NHS Dorset

SHARED CARE PROTOCOL - GUANFACINE FOR PATIENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

As well this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-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.
- For adults prior to prescribing guanfacine, obtain advice from a tertiary service on the suitability for the patient.
- Provide a review:
  - to confirm the patient meets the criteria for ADHD and needs treatment
  - of the patient's mental health and social circumstances, including:
    - presence of coexisting mental health and neurodevelopmental conditions
    - current educational or employment circumstances
    - risk assessment for substance misuse and drug diversion
    - care needs
- 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 section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside of their license
- 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 section 4) and interactions (see section 7).
- Conduct required scheduled reviews, baseline investigations and monitoring (see section 8) and communicate the results to primary care.

- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient and/or their carer. Explain the process and the potential timescales for this.
- Once treatment is optimised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter, detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- 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 should be managed by the specialist.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Provide advice to the patient and/or primary care prescriber if a patient 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

Primary care responsibilities

- To refer the patient for specialist advice using the ADHD referral pathway if not already known by a Dorset ADHD specialist team. Initial referral should include:
  - For Adults:
    - ❖ Adult Self-Report Scale Checklist (ASRS) to be completed by the patient prior to specialist assessment
    - ❖ Physical assessment (In accordance with the recommendations from NICE NG87) including:
      - Medical history
      - Medication history
      - Height and weight (measured and recorded against the normal range for age, height, and sex)

        - Baseline pulse and blood pressure (measured with an appropriately sized cuff and compared with the normal range for age)
    - ❖ Cardiovascular assessment- Consider whether further physical testing/monitoring (such as blood tests, ECG, etc) or a cardiologist opinion is required.
    - ❖ Drugs and alcohol screen
    - ❖ Psychiatric history
    - ❖ Previous treatment
  - For Children and Adolescents: patients should be referred to either CAMHS or paediatric services.
- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's 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 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.
- Refer the patient back to the specialist if the patient becomes or plans to become pregnant or if the clinical condition worsens or there is non-adherence to monitoring requirements.
- Consider referring to the specialist if withdrawal of treatment might be indicated. This could be because the patient is well controlled and has been free of ADHD symptoms for at least one year whilst taking medication; ADHD symptoms are not evident on days when medication is forgotten or missed or there has been no need to increase the dose of medication in child or adolescent patients despite growth and weight gain over the preceding one to two years
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by 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, so it is important to gradually reduce the dose under medical supervision.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping their contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend for the blood monitoring or review appointments
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- 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.
- Tell anyone who prescribes them a medicine that they are taking guanfacine.
- 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

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This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

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 NG87 Recommendations | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE. 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 by a Paediatric Service and approaching their 18th birthday, it is expected that CAMHS or the Paediatric Service will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children to adults' services for young people using health or social care services should be followed.

The NICE guidance for ADHD makes a recommendation for treatment in children 5 years and over. Medicines for treating ADHD do not have a UK marketing authorisation for use in children under the age of 6 years so the use as per the NICE recommendation is off label. For children under 5 years old, an ADHD-focused group parent-training programme should be offered to parents or carers of children under 5 years with ADHD as first-line treatment. If this fails, the advice of a specialist ADHD service with expertise in managing ADHD in young children (ideally a tertiary service) should be sought

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

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- Attention-deficit hyperactivity disorder (ADHD)

Off-label indications – not licensed in adults. See section 1 for circumstances where NICE recommend use in adults.

3. Locally agreed off-label use

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No additional use identified- see above

4. Contraindications and cautions

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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 torsade 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

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- 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.
- Additional caution (smaller initial dosing) should be considered where there are other neurodevelopmental comorbidities
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- 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.
- 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, individualised according to the patient's response and tolerability.

Dose Titration schedule for children 6-12 years

Weight Group	Week 1	Week 2	Week 3	Week 4
25 kg and up Max Dose= 4 mg	1 mg	2 mg	3 mg	4 mg

Dose Titration schedule for adolescents aged 13-17years

Weight Group[a]	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
34-41.4 kg Max Dose= 4 mg	1 mg	2 mg	3 mg	4 mg			
41.5-49.4 kg Max Dose= 5 mg	1 mg	2 mg	3 mg	4 mg	5 mg		
49.5-58.4 kg Max Dose= 6 mg	1 mg	2 mg	3 mg	4 mg	5 mg	6 mg	
58.5 kg and above Max Dose= 7 mg	1 mg	2 mg	3 mg	4 mg	5 mg	6 mg	7 mg[b]

[a] Adolescent subjects must weigh at least 34 kg.

