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Shared Care Prescribing Arrangements for the use of methylphenidate, atomoxetine, lisdexamphetamine, dexamphetamine and guanfacine in Adult ADHD between Dr Baskind and primary care

1. Introduction

This shared care guideline specifies the initiation/continuation, prescribing, and monitoring of ADHD medication in adults. These guidelines have been reviewed following the NHS England updated shared care protocols (2022)[1] and NICE guidance issued in 2018 on the diagnosis and management of ADHD in children, young people, and adults (1[2]), which states; 'After titration and dose stabilisation, prescribing and monitoring of ADHD medication should be carried out under Shared Care Protocol arrangements with primary care'.

Dr Baskind provides a private service to help support adults with suspected ADHD. Dr Baskind recognises that NHS services are under significant strain with limited NHS ADHD access and that many individuals are choosing to self-fund ADHD assessments due to the impact of ADHD on their daily lives, families and mental health well-being. Although treatment for ADHD has very high success rates, unfortunately many patients cannot continue funding long term costs of private prescriptions and therefore in line with NICE guidance, Dr Baskind kindly requests a shared care agreement to be agreed between himself and the general practitioner to enable ongoing treatment.

Dr Baskind recognises the significant and increasing demands placed on primary care, and offers reassurance he can be contacted directly by email or telephone if there are any concerns regarding a patient's management, and a prompt response will be provided, usually within 24 hours.

[1] NHS England » Shared Care Protocols (SCPs). Accessed online October 2022.
[2] National Institute for Health and Clinical Excellence [NICE] (2018) Attention Deficit Hyperactivity Disorder – Diagnosis and Management of ADHD in Children, Young People and Adults. NICE clinical guideline (NG87). https://www.nice.org.uk/guidance/ng87

2. About the service

Dr Rob Baskind offers private diagnostic (re)assessments, initiation and dose titration, of pharmacological treatment for Adult ADHD. He has been a specialist and expert in Adult ADHD since 2011, at which time he developed the Leeds NHS Adult ADHD service and acted as Clinical Lead from 2011-2022. He has also delivered training to specialist services, to primary and secondary care healthcare professionals, and also to staff working within the criminal justice system. Dr Baskind was the author of "Top tips: ADHD in adults" for the journal 'Guidelines in Practice'[3].

Dr Baskind offers both face-to-face (based at The Tower Clinic, 8 Tinshill Lane, Leeds LS16 7AP) and online consultations through Semble (formerly Heydoc) clinical patient system.

Assessments completed by Dr Baskind will include a full assessment of the patient:

- including full medical, physical, and medication history details
- full mental health and social assessment
- diagnostic interview and assessment of ADHD symptoms according to DSM-5 criteria
- full history including past and present medical and psychiatric disorders or symptoms
- concomitant medicines
- history or risk of substance misuse.

3. Formulary status of ADHD Medicines

Stimulants are usually the first-choice pharmacological treatment for ADHD in both children and adults.

NICE Guidance[1] for pharmacological treatment of ADHD is as follows.

1st line: Offer lisdexamphetamine or methylphenidate as first-line pharmacological treatment for adults with ADHD.

2nd line: Consider switching to lisdexamphetamine for adults who have had a 6-week trial of methylphenidate at an adequate dose but have not derived enough benefit in terms of reduced ADHD symptoms and associated impairment.

3rd line: Consider switching to methylphenidate for adults who have had a 6-week trial of lisdexamphetamine at an adequate dose but have not derived enough benefit in terms of reduced ADHD symptoms and associated impairment.

Consider dexamphetamine for adults whose ADHD symptoms are responding to lisdexamphetamine but who cannot tolerate the longer effect profile.

Offer atomoxetine to adults if:

· they cannot tolerate lisdexamphetamine or methylphenidate or

[3] Baskind R. top tips: ADHD in adults. *Guidelines in Practice* 2017; **20** (10): 44-49. https://www.guidelinesinpractice.co.uk/neurology-/top-tips-adhd-in-adults/453652.article

· their symptoms have not responded to separate 6-week trials of lisdexamphetamine and methylphenidate, having considered alternative formulations and doses.

Do not initiate any of the following medication for ADHD without advice:

· guanfacine for adults (see below)
· atypical antipsychotics in addition to stimulants for people with ADHD and coexisting pervasive aggression, rages, or irritability
· medication not included in the recommendations above.

