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SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	**Guanfacine**	
Indication	Guanfacine is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.	
PCN policy statement reference (if applicable)		
Author(s): Simon Whitfield **Organisation(s):** Surrey and Borders Partnership NHS Foundation Trust, Epsom and St Helier NHS Trust		
Version: 0.2	**PCN recommendation date:** mmm/yyyy	**Review date:** usually 3 yrs post PCN

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Specialist responsibilities
1. Ensure baseline monitoring of height, weight (including centiles), BMI, BP, pulse have been performed plus any additional relevant investigations such as ECG in case of family history of arrhythmia or sudden death.
2. Set the review interval and criteria. The Specialist must ensure weekly contact during dose titration to assess efficacy of treatment and to monitor for signs and symptoms of somnolence and sedation, hypotension and bradycardia, including monitoring of BP and pulse.
3. Once a child's treatment is stabilised face to face 3 monthly reviews are provided by the Specialist for the first year. Specialist ADHD nurses, junior doctors and other staff are closely involved with the monitoring of the patients. When junior / middle grade doctors are helping the Specialists in the clinic, changes should

	be made after discussion with the Specialist only, and should be clearly stated in a letter to the GP.
4.	Undertake any necessary monitoring at face to face clinic appointments (initially three monthly for first year of treatment, then 6 monthly in the long term): monitor blood pressure, pulse, weight and height (including centiles), BMI and monitor for signs and symptoms of somnolence and sedation, hypotension and bradycardia.
5.	Supply the medication until the dose is stabilised. Min 1 months' supply. For patients aged 6 to 17 years, prescribing may be transferred to the GP under shared care once the patient is stabilised on medication. The GP will not be asked to prescribe the drug outside its licensed indications.
6.	Request agreement of shared care with primary care prescriber: a detailed clinic letter highlighting relevant patient information should be sent to the GP requesting shared care including: - Information that all conditions have been discussed and appropriately actioned - the date of the next follow up review Shared care should only be requested if the patient is stable.
7.	To collate (including on centile charts) and review the physical medication monitoring results every 6 months) and advise the GP of any required actions.
8.	Maintain good communication with the GP and provide urgent advice on the following telephone number - XXXXXXX. A written letter should be sent to the GP after each clinic visit notifying the GP of changes in the medication regime, adverse effects and results of the patient's routine monitoring. The GP must be notified of non-attendance at clinic. (**NOTE**: patients that regularly do not attend their 6 monthly reviews are not appropriate for shared care)
9.	Keep the GP fully informed about the patient's condition and medication. The specialist will be available to answer queries from the GP and carers.
10.	Stop or modify the dosage as appropriate.
11.	Advise the GP when the treatment is being discontinued. The specialist will provide necessary supervision and support during the drug discontinuation phase.
12.	Liaison with other members of the multidisciplinary team responsible for the child's development and education. The parents and class teachers should be given information about guanfacine in particular the monitoring and side effects.
13.	Evaluate adverse drug reactions reported by the GP or carer.
14.	The appropriateness of medication into adulthood should be carefully reviewed. If the drug is to be continued beyond the age of 18, the Specialist will seek to make appropriate arrangements.
15.	Continue supply of medication for children under six years.

General Practitioner responsibilities	
1.	Monitor patient's overall health and wellbeing.
2.	Continued prescription of treatment, once patient is stabilised on medication and shared care is agreed. As it is not necessary for a doctor to see the child more than every 6 months, unless there are specific indications, repeat prescriptions can be issued without necessarily seeing the child on each occasion.
3.	To check that the patient is attending their 6 monthly specialist ADHD clinics and thus continued prescription is required.
4.	To record any changes in therapy in the prescribing record on receipt of such communication from secondary care and to act upon these
5.	Symptomatic management of minor adverse effects.

Patient's / Carer's role	
1	To attend appointments (both with your GP and specialist service).

Key information on the medicine

Background to disease and use of medicine for the given indication

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most commonly diagnosed behavioural disorders of childhood, affecting 1-5% of school age children. Its basic symptoms include developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity. It causes problems at home, in school and with peer relationships and may have long term adverse effects on self-confidence, academic performance, vocational success and social development.

- It can be divided into three types, depending on whether inattention or hyperactivity is the predominant presentation
- It must have been present for at least six months and be maladaptive and inappropriate for the age of the child (although in the case of developmental delay the developmental age should be taken into account).
- There must be clear evidence of impairment in social and / or academic functioning
- Some impairment must be present in at least two settings
- The symptoms must be present in at least two settings
- The symptoms must be present before the age of seven
- The symptoms must not be accountable for by any other type of mental disorder or illness although they may occur in conjunction with some development disorders.

Its consequences are low self-esteem, emotional and social problems which may lead to further problems with drug abuse etc in the longer term. These children's academic achievements are often very low consequently often leading to employment problems.

Where drug treatment is considered appropriate, methylphenidate, atomoxetine, lisdexamfetamine, dexamfetamine and guanfacine are recommended, within their licensed indications, as options for the management of ADHD in children. The decision regarding which product to use should be based on the following[1]:

- The presence of co-morbid conditions (for example, tics disorders, Tourette's syndrome, epilepsy)
- The different adverse effects of the drugs
- Specific issues regarding compliance identified for the individual child, for example problems created by the need to administer a mid-day treatment dose at school
- The potential for drug diversion (where the medication is forwarded on to others for non-prescription uses) and/or misuse
- The preferences of the child and/or his or her parent or guardian.

