body weight.

Adults over 70kg body weight – starting dose 40mg daily; increase after seven days to maximum maintenance dose of 100mg daily.

The usual maintenance dose is 80-100mg. This must be trialled for six weeks to determine effectiveness.

Atomoxetine causes clinically important changes in blood pressure and heart rate, or both, in a small proportion of patients. Regular monitoring of cardiovascular status is recommended and specialist cardiac advice should be sought if symptoms suggesting cardiac disease are found during treatment.

- Pulse and blood pressure should be recorded after every dose adjustment and at least every 6 months during treatment.

- Patients who develop symptoms that suggest heart disease during atomoxetine treatment should undergo a prompt specialist cardiac evaluation.

- Patients with additional risk factors for cerebrovascular conditions (eg, history of certain cardiovascular diseases or concomitant use of medicines that elevate blood pressure) should be assessed at every visit for neurological signs and symptoms after initiating treatment with atomoxetine.

- Patients who take atomoxetine for extended periods (ie, >1 year) should have their treatment reviewed at least once a year by a specialist to determine whether continuation is needed.

Side effects -People treated with atomoxetine, particularly younger adults, aged 30 or younger, should be monitored for **agitation, irritability, suicidal thinking and self-harming behaviour**, particularly in the first months of treatment, or after a change of dose.
Atomoxetine may cause **liver damage**, causing abdominal pain, nausea, malaise, darkening of urine or jaundice. This is rare. Routine liver function tests are not recommended.
Sexual dysfunction may occur.

5. Regimen Management

Responsibility of Consultant/ Specialist Team, where commissioned

a) Assessment of the patient and diagnosis of continuing ADHD
b) Documentation of full medical and psychiatric history. (see Section 3)
c) Completion of medication assessment pro-forma (see Appendix 1)
d) Measurement of baseline parameters (see section 3)
e) Informing patients and carers of the diagnosis, and discussing with them the care plan, treatment options and side effects of medications.
f) Promoting access to any appropriate supporting therapies or education.
g) Contacting GP to ascertain willingness to participate in shared care.
h) Liaising with the GP on prescribing for the initiation, titrating and continuation of drug treatment.
i) Provision of 6-monthly review appointments and assessment of mental state. Arrangements may be put in place for the GP to monitor weight, pulse and blood pressure and to inform the Consultant/ Specialist Team (where commissioned) of the outcome, provided this is agreed to.
j) Reporting of any adverse drug reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the Yellow Card Scheme.
k) Advising GP of discontinuation of treatment if considered clinically appropriate.

l) Advising GP of options if the patient fails recurrently to attend follow-up appointments.

Responsibility of GP

a) Responding to the request for shared care as soon as possible.
b) Prescribing of medication as agreed with consultant/ specialist team.
c) Monitoring of weight, pulse and blood pressure and informing the Consultant/ Specialist Team (where commissioned) of the outcome, where this is agreed to.
d) Referring to consultant any queries regarding treatment, side effects, concerns about drug misuse or diversion.
e) Stopping treatment on the advice of the consultant/ specialist team
f) Reporting of any adverse drug reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the Yellow Card Scheme.

6. Contra-indications, cautions, side-affects etc.

For additional information, please refer to the individual drug monographs in the latest edition of the BNF

7. Drug Interactions

Please refer to Appendix 1 of the current edition of the BNF

8. Special considerations

Potential misuse or diversion of stimulants must be minimised by careful selection of patients, prescribing of small amounts of medication and prompt discussion between consultant and the GP in the event of non-attendance at appointments or suspected drug misuse.

9. Back-up care available to GP from Hospital, including emergency contact procedures and help line numbers

Written correspondence following consultant/ specialist team (where commissioned) appointments.
Telephone advice from the consultant during office hours, to include plans for earlier review if necessary.
Out of hours on call/ emergency service contactable through hospital switchboards.

10. Statement of agreement

Shared care is an agreement between the GP and the Consultant. This form is a request by the consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care and initiating the suggested medication, please make this known to the consultant within 14 days, ideally stating the nature of your concern.

11. Written information provided to the patient

- Manufacturers' Patient Information Leaflet

- NICE CG 78 Information for the public http://guidance.nice.org.uk/CG72/PublicInfo/pdf/English Accessed 23rd December 2010

12. Supporting References

NICE Clinical Guideline CG 78 Attention Deficit Hyperactivity Disorder http://guidance.nice.org.uk/CG72

British National Formulary (BNF) 63, March 2012 http://bnf.org/bnf/index.htm

Summary of Product Characteristics/ Patient Information Leaflets Methylphenidate - http://www.medicines.org.uk/EMC/searchresults.aspx?term=methylphenidate&searchtype=QuickSearch

Atomoxetine http://www.medicines.org.uk/EMC/searchresults.aspx?term=atomoxetine&searchtype=QuickSearch

Pennine Care Shared Care Guideline - Methylphenidate and dexamphetamine for childhood and adolescent attention deficit hyperactivity disorder (ADHD). V4. February 2011

MHRA Drug Safety Update. Atomoxetine (Strattera): increase in blood pressure and heart rate – new contraindications, warnings and advice for monitoring. Volume 5 Issue 6. January 2012

APPENDIX 1

ADHD PRE-MEDICATION ASSESSMENT PRO FORMA

Name of Patient: _____ **Date:**_____

DOB: _____ **RT NO:** _____

Consultant/Psychiatrist: _____ **Case Worker:**_____

Please clarify if previous or current history includes

	Patient	**Family**
Significant anxiety		
Expresses suicidal ideas		
Low mood or depression		
Angina/MI under 55 or history of sudden death		
High or low BP/P		
Arrhythmia		
History of exercise syncope or cardiovascular symptoms		
Epilepsy		
Drug/alcohol misuse or dependency		
Tics/ Tourettes		
Thyroid Disorder		
Glaucoma		
Kidney Disease		
Liver Disease		

Drug allergies:

Other medication prescribed:

Name	**Dose**	**Duration of Treatment**

Height: _____

Weight: _____

B/P: _____ **Pulse:** _____