NHS Sunderland Clinical Commissioning Group

City Hospitals Sunderland NHS
NHS Foundation Trust

SHARED CARE GUIDELINE

Guanfacine▼ for the treatment of ADHD in Children and Young People

Implementation Date: November 2016
Review Date: November 2018
This guidance has been prepared and approved for use within Sunderland in consultation within the CCG, Secondary Care Trusts and Local Medical Committees.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting

Approved by:

Committee	Date
Sunderland Joint Formulary	**November 2016**
Sunderland CCG Medicines Guidelines Group	**December 2016**

Licensed (amber) Indications: as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children over 6 years and young people up to 18 years.

<table>
<tr><th colspan="7">SHARED CARE GUIDELINE</th></tr>
<tr><td>Non-proprietary name</td><td colspan="6">Guanfacine ▼</td></tr>
<tr><td>Dosage form and strength</td><td colspan="2">Guanfacine 1,2,3 and 4mg Prolonged Release tablets (Intuniv®)</td><td>BNF class</td><td colspan="3">4.4</td></tr>
<tr><td>Indication</td><td colspan="6">Third line treatment of ADHD unless first line stimulants and atomoxetine are contraindicated.</td></tr>
<tr><td>Eligibility criteria for shared care</td><td colspan="6">Children and adolescents 6-17 years old, for whom stimulants are not suitable, not tolerated or have been shown to be ineffective under specialist supervision.</td></tr>
<tr><td>Excluded patients</td><td colspan="6">Children under 6 years of age, adults</td></tr>
<tr><td>Dosage and Administration</td><td colspan="6">See BNF, BNFC and NICE ADHD CG 72 Clinical Guideline 2008
Careful dose titration and monitoring required as both clinical improvement and adverse effects are dose and exposure related. Advise patients that somnolence and sedation can occur, particularly early in treatment or with dose increases. If somnolence and sedation are persistent, consider dose reduction or discontinuation.
<table>
<tr><td></td><td>6–12 years (>25 kg)</td><td>13–17 years (34–41.4 kg)</td><td>13–17 years (41.5–49.4 kg)</td><td>13–17 years (49.5–58.4 kg)</td><td>13–17 years (>58.5 kg)</td></tr>
<tr><td>Initiation</td><td colspan="5">1 mg once daily; adjusted in steps of 1 mg every week if necessary and if tolerated</td></tr>
<tr><td>Maintenance</td><td colspan="5">0.05–0.12 mg/kg once daily</td></tr>
<tr><td>Maximum dose</td><td>4 mg</td><td>4 mg</td><td>5 mg</td><td>6 mg</td><td>7 mg</td></tr>
<tr><td></td><td colspan="5">For optimal weight-adjusted dose titrations, consult product</td></tr>
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	literature.http://www.medicines.org.uk/emc/medicine/31294

Take once daily either morning or evening.
Do not crush, chew or break tablets before swallowing -recommended only for children able to swallow whole tablets
Take with or without food.
Do not take with high fat meals, do not administer with grapefruit juice.
If used intended for extended periods (over 12 months) re-evaluate usefulness every 3 months for the first year and then at least yearly based on clinical judgement. Consider trial periods off medication to assess functioning e.g. during school holidays.

Specialist Responsibilities

Diagnose the condition and assess suitability for treatment with guanfacine
Initiate and titrate to a therapeutic dose then before arranging shared care. The specialist should prescribe the first 3 months treatment as a minimum.

In some circumstances it may be more appropriate for the GP to prescribe guanfacine on the advice of a specialist during the initiation and titration phase. This must be done on a case by case basis by prior arrangement and all the necessary information for the GP to do this safely must be provided by the specialist.

Pre-treatment

Evaluate cardiovascular status:	Asses for increased risk of:
• Record concomitant medicines • Review past/present medical/psychiatric conditions • Review family history of sudden cardiac/unexplained death • Assess for QTc prolongation/arrhythmia	• Somnolence + sedation • Hypotension + bradycardia(BP + heart rate) • Obesity

Usually this information will be available to the specialist, if not; the specialist will work in collaboration with the GP. Only prescribe or ask the GP to prescribe if this information is available.
Request an ECG if there is a past medical or family history of serious cardiac disease or abnormal findings on cardiac examination
Routine blood tests are not recommended unless there is a clinically indicated.

Ongoing Monitoring

Monitoring	Assess	Monitor	
	somnolence + sedation	hypotension + bradycardia (BP + heart rate)	weight + height (growth chart)
Weekly - during Titration	✓	✓	X
3 monthly during first year of treatment	✓	✓	✓
6 monthly - Ongoing treatment	✓	✓	✓
	More frequent monitoring following any dose adjustments		

Provide patient/carer with relevant information on use, side effects and need for monitoring of medication - document this is in the medical notes.

