NHS Dorset

# Shared Care Protocol - Amiodarone for patients within adult services

**As well these protocols, 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 that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- 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 patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate, assess response and optimise treatment as outlined in section 5. Prescribe the maintenance treatment until optimised. This will be at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. 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, 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 required reviews and monitoring in section 8 and communicate the results to primary care. 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.
- 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.
- Review treatment and reassume prescribing responsibilities 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

- 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 made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into account potential drug interactions in section 7.
- Adjust the dose of amiodarone prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop amiodarone and make an urgent referral to the specialist if hyperthyroidism, thyrotoxicosis, new or worsening arrhythmia or heart block, ophthalmological effects, hepatotoxicity, pulmonary toxicity, or bullous skin reactions are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

## Patient and/or carer responsibilities

- Take amiodarone as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for 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.

Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of amiodarone with their pharmacist before purchasing any OTC medicines.

Avoid grapefruit juice while taking amiodarone and for several months after discontinuation.

- Moderate their alcohol intake to no more than 14 units per week to reduce the risk of hepatotoxicity.
- 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 protocol 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.

Amiodarone is used in the treatment of arrhythmias, as detailed in section 2. It has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. Amiodarone has potentially serious adverse effects and its use requires regular monitoring.

Due to the significant safety concerns, NHS England (NHSE) and NHS Clinical Commissioners' (NHSCC) guidance advises that prescribers should not initiate amiodarone in primary care for any new patients. In exceptional circumstances, if there is a clinical need for amiodarone to be prescribed, this must be initiated by a specialist and only continued under a shared care arrangement in line with NICE clinical guidance Atrial fibrillation: NG 196. NICE defines the place in therapy of amiodarone in NG196 and has made a "Do not do" recommendation: "**Do not offer amiodarone for long-term rate control**". Amiodarone may also be suitable in patients prior and post cardioversion or in specific patients who have heart failure or left ventricular impairment.

Where there is an existing cohort of patients taking amiodarone who are not currently under shared care, it is recommended that these patients be reviewed to ensure that prescribing remains safe and appropriate, and a shared care arrangement is introduced.

This document applies to adults aged 18 and over.

## 2. Indications

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Licensed indications:

- Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.
- Atrial flutter fibrillation / atrial fibrillation when other drugs cannot be used.
- All types of tachyarrhythmias of paroxysmal nature including supraventricular, nodal, and ventricular tachycardias and ventricular fibrillation when other drugs cannot be used.

## 3. Locally agreed off-label use

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National scoping did not identify any additional appropriate off-label indications

## 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:**

- Sinus bradycardia and sino-atrial heart block/severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease (unless pacemaker fitted)
- History of thyroid dysfunction. The use of amiodarone may be considered in patients who are euthyroid, after case-by-case assessment of the risks and benefits and with appropriate monitoring.
- Known hypersensitivity to iodine or amiodarone, or any of the excipients (including patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption)
- Concurrent use with medicines that may prolong the QT interval or increase the risk of Torsade de Pointes
- Pregnancy - except in exceptional circumstances (see section 12)
- Breastfeeding

**Cautions:**

- Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin, and peripheral nervous system; it is subject to a number of cautions. Because these reactions may be delayed, patients on long-term treatment should be carefully supervised. As undesirable effects are usually dose-related, the minimum effective maintenance dose should be given.

## 5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after four weeks when the patient's dose has been optimised and with satisfactory investigation results.
- 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:**

200mg three times per day for one week, then reduce to 200mg twice per day for one week.

Amiodarone is initiated with a loading dose in order to achieve adequate tissue levels rapidly. Rarely, the specialist team may use an alternative loading regimen.

**The loading period must be prescribed by the initiating specialist.**

**Maintenance dose (following initial stabilisation):**

200mg per day, or less if appropriate. The minimum dose required to control the arrhythmia should be used.

Rarely, a higher maintenance dose may be required. The maintenance dose should be reviewed regularly, particularly if it exceeds 200mg per day.

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

**Conditions requiring dose adjustment:**

Although there is no evidence that dose requirements for elderly patients are lower, they may be more susceptible to bradycardia and conduction defects if too high a dose is prescribed. The minimum effective dose should be used. Particular attention should be paid to monitoring thyroid function.

## 6. Pharmaceutical aspects

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|---|---|
| Route of administration: | Oral |
| Formulation: | Tablets;  100mg and 200mg |

| | |
|---|---|
| Administration details: | For oral administration.<br>Maintenance dose can be given once daily, however doses >200 mg daily (including loading period) may be given as split doses to minimise nausea.<br>If necessary, tablets may be crushed and dispersed in water but have a bitter taste (unlicensed). Different brands of amiodarone may disperse in water at notably different rates. The solution for injection is irritant and should not be given orally. |
| Other important information: | The half-life of amiodarone is very long, with an average of 50 days (range 20-100 days). Side effects slowly disappear as tissue levels fall. Following drug withdrawal, residual tissue bound amiodarone may protect the patient for up to a month. However, the likelihood of recurrence of arrhythmia during this period should be considered.<br>Grapefruit juice should be avoided during treatment with oral amiodarone and for several months after discontinuation (see section 7). |

## 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.

**Amiodarone is associated with a large number of interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring (see section 4).**

Amiodarone is an enzyme inhibitor and can increase exposure to a number of medicines including:

- P-glycoprotein (PgP) substrates (e.g., digoxin, dabigatran)
- CYP2C9 substrates (e.g., warfarin, phenytoin)
- CYP3A4 substrates (e.g., ciclosporin, statins, fentanyl, sildenafil, colchicine)
- CYP2D6 substrates (e.g., flecainide)

Amiodarone interacts with other medicines that:

- induce Torsade de Points or prolong QT (e.g., other anti-arrhythmics, antipsychotics, antidepressants, clarithromycin, erythromycin)
- lower heart rate (e.g., beta-blockers, calcium channel blockers)
- induce hypokalemia (e.g. diuretics, stimulant laxatives)
- induce hypomagnesaemia (e.g., diuretics, systemic corticosteroids)

Other interactions include:

- CYP3A4 and CYP2C8 inhibitors: may increase exposure to amiodarone (e.g., cimetidine, letermovir, ritonavir, darunavir, grapefruit juice)
- Sofosbuvir with daclatasvir; sofosbuvir and ledipasvir; simeprevir with sofosbuvir: risk of severe bradycardia and heart block (mechanism unknown) see MHRA advice

- **Due to the long half-life of amiodarone, there is potential for drug interactions to occur for several weeks/months after treatment has been discontinued.** See SPC for information on managing interactions.

## 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:**

- Thyroid function tests (free T4, free T3 and TSH)
- Liver function tests (LFTs, particularly transaminases)
- Urea and electrolytes (U&Es, including magnesium and potassium)
- Electrocardiogram (ECG)
- Chest X-ray
- For patients taking warfarin: monitor international normalised ratio (INR) at baseline and during dose stabilisation period
- For patients taking digoxin: clinical monitoring is recommended, and the digoxin dose should be halved. Digoxin levels should be monitored appropriately.

**Initial monitoring:**

None specifically recommended by the manufacturer.

**Ongoing monitoring:**

- ECG (at least annually – see below regarding primary care availability)
- Chest X-ray and pulmonary function tests if respiratory symptoms or toxicity suspected

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 and advice | Frequency |
|---|---|
| • Thyroid function tests (free T4, free T3 and TSH)<br>• LFTs (particularly transaminases)<br>• U&Es (including magnesium and potassium) | Perform all tests (TFTs, LFTs, U&Es) every 6 months during treatment, and 6 months after discontinuation. |
| • ECG (monitoring may be conducted in primary care where this service is available) | Annually |
| • Blood Monitoring | Not Required |
| **(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.** | |
| **The most serious toxicity with amiodarone is seen with long-term use and patients may therefore present first to primary care. Due to the long half-life of amiodarone there is potential for adverse effects to occur for several weeks/months after treatment has been discontinued.** | |
| Electrolyte deficiency: hypokalemia / hypomagnesaemia | Continue amiodarone. Correct deficiency as per local guidelines. Review other medicines that may be contributing to a deficiency |
| **Cardiovascular effects:**<br>Bradycardia:<br>• Heart rate 50 - 60bpm without symptoms | Continue amiodarone. Repeat monitoring. No action required unless symptoms develop, or heart rate decreases further. |
| • Heart rate ≤ 50bpm, or ≤ 60bpm with symptoms | Discuss with specialist team; dose reduction may be required |
| Worsening of arrhythmia, new arrhythmia, or heart block | **Stop amiodarone.** Urgent referral to initiating specialist. |
| **Thyroid dysfunction**:<br>Borderline results according to local reference range | Continue amiodarone. Repeat test after 6 weeks. |
| Hyperthyroidism / thyrotoxicity:<br>high T4, normal/high T3, low TSH | **Stop amiodarone.** Urgent referral to initiating specialist and endocrinologist. |

| | |
|---|---|
| Hypothyroidism:<br>low/normal T4, low/normal T3, high TSH | Continue amiodarone. Inform initiating specialist. Consider starting levothyroxine based on initiating specialist's advice. Monitor levothyroxine according to local pathways. |
| Subclinical hypothyroidism<br>normal T4, raised TSH; clinical features not overtly manifest | Contact specialist team for advice, which may include input from endocrinology services.<br>Anticipate the need for additional monitoring, investigations, and potentially thyroid hormone replacement based on specialist recommendations. |
| **Ophthalmological effects:**<br>Optic neuropathy/neuritis;<br>blurred or decreased vision | **Stop amiodarone.** Urgent referral to initiating specialist and ophthalmology. |

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| Corneal micro-deposits:<br>blueish halos when looking at bright lights, with no blurred or decreased vision | Continue amiodarone; reversible on discontinuation. The deposits are considered essentially benign and do not require discontinuation of amiodarone. |
| **GI disturbance**: nausea, anorexia, vomiting, taste disturbance | Continue amiodarone. May require dose reduction; discuss with specialist if persistent. |
| **Hepatotoxicity**:<br>abnormal LFTs +/- symptoms of hepatic injury (e.g., hepatomegaly, weakness, ascites, jaundice) | If serum transaminases elevated >3xULN but no symptoms of hepatic injury continue amiodarone and – repeat LFTs in 2 weeks. If still elevated may require dose reduction; discuss with specialist.<br>If serum transaminases >5xULN or any symptoms of hepatic injury- **stop amiodarone**. Urgent referral to initiating specialist and hepatologist. |
| **Neurological symptoms**:<br>Extrapyramidal tremor, ataxia, peripheral neuropathy, myopathy | Continue amiodarone. May require dose reduction; discuss with specialist. |
| **Pulmonary toxicity**: including pneumonitis or fibrosis<br>new/worsening cough, shortness of breath or deterioration in general health (e.g., fatigue, weight loss, fever) | **Stop amiodarone.** Urgent referral to initiating specialist and respiratory specialist. Admission may be required. |

| | |
|---|---|
| **Bullous skin reactions**:<br>life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) | **Stop amiodarone.** Urgent referral to dermatology, inform initiating specialist. |
| Photosensitivity | Continue amiodarone. Reinforce appropriate self-care e.g., sun avoidance and purchasing of a broad-spectrum sunscreen (at least SPF30). |
| Skin discoloration (blue/grey):<br>occurs in unprotected, light exposed skin | Continue amiodarone. May require dose reduction; discuss with specialist.<br>Reinforce self-care measures (as for photosensitivity above). Pigmentation slowly disappears following treatment discontinuation |

## 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 should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**

- **Breathlessness, non-productive cough, or deterioration in general health (e.g., fatigue, weight loss, fever)**
- **New or worsening visual disturbances**
- **Progressive skin rash +/- blisters or mucosal lesions**
- **Signs and symptoms of bradycardia or heart block,** e.g., dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating

**The patient should be advised:**

- To use appropriate self-care against the possibility of phototoxic reactions: e.g., sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad-spectrum sunscreen (at least SPF30). These measures are to be continued for the duration of therapy and for several months after discontinuation.
- If taking a statin and amiodarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine.

- Avoid grapefruit and grapefruit juice while taking amiodarone and for several months after discontinuation.
- Although there have been no case reports on enhanced hepatoxicity with alcohol, patients should be advised to moderate their alcohol intake to no more than 14 units per week while taking amiodarone.

Patient information:

**British Heart Foundation – anti-arrhythmics:**
https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/drug-cabinet/anti-arrhythmics

NHS England » Decision support tool: making a decision about further treatment for atrial fibrillation

MHRA Amiodarone Patient Alert Card: Document

## 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:**

New pregnancies must be referred back to the specialist. Due to the risk of neonatal goitre, amiodarone should only be prescribed in pregnancy if there is no alternative. Under these circumstances prescribing and monitoring will be the responsibility of the initiating specialist.

**Breastfeeding:**

Amiodarone is excreted into the breast milk in significant quantities; breast feeding is considered contraindicated due to the potential risk of iodine-associated adverse effects in the infant.

- Information for healthcare professionals: https://www.sps.nhs.uk/medicines/amiodarone/

## 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. Alternatively:

**Dorset County Hospital**

- A&G via ERS
- E-mail cardiology: cardiology.secretaries@dchft.nhs.uk
- Call 01305-254920

**University Hospitals Dorset**

- A&G
- Consultant connect
- Arrhythmia Nurse Specialist on bleep
- Heart Failure Specialist Nurse on bleep
- Cardiology registrar on call for emergencies if not appropriate for direct ED assessment.

## 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 accessed via BNF (British National Formulary) | NICE on 15/01/2021
- Amiodarone hydrochloride 100 milligram tablets (Cordarone X 100®). Zentiva. Date of revision of the text: 14/10/2020. Accessed via Home - electronic medicines compendium (emc) on 15/01/2021.
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- Specialist Pharmacy Service – Medicines Monitoring. Published July 2021. Accessed via Amiodarone monitoring – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. On 24/06/2022.
- LiverTox. Amiodarone. Last updated 01/03/2016. Accessed via https://www.ncbi.nlm.nih.gov/books/NBK548109/ 15/01/2021.
- NEWT Guidelines: amiodarone. Last updated February 2019. Accessed via NEWT Guidelines on 15/01/2021

## 15. 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/

## 16. 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]* for 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 with regard to this treatment:

| | **Specialist to complete** |
|---|---|
| *The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:* | |
| *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 are in agreement, 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 protocol.

## 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 apply** |
|---|---|---|
| **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**<br>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.<br>**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**<br>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.<br>**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**<br>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 in order to provide them with the medication that you have recommended.<br>***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**<br>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 in order to provide them with the medication that you have recommended.<br>***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**<br>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***.***<br>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 in order to provide them with the medication that you have recommended.<br>***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

Yours sincerely

**Primary Care Prescriber signature: _____**
**Date: _____**

**Primary Care Prescriber address/practice stamp**