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| **Document title** | **Author** | **Version** | **Approval** | **Review Date** |
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| **(Medicine Name) for patients within (Service Name)** |
| **Specialist responsibilities*** Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#Two_indications)) 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](#Eleven_advice_to_patients)) 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](#Four_cx_and_cautions)) and interactions (see [section 7](#Seven_interactions)).
* Conduct required baseline investigations and initial monitoring (see [section 8](#Eight_specialist_monitoring)).
* Initiate and optimise treatment as outlined in [section 5](#Five_dosing). Prescribe the maintenance treatment for at least 4 weeks and until optimised.
* Once treatment is optimised, complete the shared care documentation and send to patient’s GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#Thirteen_specialist_contact)).
* Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
* Conduct the scheduled reviews and monitoring in [section 8](#Eight_specialist_monitoring) 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](#Nine_primary_care_monitoring) remains appropriate.
* Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
* Provide advice to primary care on the management of adverse effects if required.

**Primary care responsibilities*** Respond to the request from the specialist for shared care in writing. 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 specialists request and as per [section 5](#Five_dosing), taking into any account potential drug interactions in [section 7](#Seven_interactions).
* Adjust the dose of DRUG NAME prescribed as advised by the specialist.
* Conduct the required monitoring as outlined in [section 9](#Nine_primary_care_monitoring). Communicate any abnormal results to the specialist.
* Manage adverse effects as detailed in [section 10](#Ten_ADRs_and_Management) and discuss with specialist team when required.
* Stop DRUG NAME and make an urgent referral to the specialist if KEY/RED FLAG ADRs HERE
* 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 DRUG NAME 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](#Eleven_advice_to_patients).
* Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of DRUG NAME with their pharmacist before purchasing any OTC medicines.
* Avoid alcohol while taking DRUG NAME, as it may make some side effects worse. Avoid recreational drugs.
* Not to drive or operate heavy machinery if DRUG NAME affects their ability to do so safely.
* 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.

**NB: Check red text in particular and adapt/delete as appropriate; add any other points as necessary.**  |
| **1. Background** [Back to top](#Responsibilities) |
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| **2. Indications** [Back to top](#Responsibilities) |
| ǂ Off-label indications. (Please note licensed indications vary by manufacturer). |
| **3. Locally agreed off-label use** [Back to top](#Responsibilities) |
| To be agreed and completed locally (include supporting information) |
| **4. Contraindications and cautions** [Back to top](#Responsibilities)This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drug/) & [SPC](https://www.medicines.org.uk/emc/) for comprehensive information. |
| **Contraindications:****Cautions:** |
| **5. Initiation and ongoing dose regime** [Back to top](#Responsibilities)* 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.
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| **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** [Back to top](#Responsibilities) |
| Route of administration: |  |
| Formulation: |  |
| Administration details: |  |
| Other important information: |  |
| **7. Significant medicine interactions** [Back to top](#Responsibilities)The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drug/) or [SPC](https://www.medicines.org.uk/emc/) for comprehensive information and recommended management. |
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| **8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist**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. [Back to top](#Responsibilities) |
| **Baseline investigations:****Initial monitoring:****Ongoing monitoring:**When a patient is reviewed, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. |
| **9. Ongoing monitoring requirements to be undertaken by primary care** [Back to top](#Responsibilities)See [section 10](#Ten_ADRs_and_Management) for further guidance on management of adverse effects/responding to monitoring results. |
| **Monitoring** | **Frequency** |
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| **10. Adverse effects and other management** [Back to top](#Responsibilities)**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://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** |
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| **11. Advice to patients and carers** [Back to top](#Responsibilities)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. |
| **The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:** **The patient should be advised:**Patient information: |
| **12. Pregnancy, paternal exposure and breast feeding** [Back to top](#Responsibilities)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:**Information for healthcare professionals: (*insert link to UKTIS monograph, if available*)Information for patients and carers: (*insert link to BUMPs leaflet, if available*)**Breastfeeding:**Information for healthcare professionals: (*insert link to UKDiLAS information, if available*)**Paternal exposure**: |
| **13. Specialist contact information** [Back to top](#Responsibilities) |
| 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** [Back to top](#Responsibilities) |
| Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. |
| **15. References** [Back to top](#Responsibilities) |
| * Include hyperlinks to the original sources and access dates
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| **16. Other relevant national guidance** |
| * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
* NHSE policy – 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/>.
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| **17. Local arrangements for referral** [Back to top](#Responsibilities)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  |

APC board date: September 2022

Last updated: