Engagement Report

Topic details

Title of policy or policy statement: 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

Programme of Care: Blood and Infection

Clinical Reference Group: Infectious Diseases

URN: 2310

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Tuberculosis (TB) is a disease caused by the bacterium Mycobacterium tuberculosis (M.tuberculosis), which mainly affects the lungs, but can cause disease in other areas of the body. Rifampicin-resistant (RR) TB occurs when the TB bacterium is resistant to the antibiotic (anti-TB drug) rifampicin. Multidrug-resistant (MDR) TB is when the TB bacterium is resistant to rifampicin and isoniazid. Pre-extensively drug-resistant (pre-XDR) TB is a form of TB that is resistant to rifampicin and isoniazid, and that is also resistant to at least one fluoroquinolone (either levofloxacin or moxifloxacin). Extensively drug-resistant (XDR) TB, which is not covered in this proposition, occurs when the TB bacterium is resistant to rifampicin, isoniazid, at least one fluroquinolone and at least one other 'Group A' drug (bedaquiline or linezolid) (WHO, 2022).

Current standard treatment options for patients in whom fluroquinolone resistance has been excluded include an all-oral regimen for MDR/RR-TB comprising the combined use of seven agents, most of which will be continued for at least 9 months. Other treatment options include individualised treatment regimens with a total treatment duration of 18–20 months suggested for most patients, but this may be modified according to the patient's response to therapy (often continuing for 15–17 months after culture conversion).

In 2022, the World Health Organization (WHO) recommended the use of a 6–9-month, all-oral treatment regimen for patients with RR-TB, MDR-TB and pre-XDR TB (WHO, 2022). The regimen is known as the BPaLM regimen and comprises the following medicines: bedaquiline (B), pretomanid (Pa), linezolid (L) and moxifloxacin (M). The proposition is for BPaLM/BPaL to be available as a routine commissioning treatment option in patients aged ≥14 years old for suspected, functional, or confirmed rifampicin

resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB and pre-extensively drug resistant (pre-XDR) TB.

3. Engagement

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

The policy proposition underwent a two-week stakeholder testing between 8th and 23rd February 2024 to registered stakeholders from the following Clinical Reference Groups:

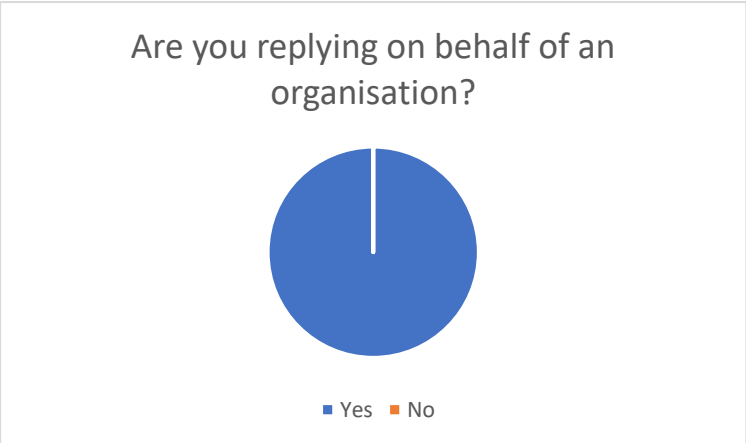
- Infectious Diseases
- Specialised Respiratory

Respondents were asked the following consultation questions:

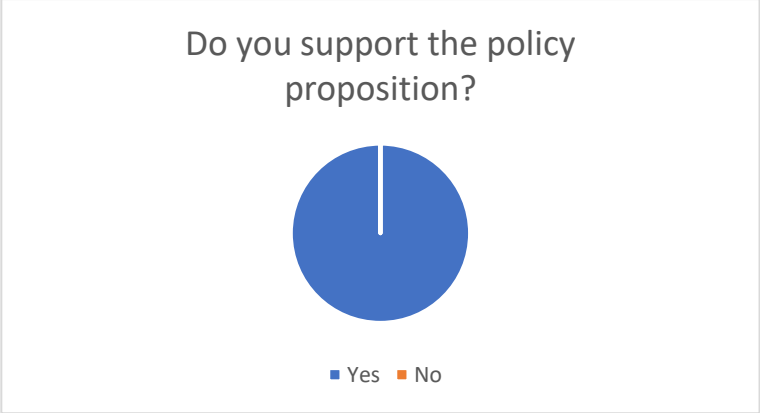
- Do you support the proposal that that BPaLM/BPaL will be routinely commissioned for patients with for BPaLM/BPaL for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB or pre-extensively drug resistant (pre-XDR) based on the evidence review and the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you support the Equalities and Health Inequalities Impact Assessment?
- Do you agree with the Patient Impact Assessment?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.

Engagement Results

In total, 5 respondents engaged with stakeholder testing for this proposition. This consisted of 5 organisations.



All respondents were supportive of the policy proposition.



In line with the 13Q assessment it was deemed that further public consultation was not required.

4. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response	
Relevant Evidence		
No additional relevant evidence with appropriate references was provided. One stakeholder responded querying whether cost had been considered.	Both the clinical effectiveness and cost of this treatment are considered as part of the policy development process. No further action required.	
Patient Impact Assessment (PIA)		
All respondents were supportive of the PIA.	No further action required.	
Current Patient Pathway		
One stakeholder commented that the UK MDRTB CAS should be referred to as the UK BTS MDRTB CAS.	This was noted and all appropriate references were amended throughout the policy proposition and supporting documents.	
Potential impact on equality and health inequalities (EHIA)		
All respondents agreed with the EHIA and no additional comments were provided.	No further action required.	
Changes/addition to policy		
One stakeholder commented that the UK MDRTB CAS should be	This was noted and all appropriate references were amended throughout	

referred to as the UK BTS MDRTB CAS.	the policy proposition and supporting documents.	
There is a separate reference to the BTS MDRTB registry on page 8 - and this should be corrected to: the UK BTS MDRTB CAS - as these are one and the same.	This was noted and amended.	
Considering needs of people living with HIV who have drug-resistant TB. Suggest add: Ensure HIV status is known at the outset and people living with HIV are immediately engaged in care if not already; MDR TB for people living with HIV should be treated at an infectious diseases centre with expertise in both, or by collaborating specialists working closely together; adverse events monitoring should be ensured considering TB and HIV treatments.	Noted	This was discussed and considered by the PWG. It was concluded that HIV status did not impact on the use of the BPaLM/BPaL regimen and should not delay treatment. It is accepted in TB Services that patients living with HIV who also have TB should be managed under a HIV physician who has expertise in both HIV and TB or cared for by collaborating physicians. No further action.

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition and/or supporting documents:

Policy Proposition	
One stakeholder commented that the UK MDRTB CAS should be referred to as the UK BTS MDRTB CAS.	This was noted and all appropriate references were amended throughout the policy proposition and supporting documents.
There is a separate reference to the BTS MDRTB registry on page 8 - and this should be corrected to: the UK BTS MDRTB CAS - as these are one and the same.	This was noted and amended.

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.