Contact the GP to seek formal agreement for the shared care.
Both the Specialist and the GP must agree to the shared care arrangement.
Provide the GP with relevant information including:
•Treatment to be undertaken by GP (dose, any dosage titrations etc.)
•System of monitoring and recording progress and adverse effects
Assess response to treatment, continuing need and any adverse effects regularly by reviewing as per specialist schedule. Ensure changes to treatment are communicated in writing to the GP as soon as possible (Sending information via fax is not acceptable in Northumberland)

Supervise treatment, downward titration, discontinuation or onward referral to adult services if appropriate.
Advise discontinuation if no improvement after a reasonable trial

	Advise patients/carers not to discontinue guanfacine without consulting their prescriber. BP and heart rate may increase following discontinuation and should be monitored during downward titration and after discontinuation. Taper dose during withdrawal to minimise potential withdrawal effects – reduce by no more than 1mg every 3 to 7 days. **Missed dose** - If a dose is missed - resume dosing the next day. If two or more consecutive doses are missed, re-titrate according to the patient's tolerability Liaise with the GP if any other additional tests/monitoring required. Monitor and liaise with the GP regarding any adverse effects Report all serious adverse drug reactions to the MHRA. Notify the GP of failed attendance
GP Responsibilities	• Prescribe Guanfacine following recommendations of the specialist. Provide the specialist with relevant medical history and background information. • To contact the specialist if concerned about any aspects of the patient's treatment. • Report significant deviations from the prescribing pattern to the specialist • Monitor and record the therapy in accordance with written directions of specialist • Report any adverse events to the specialist, and the usual bodies. (E.g. MHRA).
Adverse Effects, Precautions and Contraindications	**Adverse reactions** Guanfacine is a newly licensed drug and is classed as a 'black triangle drug ▼' It therefore requires additional monitoring. All suspected reactions (including those considered not to be serious) are reported through the Yellow Card Scheme. Very common - somnolence (40.6%), headache (27.4%), fatigue (18.1%), abdominal pain 12.0%), and sedation (10.2%). Serious adverse reactions commonly reported include hypotension (3.2%), weight increase (2.9%), bradycardia (1.5%) and syncope (uncommon) (0.7%). Somnolence and sedation occurred predominantly at the start of treatment and may typically last for 2-3 weeks and longer in some cases. **Cautions** **Hypotension, heart block, bradycardia,** or cardiovascular disease, syncope or a predisposition to syncope (such as hypotension, orthostatic hypotension, bradycardia, or dehydration). **Concomitant antihypertensives** or medicines that can reduce BPor heart rate or increase the risk of syncope. Patients should be advised to drink plenty of fluid. **QTC interval** caution patients with a known history of QT prolongation, risk factors for torsade de pointes (e.g., heart block, bradycardia, hypokalaemia) or patients who are taking medicinal products known to prolong the QT interval. These patients should receive further cardiac evaluation based on clinical judgement **Sedation and somnolence - Concomitant use with centrally active depressants** (such as alcohol, sedatives, phenothiazines, barbiturates, or benzodiazepines) consider the potential for additive sedative effects. **Alcohol** - Patients should not drink alcohol whilst taking guanfacine. **Driving** Patients are advised against operating heavy equipment, driving or cycling until they know how they respond to treatment **Suicidal ideation – monitor for suicidal ideation or beahviour** **Effects on height, weight and Body Mass index (BMI)** Children and adolescents may show an increase in their BMI. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients
Common Drug Interactions	**QT Prolonging medicinal products** - advised to avoid concomitant use with QT prolonging medicines **Valproic acid -** Co-administration of guanfacine and valproic acid can result in increased concentrations of valproic acid. **CNS depressant medicinal products** Caution –risk of additive effects with CNS depressant medicinal products (e.g., alcohol, sedatives, hypnotics, benzodiazepines, barbiturates, and antipsychotics) **Food interactions** – absorption of guanfacine increases when administered with high fat meals
Communication/Contact Details	For any queries relating to this patient's treatment with Guanfacine please contact the specialist named below. **ADHD Specialists MON – FRI, 09:00 – 17:00** Newcastle and Gateshead CYPS:- 0191 246 6913 (Benton House) North Tyneside CAMHS:- 0191 2196725 (Albion Road Clinic) Sunderland and South Tyneside CYPS Monkwearmouth Hospital 0191 5665500

	Northumberland CYPS:- 01670 394 256 (Villa 9, Northgate) 01670 798265

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

Private and Confidential

Shared Care Request/Confirmation - Guanfacine

- Consultant to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 day

		Patient details (use hospital label if preferred)	
Specialist Prescriber	……	**Name**	……
Department	……	**Address**	……
	……		……
Hospital			
	……		
Telephone	……	**Postcode**	**M/F** ……...
		NHS or Hosp. Reg. No. ……	**DoB** ……...

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement

Drug Name - Guanfacine **Dose ……** **Frequency……**
Indication – ADHD
Other info (if appropriate) **……**

Signed
(Specialist Prescriber)…….. Name (print)……Date…….

To be completed by GP

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ❑

or

I ACCEPT the proposed shared care arrangement with the caveats below ❑

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ❑

My caveats / reason(s) for not accepting include:

……..

……..

Signed …… **Name (print)** ..... **Date** ……
(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP