





## National shared care protocol:

# Guanfacine for patients within adult services

1 July 2025, Version 1

TLS Amber - 3 Months

Review date – July 2028

This shared care protocol is based on content originally published by <a href="RMOC/NHS">RMOC/NHS</a>
<a href="England">England</a>
in January 2022. As well as these protocols, please ensure that <a href="Summaries of product characteristics">summaries of product characteristics</a> (SPCs), <a href="British national formulary">British national formulary</a> (BNF) or the <a href="Medicines and Healthcare products Regulatory Agency">Medicines and Healthcare products Regulatory Agency</a> (MHRA) or <a href="NICE">NICE</a> websites are reviewed for upto-date information on any medicine.

### **Specialist responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Prior to prescribing guanfacine, obtain advice from a tertiary service on the suitability for the patient.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with
  the patient and/or their carer and provide the appropriate counselling (see <u>section 11</u>), to
  enable the patient to reach an informed decision. Obtain and document consent. Provide an
  appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see <u>section 4</u>) and interactions (see <u>section 7</u>).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in <u>section 5</u>. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.

- Once treatment is optimised, complete the shared care documentation and send to patient's GP detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist. Provide advice to primary care on the management of adverse effects if required.

### **Primary care responsibilities**

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of guanfacine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with guanfacine when starting new medicines (see section 7).
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Make an urgent referral for appropriate care if suicidal behaviour or ideation, syncope, or other signs or symptoms of cardiovascular adverse effects occur.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

### Patient and/or carer responsibilities

- Take guanfacine as prescribed and avoid abrupt withdrawal unless advised by their prescriber. Stopping guanfacine suddenly increases the risk of withdrawal effects, namely rebound hypertension, so it is important to gradually reduce the dose under medical supervision.
- Attend all monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their 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, and inform the DVLA if their ability to drive safely is affected (see section 11).
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background Back to top

Guanfacine is a centrally-acting adrenergic medicine 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 (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

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) or Community Paediatric service but is approaching their 18th birthday, it is expected that CAMHS/Community Paediatric service will refer to the appropriate adult service if need for

ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed.

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. Indications Back to top

- Attention-deficit hyperactivity disorder \*
- <sup>‡</sup> Off-label indications not licensed in adults. See section 1 for circumstances where NICE recommend use in adults.

## 3. Locally agreed off-label use

Back to top

To be agreed and completed locally (include supporting information)

N/A

#### 4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

#### 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.

## 5. Initiation and ongoing dose regimen

Back to top

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- To minimise the risk of an increase in blood pressure upon discontinuation, the manufacturer advises that the total daily dose should be tapered in decrements of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when reducing the dose or discontinuing treatment. Termination of treatment can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

#### **Initial stabilisation:**

1 mg once daily, adjusted in increments of not more than 1 mg every week, if necessary and tolerated.

The initial stabilisation 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 29-15 mL/min), end stage renal disease (GFR <15 mL/min) or in patients requiring dialysis.

#### Patients taking CYP3A inhibitors or inducers:

A 50% reduction in guanfacine dose is recommended with concurrent use of moderate and potent inhibitors of CYP3A4. Dose titration may be required with concurrent use of potent inducers of CYP3A4.

6. Pharmaceutical aspects  Back to top		
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. Discuss with the specialist team or HCP with expertise in ADHD who conducts the annual review for advice on re-titrating 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.	

Discontinuation should be managed by the specialist team or HCP with expertise in ADHD who conducts the annual review.

## 7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or 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, see section 5.
- **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.

## 8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Back to top

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 further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

#### **Baseline investigations:**

- A full assessment, as recommended by NICE guidance for ADHD. This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for guanfacine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
- Height, weight, and body mass index (BMI).
- Blood pressure (BP) and heart rate.

- Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:
  - history of congenital heart disease or previous cardiac surgery
  - o 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
- ECG is recommended if the patient has a co-existing condition treated with a medicine that may increase cardiac risk.

#### **Initial monitoring:**

Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

#### Ongoing monitoring:

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, and 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.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

## 9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
<ul> <li>Blood pressure and heart rate</li> <li>Weight and appetite</li> </ul>	Every 3 months for the first year, and every 6 months thereafter.  More frequent monitoring is recommended following dose adjustment, which may be done in primary care if directions have been discussed and agreed with the specialist service.
Assessment of adherence	As required, based on the patient's needs and individual circumstances.
<ul> <li>Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD.</li> <li>Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.</li> </ul>	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake).

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

## 10. Adverse effects and other management

Back to top

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  Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or	Refer for urgent specialist cardiac evaluation		
other signs or symptoms suggestive of cardiac disease			
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		
Sedation and somnolence	with specialist team.  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 for psychiatric assessment and notify the ADHD specialist team.  Consider discontinuing guanfacine.

## 11. Advice to patients and carers

Back to top

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, and to inform the DVLA if their ability to drive safely is affected. See https://www.gov.uk/adhd-and-driving.
- 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.

#### Patient information:

- Royal College of Psychiatrists ADHD in adults. <a href="https://www.rcpsych.ac.uk/mental-">https://www.rcpsych.ac.uk/mental-</a> health/problems-disorders/adhd-in-adults
- NHS Attention deficit hyperactivity disorder. <a href="https://www.nhs.uk/conditions/attention-deficit-">https://www.nhs.uk/conditions/attention-deficit-</a> hyperactivity-disorder-adhd/

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=guanfacine

## 12. Pregnancy, paternal exposure and breast feeding

Back to top

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 primary care prescriber and the specialist.

#### **Pregnancy**:

Guanfacine is not recommended for use during pregnancy. 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.

## 13. Specialist contact information

Back to top

Name: Dr Dietmar Hank

Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP

Daytime telephone number: 01275 796262 M-F 9-5

Email address: Awp.specialisedadhdservices@nhs.net

### 14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References Back to top

- eBNF. Guanfacine. Accessed via <a href="https://bnf.nice.org.uk/drug/guanfacine.html">https://bnf.nice.org.uk/drug/guanfacine.html</a> on 02/06/2025
- Guanfacine hydrochloride 1 mg prolonged-release tablets (Intuniv®). Date of revision of the text 23/05/23. Accessed via <a href="https://www.medicines.org.uk/emc/product/5099">https://www.medicines.org.uk/emc/product/5099</a> on 02/06/2025
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 02/06/2025
- NICE NG43: Transition from children's to adults' services for young people using health or social care services. Last updated February 2016. Accessed via https://www.nice.org.uk/guidance/ng43/ on 02/06/2025

## 16. Other relevant national guidance

Back to top

- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-betweenprimary-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/ethicalguidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-anddevices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

## 17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

The patient finds the medication intolerable for any given reason

- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter. Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

APC board date: JFG July 2025