[b] Adolescents weighing 58.5 kg and above may be titrated to a 7 mg/day dose after the subject has completed a minimum of 1 week of therapy on a 6 mg/day dose and the physician has performed a thorough review of the subject's tolerability and efficacy.

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 (see table above). Adolescents weighing 58.5 kg and above may be titrated to a 7 mg/day dose after they have completed a minimum of 1 week of therapy on a 6 mg/day dose and the specialist has performed a thorough review of the tolerability and efficacy.

Adults who have shown clear benefit from guanfacine in childhood or adolescence may continue treatment into adulthood at the same daily dose (off label use).

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Hepatic or renal insufficiency:

Dose reduction may be required in patients with hepatic impairment, severe renal impairment (CrCl 29-15 mL/min), end stage renal disease (CrCl <15 mL/min) or in patients requiring dialysis.

Patients taking CYP3A inhibitors or inducers:

CYP3A4/5 inhibitors have been shown to have a significant effect on the pharmacokinetics of guanfacine when co-administered. Dose adjustment is recommended with concomitant use of moderate/strong CYP3A4/5 inhibitors (e.g., ketoconazole, grapefruit juice), or strong CYP3A4 inducers (e.g., carbamazepine). In case of concomitant use of strong and moderate CYP3A inhibitors, a 50% reduction of the guanfacine dose is recommended. If guanfacine is combined with strong enzyme inducers, a re-titration to increase the dose up to a maximum daily dose of 7 mg may be considered if needed. If the inducing treatment is ended, re-titration to reduce the guanfacine dose is recommended during the following weeks

6. Pharmaceutical aspects

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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 not be crushed, chewed, or broken before swallowing because this increases the rate of guanfacine release. Treatment is recommended only for patients who can swallow the tablet whole without problems. 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 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 with expertise in ADHD who conducts the annual review.

7. Significant medicine interactions

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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

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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, considering 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
    - 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:

- Weekly monitoring for signs and symptoms of somnolence, sedation, 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 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 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 in section 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
• Blood pressure and heart rate/pulse • Somnolence and sedation • Weight and appetite • Signs or symptoms of cardiovascular adverse effects, e.g. syncope, bradycardia • Suicidal ideation or behaviour	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
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

(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

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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 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	Stop treatment and discuss with specialist. Consider referral for urgent psychiatric assessment if suicide related behaviour, mania or psychosis are present. Consider discontinuing guanfacine.

11. Advice to patients and carers

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The specialist will counsel the patient regarding 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 and/or carer 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. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- Royal College of Psychiatrists ADHD and hyperkinetic disorder for parents
- NHS – attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

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

Guanfacine for ADHD – Medicines for Children

12. Pregnancy, paternal exposure, and breast feeding

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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, considering 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.

Paternal exposure:

- No evidence regarding adverse outcomes following paternal exposure in humans was identified.

13. Specialist contact information

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Please approach the patient's named secondary care clinician via the usual method of communication, mainly currently email or letter. Phone numbers and email available on clinic letters

Paediatrics:

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

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- eBNF. Guanfacine | Drugs | BNF | NICE
- eBNF (children's) Guanfacine | Drugs | BNFC | NICE
- Guanfacine hydrochloride 1 mg prolonged-release tablets (Intuniv®). Intuniv 1 mg prolonged-release tablets - Summary of Product Characteristics (SmPC) - (emc)
- 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
- NICE NG43: Transition from children 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 01/09/21

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – 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/.

17. Local arrangements for referral

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

Via the usual methods

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on, *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you agree, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which applies
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	

2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	

5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed**.** For this reason, I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Integrated Medicines Optimisation Committee

Yours sincerely

Primary Care Prescriber signature: _____

Date: _____

Primary Care Prescriber address/practice stamp