The first-line choices of medication in adults include lisdexamphetamine and methylphenidate (adult use for the latter is an unlicensed indication; however, it is recommended under NICE guidance and British Association for Psychopharmacology[4] in view of the supporting evidence).

Combination of immediate and modified release of a stimulant class is recognized practise and consistent with NICE guidance to extend the duration of action.

Combination of stimulant and non-stimulant medication may be recommended by Dr Baskind if symptoms are not optimally controlled in some symptom areas (such as emotional regulation), or if lower doses of stimulants are advisable to reduce side effects.

There are some instances where **guanfacine** treatment is necessary, detailed below. For such patients, GPs are requested to continue prescribing guanfacine for:

· adolescents transitioning from a children's service, or adults re-engaging with treatment, and whose treatment has been recently assessed by a specialist as effective and necessary to continue.
· adults moving from another service already stabilised on guanfacine, where guanfacine has been assessed by an appropriate specialist as a necessary effective alternative to NICE NG87 (September 2019) recommendations.
· those where treatment has been recommended by Dr Baskind.

Important: Please refer to the full Summary of Product Characteristics (SPC) for each drug for details of side effects, cautions, contraindications and drug interactions via www.medicines.org.uk.

4. Shared care responsibilities

Dr Baskind

- Diagnostic assessment, assessment report, and decision about the indication for treatment with ADHD medication.
- Ensure the patient understands that medication may be stopped if they do not attend for monitoring and treatment review
- To take physical health history including past medical (exercise syncope, undue breathlessness and other cardiovascular symptoms) and family history of serious

[4] British Association for Psychopharmacology [BAP] (2014) Evidence-based guidelines for management of attention deficit hyperactivity disorder: Update on recommendation from the British Association for Psychopharmacology. Journal of Psychopharmacology 1-25.

cardiac disease, a history of sudden death in young family

- Conduct required baseline readings of blood pressure, heart rate, and weight
- Note that NICE advise; 'that an ECG is not needed before starting stimulants, atomoxetine or guanfacine if cardiovascular history and examination are normal and the person is not on medicine that poses an increased cardiovascular risk'. If patient has cardiovascular risk factors (including family history such as history of sudden death of first-degree relative under 40 suggesting cardiac disease), an ECG and/or referral to cardiology will be requested
- For patients with other cardiovascular problems, Dr Baskind will discuss planned ADHD medications with the GP or a cardiologist as appropriate
- Assess for cautions, contraindications and interactions
- To discuss benefits and side effects of treatment with the patient/carer
- Informed consent for the off-label use of the drugs be obtained and documented prior to starting treatment
- To initiate methylphenidate, atomoxetine, guanfacine, dexamphetamine or lisdexamphetamine in appropriate patients and prescribe until the patient has been stabilised for one month
- To follow-up the patient during dose titration and monitor the patient's BP and pulse before any dose increase
- To contact the patient's GP to request prescribing under shared care
- To advise the GP regarding continuation of treatment, including the length of treatment, any changes to the treatment plan, or any planned drug treatment breaks/periodical discontinuation
- To discuss any concerns with the GP regarding the patient's therapy
- To be available by email and/or phone to respond to any that are raised by the GP usually within 24 hours but in all cases within 2 working days
- To conduct an annual medication and effectiveness review for each patient including the recommended physical monitoring.

<u>General Practitioner</u>

- To agree to prescribe for patients in line with the shared care agreement
- To treat hypertension according to relevant NICE guidance (if necessary)
- To report any adverse reaction(s) to Dr Baskind
- To continue to prescribe for the patient as advised by Dr Baskind and adjust dose as advised by Dr Baskind
- Assess for possible interactions with lisdexamfetamine when starting new medicines
- To monitor the patient's weight, pulse, and BP 6-monthly as per the recommendations
- To inform Dr Baskind if the patient discontinues treatment for any reason
- Stop medication and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.
- Manage adverse effects as detailed in section 6 if feel comfortable to do so. Seek advice from Dr Baskind as required.

Bioequivalence issues with different brands of methylphenidate modified release.

There are many different brands of methylphenidate 'XL' including those listed below: Medikinet XL® Equasym XL® Xenidate XL® Concerta XL®, is bioequivalent to Matoride® and Xenidate®; both release approx. 21% immediate release methylphenidate with the remainder released over time.
Medikinet XL, Xenidate XL, Matoride XL, Xaggitin XL and Delmosart are also branded generics and so are cheaper than Concerta XL and Equasym XL.
When initiating methylphenidate, please ensure you start and continue to prescribe the same brand every time.

