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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Shared Care Protocol**  **(Medicine Name) for patients within (Service Name)**  **This SCP is approved and adopted by the following CCGs and Trusts:** | | | | | | | | | | |
| *If not applicable to Trust or CCG state not applicable* | County Durham | Tees Valley | | North Yorkshire | | County Durham & Darlington Foundation Trust | | North Tees & Hartlepool Foundation Trust | South Tees Foundation Trust | Tees, Esk & Wear Valleys Foundation Trust |
| **Date** | *Tbc* | *Tbc* | | *Tbc* | | *Tbc* | | *Tbc* | *Tbc* | *Tbc* |
|  |  |  | |  | |  | |  |  |  |
| **1. Background** | | | *Please include brief details of the medication and its place in therapy/ therapeutic background. Links to supportive information for further reading may also be provided here e.g. society websites etc.* | | | | | | | |
| **2. Indication(s) covered by this SCP**  **(Please state whether licensed or unlicensed)** | | | *Please detail which indication(s) this protocol will cover and use indicate if the indication falls outside of the product license (i.e. off-label use).* | | | | | | | |
| **3. Locally agreed off-label use** | | | To be agreed and completed locally (include supporting information) | | | | | | | |
| **4. Contraindications and cautions**  Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. | | | **Contraindications:**  *Please detail any key contraindications/ cautions as per BNF or product information.*  **Cautions:**  Please see [SPC](https://www.medicines.org.uk/emc/search?q=amiodarone) for comprehensive information. | | | | | | | |
| **5. Initiation and ongoing dose regime**  Note -  •Transfer of monitoring and prescribing to primary care is normally after the patient’s dose has been optimised and with satisfactory investigation results for at least 4 weeks  •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 bethe responsibility of the specialist. | | | *Please include details on initial dosing and any relevant titration, as well as usual maintenance dose. Please also detail any conditions that may require dose adjustment e.g. renal impairment and what the appropriate action is.*  **Initial stabilisation:**  **The loading period** **must be prescribed by the initiating specialist.**  **Maintenance dose (following initial stabilisation):**  **The initial maintenance dose must be prescribed by the initiating specialist.**  **Conditions requiring dose adjustment:** | | | | | | | |
| **6. Pharmaceutical aspects**  *Please include relevant details such as:*  *- if the SCP covers specific formulations or presentations of a medicine (e,g. particular brands, particular strengths, pre-filled syringes vs. vials etc.)*  *- whether the medicine should be taken with food or on an empty stomach*  *- any safety precautions (e,g. must be swallowed whole, cannot be crushed etc.)* | | | Route of administration: | |  | | | | | |
| Formulation: | |  | | | | | |
| Administration details: | |  | | | | | |
| Other important information: | |  | | | | | |
| **7. Significant medicine interactions**  For a comprehensive list consult the BNF or Summary of Product Characteristics. [SPC](http://www.medicines.org.uk/emc/)  *Please detail any key contraindications/ cautions as per BNF or product information.* | | | **The following list is not exhaustive; please see** [**SPC**](https://www.medicines.org.uk/emc/search?q=amiodarone) **for comprehensive information and recommended management.**  The following drugs must not be prescribed without consultation with the specialist:  The following drugs may be prescribed with caution: | | | | | | | |
| **8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist** | | | **Baseline investigations:** *Any investigations which must be carried out by the specialist team at the onset of therapy e.g. chest x-ray, DEXA scan. This is to ensure assessment of all patients is standardised and evidence-based.*  **Initial monitoring:** *Please populate with the standard initial and ongoing monitoring that will be undertaken by the specialist service for the medication.*   * 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 the GP.   **Ongoing monitoring:** *Please populate with the standard initial and ongoing monitoring that will be undertaken by the specialist service for the medication.* | | | | | | | |
| **9. Ongoing monitoring requirements to be undertaken by primary care**  See section 10 for further guidance on management of adverse effects/ responding to monitoring results. | | | Monitoring | | | | Frequency | | | |
| *Please outline what routine monitoring/ actions are required of primary care and appropriate frequency, e.g. FBC every 12 months* | | | |  | | | |
| **10. Adverse effects and management**  **Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) | | | Result | | | | Action for GP | | | |
| *Please complete with:*  *- details on how to respond to any abnormal monitoring results, including thresholds where relevant –e.g. “Creatinine increase >30% above baseline over 12 months and/or calculated GFR <60 mL/min – contact specialist as dose adjustment may be required” or “Any sudden increases in LFT parameters (e.g. double of baseline ALT) or jaundice – withhold therapy and discuss with specialist”*  *-details of adverse effects and how they should be managed- e.g. “persistent nausea- discuss with specialist, may require split dosing or dose reduction” or “rash or oral ulceration – withhold therapy and discuss with specialist”* | | | | | | | |
|  | | | |  | | | |
|  | | | |  | | | |
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|  | | | |  | | | |
|  | | | |  | | | |
| **11. Advice to patients and carers**  The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines. | | | *List any ‘red flag’ symptoms that patients should be advised to report. This may include exposure to chicken pox/ shingles for immunosuppressants.*  *Also list any key counselling points e.g. avoidance of sun/ sun beds, avoidance of any interacting foods (grapefruit etc).*  *Include suggested link to helpful patient information source for medication (e.g nhs.uk medicines guides***)**  **The patient should be advised to report any of the following signs or symptoms to their GP without delay:**  Patient information on this medicine can be found at the following links: | | | | | | | |
| **12. Pregnancy, paternal exposure and breast feeding**  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 GP and the specialist. | | | *Please detail appropriate advice/ actions e.g. whether additional contraceptive measures are required.*  **Pregnancy:**  **Breastfeeding:** | | | | | | | |
| **13. Specialist contact information** | | | Name: *[insert name]*  Role and specialty: *[insert role and specialty]*  Daytime telephone number: *[insert daytime telephone number]*  Email address: *[insert email address]*  Alternative contact: *[insert contact information, e.g. for clinic or specialist nurse]*  Out of hours contact details: *[insert contact information, e.g. for duty doctor]* | | | | | | | |
| **14. Additional information**  *Include any additional information of relevance- e.g. advice to withhold the medicine in the event of an infection, advice for missed doses etc* | | | Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. | | | | | | | |
| **15. References** | | | * *Add any key references in addition to BNF and SPC e.g. national or society guidelines* * *Include hyperlinks to the original sources and access dates* | | | | | | | |
| **16. To be read in conjunction with the following documents** | | | * RMOC Shared Care Guidance * NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs * NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care | | | | | | | |
| **17. Local arrangements for seeking specialist advice**  Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. | | | To be agreed and completed locally    **The following circumstances/ changes in the patient’s condition require discussion with the specialist team:**   * If pregnancy occurs or if the patient is planning to become pregnant or breastfeed. * If non-compliance is suspected or the patient fails to attend monitoring appointments and the primary care prescriber considers it no longer safe to continue prescribing. (All appropriate steps must first be taken by primary care to reinforce the importance of attendance to the patient) * The patient’s clinical condition deteriorates such that the primary care prescriber feels a dose change is required/ the patient no longer appears to be benefiting from therapy * *[Insert any additional information].* | | | | | | | |
| **18. Version Control** | | | Prepared by:  Checked by:  Version:  Date of Issue / Review:  Date for next Review:  Approved by: | | | | | | | |

# 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 guideline.

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

# Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

**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**  As the patients 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 in order 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 in order 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 in order 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

Yours sincerely

**Primary Care Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_**

**Primary Care Prescriber address/practice stamp:**