Subject: Specialised Services Circular (SSC 2678) Sent on behalf of: Chair of the SW Specialised Service Circular Group

Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

SSC Numbe	r SSC Title	Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place
2679	Treatment for defined patients with rifampicin resistant (RR) tuberculosis (TB), multidrug- resistant (MDR) TB, pre-extensively drug resistant (pre-XDR) TB and XDR-TB including bedaquiline and delamanid (All Ages) [URN:2317] And BPaLM/BPaL for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug- resistant (MDR) TB or pre- extensively drug resistant (pre-XDR) TB [URN: 2310]	 University Hospitals Bristol and Weston NHS Foundation Trust for Paediatrics North Bristol Trust for Adults

Is an implementation plan required for this SSC? NO

For all other SouthWest region trusts this is for information only.

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: england.speccomm-southwest@nhs.net

Specialised Commissioning South West NHS England 360 Bristol Marlborough Street Bristol BS1 3NX Email: <u>england.speccomm-</u> southwest@nhs.net

12 July 2024

All Chief Executives

All Medical Directors

All Chief Pharmacists

Re: Treatment for defined patients with rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB, pre-extensively drug resistant (pre-XDR) TB and XDR-TB including bedaquiline and delamanid (All Ages) [URN:2317]

Re: BPaLM/BPaL for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB or pre-extensively drug resistant (pre-XDR) TB [URN: 2310]

I am writing to advise you regarding the funding position of two recently published NHS England policy products;

1. The updated Clinical Commissioning Policy Statement (CCPS); Treatment for defined patients with RR-TB, MDR-TB, pre-XDR TB and XDR-TB including bedaquiline and delamanid (All Ages).

The CCPS can be found at: <u>NHS England » Clinical commissioning policy</u> statement (2317): treatment for defined patients with rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB and extensively drug-resistant (XDR-TB) including bedaquiline and delamanid (all ages). NHS England will routinely commission bedaquiline and delamanid from 28th June 2024 in line with the CCPS.

The new Clinical Commissioning Policy (CCP); BPaLM/BPaL for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB or pre-extensively drug resistant (pre-XDR) TB.

The CCP can be found at: <u>NHS England » Clinical commissioning policy</u>: bedaquiline (B), pretomanid (Pa), linezolid (L) +/- moxifloxacin (M) (BPaLM/BPaL) for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB or pre-extensively drug resistant (pre-XDR) TB [URN: 2310]. NHS England will routinely commission BPaLM/BPaL from 26th June 2024 in line with the CCP.

- Trusts must ensure that only the drug procurement costs of bedaquiline and delamanid (for CCPS 2317) and the high cost elements of the BPaLM/BPaL regimen (that being bedaquiline and pretomanid for CCP 2310) are invoiced to NHSE and that they are also submitting complete and accurate information via the minimum dataset (MDS). All other on costs are in tariff or block arrangements.
- In line with the terms and conditions included in the NHS Standard Contract, Schedule 6a Reporting Requirements for drugs will apply. Payment of Trust invoices will be contingent on the completion of the MDS record and this information being made available in a timely way.
- Patients must be registered via Blueteq and meet the clinical criteria on the registration form. This letter gives the required one month's notice as per Schedule 2 Part G (Other Local Agreements, Policies and Procedures) of your Specialised Services contract for prior approval for this treatment/indication. From one month of the date specified above, NHS England will only reimburse these treatments for patients that have been confirmed as meeting the eligibility criteria via the formal Prior Approval Scheme (i.e. Blueteq). You may wish to use the prior approval mechanism earlier than this to expedite access to this drug.
- Trusts must ensure that they are completing the appropriate Blueteq forms to register new patients and continuation forms for extended treatment.
- In order to receive treatment with bedaquiline or delamanid for longer than 6 months the criteria contained in the policy 2317 must be satisfied, including the requirement for the case to be discussed, and treatment agreed with the UK BTS MDR-TB CAS and in conjunction with the appropriate MDR-TB centre.
- In order to receive treatment with BPaLM/BPaL for longer than 6 months the criteria contained in the policy 2310 must be satisfied, including the requirement for the case to be discussed, and treatment agreed with the UK BTS MDR-TB CAS and in conjunction with the appropriate MDR-TB centre.
- Payment of Trust invoices will be contingent on Blueteq registration, the MDS being completed and this information being made available in a timely way.
- Trusts must ensure that local governance aspects (e.g. technical issues, education & training, patient information) have been identified and addressed for all staff groups (as appropriate) in order to permit the safe delivery of this therapy.

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

Yours sincerely,

Alulvey .



Luke Culverwell Deputy Director of Specialised Commissioning Tracey Williams Principle Pharmacist