5. Considerations for treatment review and other mental health concerns

Adult ADHD often comes along with other comorbid mental health problems.

For ADHD-related problems the patient can be re-referred to Dr Baskind or local ADHD services.
For any other deterioration in mental state/behaviour that causes concern and is not related to changes with ADHD medication, and could not be managed by the GP, the patient should be referred to local mental health NHS services or preferred private consultant.

Trial Discontinuation

There should be a discussion with the patient at their Annual Review to consider whether the medication is still needed, especially where treatment has continued for 12 months. If there has not already been a trial off medication, the specialist may recommend a trial without treatment where on-going symptoms are unclear. This should be offered and discussed with the patient and the outcome recorded. Consideration must be given to patient choice.

Methylphenidate and dexamphetamine can generally be withdrawn by treatment discontinuation but monitor for signs of withdrawal (uncommon).

For **atomoxetine**, the dose can be halved and discontinued over a 2-4 week period.

Guanfacine – where this is prescribed, it should not be stopped suddenly, but the total daily dose of guanfacine should be tapered in decrements of no more than 1 mg every 3 to 7 days with blood pressure and pulse monitoring. Sudden cessation of guanfacine has been associated with hypertensive encephalopathy (very rarely reported). In cases where a patient has been referred to Adult ADHD Services, and their supplies are running out before they can be seen, consider prescribing guanfacine at current dose, or sufficient supplies to be able to taper down safely to stop until their appointment with the Service.

6. Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard For information on incidence of ADRs see relevant summaries of product characteristics	
Result	**Action for primary care**
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with Dr Baskind or cardiology for further advice.
Weight or BMI outside healthy range, anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with Dr Baskind if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Haematological disorders For stimulants: Including leukopenia, thrombocytopenia, anaemia or other alterations NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.	Contact Dr Baskind. Discontinuation should be considered. Referral to haematology may be warranted; use clinical discretion.

For atomoxetine: Signs or symptoms of liver injury, e.g. abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine	Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team. Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist).
Psychiatric disorders New or worsening psychiatric symptoms, e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression	Discuss with Dr Baskind. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present Treatment should not be continued unless the benefits outweigh the risks.
Nervous system disorders Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue medication, refer urgently for neurological assessment
Gastrointestinal disorders (relevant to atomoxetine) Including abdominal pain, vomiting, nausea, constipation, dyspepsia	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally resolves.
New or worsening seizures	Discuss with Dr Baskind. Consideration of discontinuation.
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with Dr Baskind to determine whether medication can be re-started.
Insomnia or other sleep disturbance	Review timing of dose and advise as appropriate. Splitting atomoxetine dose can be helpful. Give advice on sleep hygiene. Discuss with Dr Baskind if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Discuss with Dr Baskind

7. Pregnancy and Lactation

As with most medicines, the safety of these drugs in pregnancy and lactation cannot be guaranteed.

For lisdexamphetamine and atomoxetine, there is insufficient data available regarding pregnancy outcome data to be able to make any recommendation[5]
There is most data available about methylphenidate exposure in pregnancy; however, this is still limited and, again, is insufficient to make any general recommendations of safety.
Guanfacine: the manufacturers do not recommend the use of guanfacine in pregnancy or in women of childbearing potential not using contraception. Animal studies have shown reproductive toxicity. If a patient taking any of these drugs reports a pregnancy or is planning a pregnancy, they should be offered a full risk vs. benefit assessment discussion within primary care. This should include a discussion around breastfeeding after birth.
Methylphenidate can be used in the breastfeeding mother if considered clinically appropriate to do so, with extra monitoring for adverse effects in the infant i.e. weight. There is little or no data available about the other alternatives in order to make any specific recommendation. The GP can call the Medicines Information Service on 0118 960 5075, who can give advice on a case-by-case basis or speak to Dr Baskind for further advice.

Patients can be referred to written information via: www.medicinesinpregnancy.org and also via Choice and Medication to help in making an informed choice.

8. Contact numbers for advice and support

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[5] TOXBASE. Newcastle Teratology Information Service. Monographs for; methylphenidate (Jan 2018; version 3), amphetamines (Sep 2012; version 1), atomoxetine (Dec 2017, version 2).