Avon & Wiltshire Mental Health Partnership NHS Trust (AWP), BaNES, Swindon & Wiltshire (BSW) CCG and Bristol, North Somerset & South Gloucestershire (BNSSG) CCG

SHARED CARE AGREEMENT

Guanfacine (Intuniv®) tablets for the treatment of ADHD in Adults

Amber TLS – 3 month (oral)

Principles of Shared Care

Shared care agreements provide a framework for the seamless transfer of care from a hospital or specialist service setting to general practice, where this is appropriate and in the patient's best interest. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP (or other primary care prescriber) concerned and the patient to share their care.

Patients and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines.

The existence of a shared care agreement does not necessarily mean that the GP has to agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition. Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.

Responsibilities of Secondary Care Specialist (DO NOT EDIT)

- Initiate treatment and prescribe for the length of time agreed (1 or 3 months) – this should be a sufficient amount of time to allow optimisation of treatment and demonstrate that the patient's response is consistent.
- Discuss the benefits and side effects of treatment with the patient.
- Review concurrent medications for potential interactions prior to initiation.
- Undertake the clinical assessment and relevant monitoring at baseline and during the initiation period.
- Communicate details of treatment to GP (in writing or via secure email) within the first month of treatment and ask the GP whether he or she is willing to participate in shared care.
- Discuss shared care arrangements with the patient/carer, obtain their consent and explain their responsibilities.
- Review the patient's condition and monitor response to treatment regularly where indicated.
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring.
- Supply GP with clinic letter or discharge summary within 14 days of an outpatient review or inpatient admission, and inform GP if patient does not attend scheduled clinic appointments.
- Ensure that clear arrangements exist for GPs to obtain advice and support.
- Report adverse events to the MHRA via the Yellow Card scheme.
- Stop treatment where appropriate or provide GP with advice on when to stop.
- If the medicines is to be used off-label, explain to the patient and obtain consent
- Conduct/seek required baseline investigations and initial monitoring (see section 5).
- Conduct the required annual reviews and monitoring in section 5.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued. Trial discontinuations should be managed by the specialist. Where dose adjustments of guanfacine are required that are not detailed within the SCP the specialist should advise the primary care prescriber as to how the dose should be adjusted

Responsibilities of GP/Primary Care Prescriber (DO NOT EDIT)

- Reply to the request as soon as practicable if they are unable to support shared care (in writing or via secure email).
- Prescribe medicine at the dose recommended after the initiation period (1 or 3 months).
- Undertake ongoing clinical assessment and relevant monitoring following initiation period.
- Review any new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.

- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Report adverse events to the specialist and to the MHRA via the Yellow Card scheme.
- Stop treatment on the advice of the specialist.
- Make an urgent referral to the specialist if suicidal behaviour or ideation, syncope, or other signs or symptoms of cardiovascular adverse effects occur.
- 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.

Responsibilities of Patient/Carer (DO NOT EDIT)

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with medicine.
- Report any adverse effects to the specialist or GP whilst taking the medicine.
- Attend appointments for clinical review and monitoring.
- Take guanfacine as prescribed and avoid abrupt withdrawal unless advised by their primary care prescriber or specialist. Stopping guanfacine suddenly increases the risk of side effects, it is important to gradually reduce the dose of guanfacine under medical supervision.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of guanfacine with their pharmacist before purchasing any OTC medicines.
- Avoid alcohol and grapefruit juice while taking guanfacine, and drink plenty of other fluids.
- Not to drive, cycle, or operate heavy machinery if guanfacine affects their ability to do so safely.
- Women of child-bearing potential should:
    - take a pregnancy test if they think there is a possibility they could be pregnant
    - inform the specialist or GP immediately if they become pregnant or wish to become pregnant