If there is a choice of one or more appropriate drugs, the product with the lowest cost (taking into account the cost per dose and number of daily doses) should be prescribed[1].

Diagnosis

Should be made by a child / adolescent psychiatrist or paediatrician with a special interest in ADHD, involving the child, its carers and school. A multidisciplinary assessment including educational and clinical psychologists, social workers etc may be necessary in individual cases. **Almost 50% of children who have ADHD may have other co-morbid conditions which include autistic spectrum/Asperger's syndrome, dyslexia, dyspraxia and oppositional-defiant difficulties. Recognising these conditions is important to ensure comprehensive planning is made.**

Technology

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Guanfacine is a selective alpha$_{2A}$-adrenergic receptor agonist. It should only be initiated following assessment and diagnosis by a specialist with expertise in ADHD, as part of a comprehensive treatment plan.

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Indication
Intuniv is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

Intuniv must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.

Dosage and Administration
The starting dose is 1mg once a day. This may be increased, depending on the patient's response and tolerability, by increments of 1mg on a weekly basis up to the recommended maintenance dose range of 0.05-0.12 mg/kg/day. Patients/carers should be advised not to stop treatment abruptly. Re-titration of dose may be required if two or more consecutive doses are missed.

Maximum recommended doses *after* appropriate dose titration:

Age:	**6-12 years old**	**13-17 years old**			
Weight:	25kg and above	34 – 41.4kg	41.5 – 49.4kg	49.5 – 58.4kg	58.5kg and above
Maximum Dose:	4mg	4mg	5mg	6mg	7mg

Tablets should not be crushed, chewed or broken before swallowing.

Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	**Responsible clinician**
Pre-treatment Prior to prescribing, it is necessary to conduct a baseline evaluation to identify patients at increased risk of somnolence and sedation, hypotension and bradycardia, QT-prolongation arrhythmia and weight increase/risk of obesity. This evaluation should address a patient's cardiovascular status including blood pressure and heart rate, documenting comprehensive history of concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart Baseline • Height, weight (including centiles), BMI, BP and pulse rate • ECG in case of family history of arrhythmia or sudden death.	*Specialist*
Dose titration: • Monitor weekly (until dose stable) for signs and symptoms of somnolence and sedation, hypotension and bradycardia, including monitoring of BP and pulse.	*Specialist*

First year of treatment:
• The patient will be reviewed 3 monthly in line with the product license, for the first year of treatment:
  ○ Height and weight (including centiles)
  ○ Blood pressure and pulse
  ○ monitor for signs and symptoms of somnolence and sedation, hypotension and bradycardia, including monitoring of BP and pulse.
	Specialist

Maintenance (after first year of treatment):
• The patient will be reviewed 6 monthly in line with the product license, monitoring:
  ○ Height and weight (including centiles)
  ○ Blood pressure and pulse
  ○ for signs and symptoms of somnolence and sedation, hypotension and bradycardia, including monitoring of BP and pulse.
	Usually Specialist Clinician

If dose change when on maintenance: • Monitor weekly (until dose stable) for signs and symptoms of somnolence and sedation, hypotension and bradycardia, including monitoring of BP and pulse.	Specialist

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Support and Advice for Primary Care

Name	Speciality	Telephone No.	Email address
Hospital Pharmacy	XXXXX		XXXXX
Out of Hours			

Annex A: PCN agreed core roles and responsibilities for the shared care of medicines

Patients
To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests. • You must make sure that you understand about your treatment • If you do not understand ask for more information from the person prescribing the medicine • Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication • You must raise concerns about your treatment with the person prescribing the medicine • Talk to the specialist and come to an agreement of how the treatment should be provided to you • Give permission to have aspects of your care communicated to healthcare providers • Ensure that you are provided with contact details for support and help if required; both in and out of hours. • You must attend all appointments • You must keep a written list of all of the medicines you are taking • You must keep lists of any additional vitamins, minerals, or other dietary supplements • You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital • You must carry these lists on you in case of an emergency • You must not let anyone else take your medication. It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit, www.gov.uk/government/publications/the-nhs-constitution-for-england
Relatives and Carers
As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care. • To support the patient in fulfilling their roles and responsibilities as outlined above.
Consultant/ Specialist
Good Prescribing Guidelines • Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC). • Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. • Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care. • Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG • Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.

- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary.

For the attention of the Practice Manager

FAX – Confirm you have the correct Safe Haven Fax Number before sending
E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To:	[Recipient Name]	Fax:	[fax number]
From:	[Your Name]	Date:	[Click to select date]
Re:	[Subject]	Pages:	[number of pages]
cc:	[Name]		

[Notes]

Name of medicine	Guanfacine
Indication	Guanfacine is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

Person removing form from fax machine	
Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	Yes/ No
If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	Specialist safe haven fax number
Blood pressure:		Date:	
Pulse		Date:	

Height		Date:	
Weight		Date:	
BMI		Date:	
Discharge letter written and sent:			
Please refer to the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary for relevant shared care documents			

Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient