BSW APC: BaNES, Swindon & Wiltshire (BSW) ICB, Avon & Wiltshire Mental Health Partnership NHS Trust (AWP), Royal United Hospitals Bath NHS Foundation Trust, Great Western Hospitals NHS Foundation Trust, Salisbury NHS Foundation Trust, HCRG Care Group, Swindon Community Health Services, Wiltshire Health & Care

SHARED CARE AGREEMENT

Rifampicin for serious staphylococcal infections (e.g. bone and joint infections) in combination with other antibacterials in adult patients.

Amber TLS – 1 month

Principles of Shared Care

Shared care agreements provide a framework for the seamless transfer of care from a hospital or specialist service setting to general practice, where this is appropriate and in the patient's best interest. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP (or other primary care prescriber) concerned and the patient to share their care.

Patients and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines.

The existence of a shared care agreement does not necessarily mean that the GP has to agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition. Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.

Responsibilities of Secondary Care Specialist

- Initiate treatment and prescribe for a **minimum of 28 days post discharge** to allow optimisation of treatment and demonstrate that the patient's response is consistent.
- Discuss the benefits and side effects of treatment with the patient.
- Review concurrent medications for potential interactions prior to initiation.
- Undertake clinical assessment and relevant monitoring at baseline and during the initiation period.
- Communicate details of treatment to GP (in writing or via secure email) within the first month of treatment and ask the GP whether he or she is willing to participate in shared care.
- Ensure the patient's treatment plan is communicated to GP at the point of transfer of prescribing. Each patient will have targeted treatment which could include more than one agent depending on cultures and sensitivities.
- Discuss shared care arrangements with the patient/carer, obtain their consent and explain their responsibilities.
- Review the patient's condition and monitor response to treatment regularly where indicated.
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring.
- Supply GP with clinic letter or discharge summary within 14 days of an outpatient review or inpatient admission, and inform GP if patient does not attend scheduled clinic appointments.
- Ensure clear arrangements exist for GPs to obtain advice and support.
- Stop treatment where appropriate or provide GP with advice on when to stop. Report adverse events to MHRA.

Responsibilities of GP/Primary Care Prescriber

- Reply to the request as soon as practicable if **unable** to support shared care (in writing or via secure email).
- Prescribe medicine at the dose recommended after the initiation period.
- Undertake ongoing clinical assessment and relevant monitoring following initiation period.
- Review any new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
- Report to and seek advice from the specialist on any aspect of care that is of concern and may affect treatment.
- Report adverse events to the specialist and MHRA.
- Stop treatment on the advice of the specialist.

Responsibilities of Patient/Carer

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with medicine.
- Report any adverse effects to the specialist or GP whilst taking the medicine.
- Attend appointments for clinical review and monitoring.

<table>
<tr><td>1. Summary of condition and treatment aims
Include links to relevant clinical guidelines e.g. NICE</td><td colspan="2">Bone and joint infection is a relatively rare condition usually requiring a combination of surgical and medical management. Definitive treatment is usually initiated in hospital.
Until recently, the initial course of post-operative antibiotic therapy was routinely administered intravenously (IV), and management of such patients in the community was supervised by the Outpatient Parenteral Antibiotic Therapy (OPAT) teams. There has been a shift to earlier oral antibiotic therapy which has the advantages of earlier discharge, reduced costs and lower risk of complications relating to long-term IV access devices. Most bone and joint infection patients will now go home on oral antimicrobial therapy, with the initial 4-week supply of oral medicines provided by the hospital, and the remainder of the course through primary care.</td></tr>
<tr><td>2. Details of medicine and indication
Please state whether licensed or unlicensed (off-label) use. Note that shared care is generally unsuitable for off-label prescribing unless it is a widely recognised use (e.g. included in BNF)</td><td colspan="2">Rifampicin is routinely used in combination with other antimicrobial agents for targeted treatment of skin and soft tissue infections and bone and joint infections based on cultures and sensitivities. Licensed use.</td></tr>
<tr><td rowspan="4">3. Pharmaceutical aspects</td><td>Route of administration:</td><td>Oral</td></tr>
<tr><td>Formulation:</td><td>150mg and 300mg capsules.
Also available in 100mg/5mL syrup; reserved ONLY for those unable to swallow capsules.</td></tr>
<tr><td>Administration details:</td><td>Take on an empty stomach at least 30 minutes before food.</td></tr>
<tr><td>Other important information:</td><td>Rifampicin will make all body fluids an orange or red colour. Contact lenses may be stained. This is not harmful.</td></tr>
<tr><td>4. Usual dose and frequency (including details of dose adjustments, e.g. in renal impairment) and duration of therapy
Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results.
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.
The duration of treatment will be determined by the specialist, based on clinical response and tolerability.
Termination of treatment will be the responsibility of the specialist.</td><td colspan="2">Usual dose is rifampicin 300mg twice daily. Can be up to 450mg twice daily.
Dose and duration will be specified by the Bone Infection Team or other relevant specialist.</td></tr>
<tr><td rowspan="2">5. Baseline investigations and initial monitoring</td><td colspan="2">Baseline investigations</td></tr>
<tr><td colspan="2">• FBC, U&Es, and LFTs</td></tr>
</table>

<table>
<tr><td rowspan="2">to be undertaken by specialist</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>• Monitoring at baseline and during initiation is the responsibility of the specialist.</td><td>• Once patient is optimised on the individualised target treatment, with no anticipated further changes expected in immediate future, prescribing and monitoring can be transferred to the GP.</td></tr>
<tr><td rowspan="2">6. Ongoing monitoring requirements to be undertaken by primary care</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>• FBCs and U&Es

• LFTs</td><td>• According to clinical need as directed by the specialist or in response to emerging clinical indicators– discuss any concerns with specialist.
• In patients with pre-existing liver disease, hepatic impairment, or alcohol dependence, monitor liver function weekly for the first 2 weeks, then every 2 weeks until rifampicin stops.
• In other patients, hepatic function should be checked before treatment and then 1 month after starting rifampicin. If no evidence of liver disease (and pre-treatment liver function is normal), further checks are only necessary if patient develops fever, malaise, vomiting, jaundice or unexplained deterioration during treatment.</td></tr>
<tr><td>7. Action(s) to be taken by primary care if abnormal result(s)</td><td colspan="2"><table><tr><td>Result</td><td>Action for GP</td></tr><tr><td>WBC less than 3x 10^9/L
Neutrophils less than 2x 10^9/L
Platelets less than 100 x 10^9/L</td><td>Repeat FBC - if low discuss with specialist</td></tr><tr><td>AST/ALT greater than 3 times the upper limit of normal reference range

Bilirubin 3 times the upper limit of normal</td><td>Moderate rises in bilirubin and/or transaminase levels may occur and is not in itself a reason for stopping treatment. The decision should be made after repeating the tests, noting trends and considering them in conjunction with the patients' clinical condition and rate of change of parameters. Any concerns should be discussed with the specialist.</td></tr></table></td></tr>
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<table>
<tr><td>8. Cautions and contraindications
Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.</td><td colspan="2">Cautions
• See SPC for comprehensive information.

Contraindications
• Jaundice or acute porphyria
• Hypersensitivity to rifampicin or any of the excipients [see SPC]
• Concurrent use of saquinavir/ritonavir therapy or ticagrelor</td></tr>
<tr><td>9. Significant medicine and food interactions and management
For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)</td><td colspan="2">Rifampicin is a potent inducer of several drug metabolizing enzymes and transporters. This list is not exhaustive; see SPC for full information & recommended management.
• Using saquinavir/ritonavir therapy with rifampicin is a contraindication
• Rifampicin reduces systemic exposure of oral contraceptives. Patients should use alternative, non-hormonal methods of birth control e.g. Cu IUD, during rifampicin therapy and for 4 weeks after stopping.
• Anti-epileptics: rifampicin increases the clearance of lamotrigine and decreases the concentration of phenytoin. Use with caution and adjust dose where necessary.
• Warfarin: rifampicin reduces the anticoagulant effect of warfarin – monitor INR closely and adjust warfarin dose accordingly. There is a significant risk of over-anticoagulation on stopping rifampicin unless appropriate dose adjustments are managed in a carefully planned manner
• DOACs: rifampicin may reduce the anticoagulant effect of apixaban, edoxaban, dabigatran and rivaroxaban.
• Ciclosporin: rifampicin decreases concentration of ciclosporin; monitor levels closely.
• Mycophenolate: rifampicin decreases the concentration of mycophenolate; monitor levels closely.</td></tr>
<tr><td rowspan="2">10. Adverse effects and management
Include details of incidence, identification, importance and management.

Serious adverse reactions should be reported to MHRA via Yellow Card scheme
www.mhra.gov.uk/yellowcard</td><td>Adverse Effect</td><td>Action to be taken if detected</td></tr>
<tr><td>• Signs of liver disorder: jaundice, malaise, pruritis, persistent nausea & vomiting
• Hypersensitivity reactions</td><td>• Check LFTs and discuss with specialist

• Anaphylaxis, rash – stop rifampicin and discuss with specialist</td></tr>
<tr><td>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.</td><td colspan="2">Advise patient to report any of these signs or symptoms to their GP without delay:
• Temperature, nausea and vomiting, feeling more unwell, loss of appetite, yellowing of the skin, gums, or eyes.</td></tr>
<tr><td>12. Pregnancy 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.</td><td colspan="2">• Rifampicin should only be used in pregnancy if benefit of treatment outweighs risk. Patient info leaflet at Rifampicin (medicinesinpregnancy.org)
• Rifampicin is excreted in breast milk but the amount is too small to be harmful</td></tr>
</table>

13. Specialist contact information	**Lead pharmacist – antimicrobials as first point of contact**		
	GWH	Jonathan URCH jonathan.urch@nhs.net,	Adrian TAIT adrian.tait1@nhs.net
	RUH	Nicola MARSH nicola.marsh11@nhs.net	
	SFT	Rebecca STONELL rebecca.stonell@nhs.net	Peter DAVIES peterdavies1@nhs.net
14. Additional information For example, process for when Specialist or GP changes roles; specific issues related to patient age/ capacity/ specific monitoring.	• Click or tap here to enter text.		
15. References	• Summary of Product Characteristics for rifampicin capsules accessed via https://www.medicines.org.uk/emc • BNF online via https://bnf.nice.org.uk/ • Click or tap here to enter text.		
16. To be read in conjunction with the following documents	• NHS England: Responsibility for Prescribing Between Primary & Secondary/ Tertiary Care. Ref 07573, Version 1.0, Published January 2018. Accessed via: https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ • Click or tap here to enter text.		

Written by (Organisation & Role):	Formulary pharmacist - BSW ICB Microbiology prescribing lead pharmacists – BSW ICB and GWH Based on work written by Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust and approved by Area Prescribing Committee Oxfordshire
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