1. Summary of condition and treatment aims Include links to relevant clinical guidelines e.g. NICE	Guanfacine is a centrally-acting adrenergic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents. Use in adults is off-label, and should only be considered on the advice of a tertiary ADHD service. It may be recommended for people who have not responded to one or more stimulants, and one non-stimulant (NICE NG87). Guanfacine should be used as part of a comprehensive treatment programme, typically including psychological, educational and social measures. Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated. Long-term usefulness of guanfacine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate.	
2. Details of medicine and indication Please state whether licensed or unlicensed (off-label) use. Note that shared care is generally unsuitable for off-label prescribing unless it is a widely recognised use (e.g. included in BNF)	Intuniv® 1,2,3,4mg prolonged-release tablets Attention-deficit hyperactivity disorder ‡ ‡ Off-label indication in adults recognised by NICE. (Please note licensed indications vary by manufacturer).	
3. Pharmaceutical aspects	Route of administration:	Oral
	Formulation:	Guanfacine hydrochloride (Intuniv®▼) Prolonged-release tablets: 1 mg, 2 mg, 3 mg, 4 mg

	Administration details:	Guanfacine can be taken with or without food, but should not be given with high fat meals due to increased exposure. Tablets should be swallowed whole and not split, crushed or chewed. Guanfacine should be taken once daily in the morning or evening. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. If two or more consecutive doses are missed, re-titration is recommended, a lower starting dose may be required based on the patient's tolerance to guanfacine.
	Other important information:	Grapefruit juice should be avoided during treatment with guanfacine. Due to risk of blood pressure increase upon discontinuation, guanfacine should be gradually tapered at a rate of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when discontinuing treatment.
4. Usual dose and frequency (including details of dose adjustments, e.g. in renal impairment) and duration of therapy Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results. All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. The duration of treatment will be determined by the specialist, based on clinical response and tolerability. Termination of treatment will be the responsibility of the specialist.	**Initial stabilisation:** 1 mg once daily, adjusted in increments of not more than 1 mg every week, if necessary and tolerated. **The loading period must be prescribed by the initiating specialist.** **Maintenance dose (following initial stabilisation):** 0.05-0.12 mg/kg/day. Maximum dose 7 mg daily. **The initial maintenance dose must be prescribed by the initiating specialist.** Adults who have shown clear benefit from guanfacine in childhood or adolescence may continue treatment into adulthood at the same daily dose. **Conditions requiring dose adjustment:** Hepatic or renal insufficiency: Dose reduction may be required in patients with hepatic impairment, severe renal impairment (GFR 15-29 mL/min), end stage renal disease (GFR <15 mL/min) or in patients requiring dialysis. Patients taking CYP3A inhibitors or inducers: Dose adjustment required, see section 8.	
5. Baseline investigations and initial monitoring to be undertaken by specialist	**Baseline investigations**	
	Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated changes expected in the immediate future will prescribing and monitoring be transferred to the GP. **Baseline investigations:** • A medical history and full cardiovascular assessment (this should include consideration of any family history of sudden cardiac/unexplained death), taking into account conditions which may be contraindicated, risk of pregnancy (where applicable). • Height, weight, and body mass index (BMI) • Blood pressure (BP) and heart rate • Electrocardiogram (ECG) is recommended only if the patient has any of the following: o History of congenital heart disease or previous cardiac surgery, sudden death in a first-degree relative under 40 years suggesting a cardiac disease, shortness of breath on exertion compared with peers, fainting on exertion or in response to	

fright or noise, palpitations, chest pain suggestive of cardiac origin, signs of heart failure, heart murmur or hypertension, or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk

- Risk of somnolence and sedation
- Suicidal ideation or behaviour

Initial monitoring:

- Weekly monitoring for signs and symptoms of somnolence, sedation, suicidal ideation or behaviour, hypotension and bradycardia during dose titration and stabilisation
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring:

- Before and after every change of dose: assess heart rate and blood pressure.
- Monitoring for signs and symptoms of somnolence, sedation and suicidal ideation or behaviour during any dose adjustments or discontinuation. Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements. This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.
- Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined below remains appropriate.

