Name: Attach Banda Label here
Address:

Date of Birth:
NHS number:

Coventry & Warwickshire Area Prescribing Committee

Drug Name: Clonidine

SCA: *for the prescribing of clonidine in children, for the unlicensed indications of, treatment of attention deficit hyperactivity disorder (ADHD), and tics*

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of clonidine in children as part of the treatment of ADHD, insomnia or tics can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.
Sharing of care assumes communication between the specialist, GP and patient/parent/guardian. The intention to share care is usually explained to the patient by the specialist initiating treatment. It is important that the patient/parent/guardian is consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Discuss the benefits and side effects of treatment with the patient & parent/guardian; including gaining informed consent for unlicensed use of clonidine and the importance of avoiding abrupt cessation of treatment.
2. Initiate and stabilise treatment with clonidine.
3. Ask the GP whether he or she is willing to participate in shared care by faxing the template letter.
4. Continue to prescribe until GP has agreed to take over prescribing.
5. Communicate to the GP re established regimen, follow up arrangements and when to refer back.
6. Communicate promptly with the GP when treatment is changed.
7. Monitor treatment as stated overleaf.
8. If appropriate, to obtain school and parental/carer's reports to assist with the assessment of the patient's progress.
9. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition.
10. Notify GP of review date (at least 6 monthly), and give advice on stopping treatment.
11. Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard, and to the GP and appropriate Medicines Management team (via the Clinical Governance Pharmacist - see Medicines Policy and Medicines Manual Guidance (MMG20).
12. Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable by faxing back signed form. If declining the request, please indicate the reason for declining.
2. Prescribe the clonidine at the dose recommended.
3. Adjust the dose as advised by the specialist.
4. Review patient annually between consultant appointments.
5. Monitor treatment as stated overleaf.
6. Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
7. Refer back to specialist if the patient's condition deteriorates, or if there are concerns over patient compliance.
8. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
9. Report adverse events to the MHRA on a Yellow Card (www.mhra.gov.uk/yellowcard), the specialist, and the appropriate Medicines Management team.

Patient/parent/guardian's role
1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with clonidine.
3. Inform specialist or GP of any other medication being taken, including over-the-counter products.
4. Report any adverse effects of warning symptoms to the specialist or GP whilst taking clonidine.
5. The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card form, available. at www.mhra.gov.uk/yellowcard, pharmacies, GP surgeries or from the Yellow Card hotline (0808 100 3352 business hours)

BACK-UP ADVICE AND SUPPORT: See patient letters

SUPPORTING INFORMATION (see SPC for complete details/specific guidance http://emc.medicines.org.uk)

Licensed indications: Clonidine is not licensed in the UK for use for the indications below in any age group. It should only be used where licensed treatments (where available) have been trialled and failed.
An extended release formulation is licensed in the USA in 6 to 17 year olds as mono or adjunctive therapy with stimulants (Kapvay®).

ADHD: NICE[1] recommends that in children and young people whose ADHD is unresponsive to methylphenidate, atomoxetine and dexamfetamine, further treatment may include medication unlicensed for ADHD, but this should only be considered in the context of tertiary services.

Tics: some evidence of efficacy in the literature. However, these tend to involve small numbers/use for a short period of time.

Dosage and administration:
ADHD[3]: 25microgram twice daily gradually increased as required by 25 microgram increments to 75micrograms twice daily if necessary. Maximum dose 150micrograms twice daily depending on response and tolerability.
Tics[3]: 25 micrograms to 50micrograms per day, increased in increments of 25microrgams to 50micrograms per day every 5 to 7 days. Therapeutic doses are in the order of 3-5 mcg/kg (4). The dose should be built up gradually depending on response and tolerability. Max doses of 300mcg/day are reported in literature for Tourette's (5)

Monitoring:
Consultant: Pulse and blood pressure; at baseline, after each dose adjustment and 6 monthly thereafter. NICE recommends that a cardiovascular examination and ECG should be carried out before starting treatment with clonidine in children or young people with ADHD. Monitor for any signs of adverse reactions, including over-sedation. *As a general assessment before starting any drug treatment for ADHD, NICE also recommends a full mental health and social assessment, full history and physical examination including an assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms, height and weight, family history of cardiac disease.*
GP: Annual pulse and blood pressure (in between consultant visits). Monitor for any adverse reactions/interactions, including over-sedation.

Cautions – Should not be stopped abruptly (reduce dose gradually over a two week period to prevent rebound hypertension and possible marked worsening of tics); mild to moderate bradyarrhythmia; constipation; polyneuropathy; Raynaud's syndrome or other occlusive peripheral vascular disease; history of depression.

Contra-indications: severe bradyarrhythmia secondary to second- or third-degree AV block or sick sinus syndrome

Side effects[5]:
constipation, nausea, dry mouth, vomiting, salivary gland pain, postural hypotension, dizziness, sleep disturbances, headache, malaise, drowsiness, depression, sexual dysfunction; *less commonly* bradycardia, Raynaud's syndrome, delusion, hallucination, paraesthesia, pruritus, rash, urticaria; *rarely* colonic pseudo-obstruction, AV block, gynaecomastia, decreased lacrimation, nasal dryness, alopecia; *also reported* hepatitis, fluid retention, bradyarrhythmia, confusion, impaired visual accommodation.

Drug interactions (see also above under cautions)[5]:

Potentially serious interactions: **serious adverse events reported with concomitant use of clonidine and methylphenidate (causality not established); hypotensive effect of clonidine antagonised by tricyclic antidepressants (also increased risk of hypertension on clonidine withdrawal); increased risk of withdrawal hypertension when clonidine given with beta-blockers (withdraw beta-blockers several days before slowly withdrawing clonidine).**
Less serious interactions: Refer to latest edition of BNF

Cost:
Cost of one years treatment (based on Drug tariff prices for 25mcg tablets, October 2015): 75mcg twice daily - £82.44

References:

1. NICE CG72, Attention deficit hyperactivity disorder: diagnosis and management of ADHD in children young people and adults
2. ESUOM8: Attention deficit hyperactivity disorder in children and young people: clonidine, April 2013
3. Developing Mental Health Services for Children and Adolescents with Learning Disabilities Edited by Dr Sarah Bernard & Professor Jeremy Turk A Toolkit for Clinicians RCP Publications 2009
4. Maudsley Prescribing Guidelines 11th edition.
5. Jimenez-Juiminez FJ, Garcia-Ruiz PJ. Pharmacological options for the treatment of Tourette's Disorder. Drugs 2001;61(15): 2207-2220
6. Bazire, Psychotropic Drug Directory 2014.
7. BNFc 2015/16