Monitoring to be carried out in primary care	Frequency
• Blood pressure and heart rate* • Somnolence and sedation • Height, weight, and BMI • Signs or symptoms of cardiovascular adverse effects, e.g. bradycardia and hypotension	Every 3 months for the first year of treatment, and every 6 months thereafter. N.B. More frequent monitoring is recommended following dose adjustment or discontinuation. Additional monitoring to be carried out by team initiating the dose change (usually secondary care).
• Assessment of adherence	As required based on the patient's needs and individual circumstances
• Suicidal ideation or behaviour	Annually or if dose is adjusted / titrated / discontinued
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

	*Primary care may encourage patients to self-monitor blood pressure and heart rate at the intervals set out in this SCP and submit readings to the practice for review. Please note, it is the responsibility of primary care to ensure that minimum monitoring standards are met, and practices must ensure that patients are called for review of blood pressure and heart rate in person where patients are not self-monitoring.
6. Action(s) to be taken by primary care if abnormal result(s)	Refer patient back to specialised ADHD Service.
7. Cautions and contraindications Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	**Contraindications:** • Hypersensitivity to guanfacine or to any of the excipients • Hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Cautions:** • Risk factors for torsades de pointes: bradycardia, heart block, hypokalaemia, history of QT interval prolongation, concomitant use of other medicines which may prolong the QT interval. • History of cardiovascular disease, hypotension, orthostatic hypotension, or syncope. • Family history of cardiac or unexplained death. • Dehydration (may increase risk of syncope). • Alcohol consumption (not recommended during treatment). • Concomitant treatment with centrally acting depressants or antihypertensives (see section 7). • Suicidal ideation or behaviour. • Prescribing in the elderly is potentially inappropriate. See BNF information on prescribing in the elderly. Please see SPC for comprehensive information.
8. Significant medicine and food interactions and management For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)	**The following list is not exhaustive; please see SPC for comprehensive information and recommended management.** • Drugs which prolong the QT interval. Concomitant use with guanfacine is not recommended. • **CYP3A4 and CYP3A5 inhibitors**, e.g. ketoconazole, clarithromycin, erythromycin, ciprofloxacin, diltiazem, fluconazole, verapamil, grapefruit juice, ritonavir: increased exposure to guanfacine. Dose reduction may be required. • **CYP3A4 inducers**, e.g. carbamazepine, modafinil, phenytoin, rifampicin, St John's wort: reduced exposure to guanfacine. Dose increase may be required. • **Valproic acid**: concomitant use may increase concentrations of valproic acid • **Antihypertensive medicines**: risk of additive effects, e.g. hypotension, syncope • **CNS depressants**, e.g. alcohol, sedatives, hypnotics, benzodiazepines, barbiturates, antipsychotics: risk of additive effects, e.g. sedation, somnolence **Administration with high fat meals:** increased exposure to guanfacine.
9. Adverse effects and management Include details of incidence, identification, importance and management.	

Result	Action for primary care
Cardiovascular Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation

Marked decrease from baseline in heart rate	Discuss with specialist team; dose reduction or cardiac evaluation may be required
Hypotension or orthostatic hypotension	Give lifestyle advice (e.g. drinking plenty of fluids, getting up slowly from standing or sitting) and repeat monitoring. If blood pressure decreases markedly from baseline, reduce dose by 1mg and discuss with specialist team.
Sedation and somnolence	Sedation and somnolence typically occur during the start of treatment and with dose increases. Review timing of dose; guanfacine may be taken in the morning or evening. Review lifestyle factors, and reinforce that alcohol should be avoided. Seek specialist advice if sedation persists. Dose reduction or discontinuation may be indicated.
Weight or BMI outside healthy range	Provide appropriate support on multicomponent interventions to increase physical activity levels, improve eating behaviour and quality of diet. Discuss with specialist if difficulty persists; dose reduction, or treatment break, or change of medicine may be required.
Psychiatric disorders Suicidal ideation or behaviour	Review patient and exclude other causes. Refer urgently to ADHD specialist team. Consider discontinuing guanfacine.

10. Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- New or worsening psychiatric symptoms, such as suicidal ideation or behaviour
- Signs and symptoms of bradycardia or hypotension, e.g. fatigue, dizziness, palpitations, feeling faint or fainting

The patient should be advised:

- To drink plenty of fluids; dehydration can increase the risk of falls or fainting.
- Not to drive, cycle, or operate machines if guanfacine affects their ability to do so safely, e.g. by causing dizziness or drowsiness.
- Avoid alcohol while taking guanfacine, as it may make side effects worse.
- Avoid grapefruit juice while taking guanfacine.
- Not to stop taking guanfacine without talking to their doctor. Due to risk of side effects, it is important to gradually reduce the dose of guanfacine under medical supervision.
- To take a pregnancy test if they think there is a possibility they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant (women of child-bearing potential).

Patient information:

- Choice and Medication https://www.choiceandmedication.org/awp
- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

	• NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
11. Pregnancy and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.	**Pregnancy:** Guanfacine is not recommended for use during pregnancy and in women of childbearing potential not using contraception. There are no or limited data from the use of guanfacine in pregnant women, and animal studies have shown reproductive toxicity. Patients who become pregnant while taking guanfacine, or who plan a pregnancy, should be referred to the specialist team for review. **Breastfeeding:** There is no published evidence on the safety of guanfacine in breastfeeding. Decisions on whether to use while breastfeeding should be made on a case-by-case basis with specialist input e.g. UKTIS, taking into account the risks to the infant and benefits of therapy. The long half-life increases the risk of accumulation in breastfed infants. It may interfere with lactation, as guanfacine decreases prolactin levels in the mother. Infants should be monitored for decreased appetite/weight gain, sleep disturbances, gastrointestinal symptoms (e.g. pain, vomiting, constipation), although some of these may be difficult to detect. Information for healthcare professionals: https://www.sps.nhs.uk/medicines/guanfacine// **Paternal exposure**: No evidence regarding adverse outcomes following paternal exposure was identified.
12. Specialist contact information	**AWP Team (Adults)** Specialised ADHD Service | 01275 796262 | Awp.specialisedadhdservices@nhs.net **Other Specialist Contact Information**
13. Additional information For example, process for when Specialist or GP changes roles; specific issues related to patient age/ capacity/ specific monitoring.	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
14. References	• eBNF. Guanfacine, last updated 27th July 2020. Accessed via www.medicinescomplete.com on 03/06/2021 • Guanfacine hydrochloride 1 mg prolonged-release tablets (Intuniv®). Date of revision of the text 25/06/20. Accessed via https://www.medicines.org.uk/emc/product/5099 on 03/06/2021 • NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 04/06/2021 • Guanfacine risk minimisation materials. Updated November 2017. Accessed via https://www.medicines.org.uk/emc/product/5099/rmms on 03/06/21. • Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/ on 26/05/2021 • Specialist Pharmacy Service. Guanfacine Lactation Safety Information. Last updated January 2018. Accessed via https://www.sps.nhs.uk/medicines/guanfacine/ on 03/06/2021
15. To be read in conjunction with	• Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/

the following documents	• NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ • General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care • NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

Written by (Author Name, Organisation & Role):	James Scott, AWP, Clinical Lead Pharmacist and ADHD NMP
Contributors:	Specialised Pharmacy Service RMOC Draft SCP
Date Last Updated:	01/11/2022
Date Approved by AWP:	24/03/2022
Date Approved by BNSSG:	01/11/2022
Date Approved by BSW:	Click or tap here to enter text.
Review Date:	01/11/2024
Document Version:	1.0

Shared Care Agreement template adapted by Ellen Brennan-Rist from Appendix 5 of Shared Care Guidance – A Standard Approach for RMOC Consultation (SPS Website). Template approved by AWP, BSW and BNSSG September 2020, Version 1.2