NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. Name of the proposal (policy, proposition, programme, proposal or initiative): BPaLM/BPaL for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant TB or pre-extensively drug resistant TB [2310]

2. Brief summary of the proposal in a few sentences

Tuberculosis (TB) is a disease caused by the bacteria Mycobacterium tuberculosis, which mainly affects the lungs, but can cause disease in other areas of the body. Rifampicin-resistant (RR) tuberculosis (TB) occurs when the TB bacteria is resistant to the antibiotic (anti-TB drug) rifampicin. Multidrug-resistant (MDR) TB is when the TB bacteria is resistant to rifampicin and isoniazid. Pre-extensively drug-resistant (pre-XDR) TB is a form of TB that is resistant to rifampicin, isoniazid and at least one fluoroquinolone (either levofloxacin or moxifloxacin). Extensively drug-resistant (XDR) TB, which is not covered in this policy occurs when the TB bacteria is resistant to rifampicin, isoniazid, at least one fluroquinolone and at least one other 'Group A' drug (bedaquiline or linezolid) (WHO, 2022). Patients usually acquire drug resistant disease either as a result of the spread of a drug resistant strain from another person or as a result of ineffective or incomplete treatment.

TB is a notifiable disease in England. The incidence of TB in England was 7.8 per 100,000 of the population in 2021. In 2021 a total of 4,425 people were notified with TB in England (UKHSA, 2023). Overall, TB incidence has decreased in England since 2011, but the rate of decline is slowing (UKHSA, 2023). MDR TB made up 1.9% of culture-confirmed cases in England in 2021 (Gov.uk, 2021). MDR TB centres are TB treatment centres with established experienced and expertise in managing patients with RR, MDR and pre-XDR TB. Across England there is an annual case load of approximately 50-60 patients per year with RR-TB, MDR-TB or pre-XDR TB.

The current standard treatment for patients with RR-TB, MDR-TB and pre-XDR TB involves an individualised treatment regimen consisting of at least seven agents, with an average duration of 18-24 months. The 6–9-month Bedaquiline (B), Pretomanid (Pa), Linezolid (L) +/- Moxifloxacin (M) (BPaLM/BPaL) treatment regimen represents a shorter, more patient-centred model for the management of patients with RR, MDR and pre-XDR TB, with a reduced polypharmacy burden (Vanino et al. 2023).

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age: older people; middle years; early years; children and young people.	Individuals of all ages can develop TB. In 2021, the number of TB notifications was highest in people aged 25 to 34 years (23.8%, 1,055 people), and lowest in children (aged under 15 years) with a total of 129 children (2.9% of total) notified with TB (Gov.uk, 2021). The BPaL/BPaLM treatment regimen described in this policy will be available for those age 14 years and older, in line with the evidence returned in the evidence review and the WHO guidelines.	This policy is expected to positively impact patients aged 14 years old and older with RR-TB, MDR-TB or pre-XDR TB. The BPaLM/BPaL treatment regime reduces treatment duration and polypharmacy burden compared to individualised, longer treatment regimes. This policy is restricted to this age group as this is the age group for which evidence is available and aligns with the updated WHO guidelines. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Comorbidities with other infections or non-communicable diseases or long-term conditions such as diabetes or chronic liver disease may affect TB treatment strategies and outcomes. In 2021, 20.5% (896 out of 4,425) of all people with TB were known to have at least one co-morbidity; the most	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. The evidence review returned evidence that the BPaLM/BPaL treatment regimen may lead to a reduction in Disability Adjusted Life Years (DALYs) compared to standard care.

	frequent reported co-morbidity was diabetes (11.9%) (Gov.uk, 2021). The second most frequent co-morbidity was immunosuppression (6.7%) with the most frequent documented cause being biological therapy (18.5% of those with immunosuppression co-morbidity) (Gov.uk, 2021). Untreated HIV infection increases the risk of developing TB disease and universal HIV testing is conducted within TB programmes (Gov.uk, 2021).	Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and/or people who identify as transgender in England are not at increased risk of developing TB compared to the general population.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Marriage & Civil Partnership: people married or in a civil partnership.	Marriage or civil partnership is not a recognised risk factor for developing TB compared to the general population.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient.

		A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The risk of TB in pregnant and post-partum women is substantially increased compared to women of the same age. This is because the physiological and immunological changes that occur during pregnancy are likely to have a negative impact on the course of the disease and may make it more difficult to confirm the diagnosis.	The BPaLM/BPaL treatment regimen is not recommended for patients who are pregnant. For patients who become pregnant during treatment, it will be necessary to discontinue the BPaLM/ BPaL regimen and prescribe another regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Race and ethnicity[1]	TB disproportionately affects ethnic minority groups in the UK who may face additional barriers to accessing healthcare. In 2021, TB incidence in the UK in the non-UK-born population was 37.6 per 100,000, (95% CI 35.5 to 38.1) compared with 2.1 per 100,000 (95% CI 2.0 to 2.3) in the UK-born population. The top 5 countries of birth for people with TB in the non-UK born population were: India, Pakistan, Romania, Somalia and Eritrea respectively (Gov.uk, 2021).	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Patients will be treated in MDR-TB Centres, which are TB treating centres with established experience and expertise in managing and supporting patients with MDR- and XDR-TB. This should include every reasonable effort to understand any potential barriers to treatment uptake or compliance. If required, an interpreter should be made available to facilitate patient understanding. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).

Religion and belief: people with different religions/faiths or beliefs, or none.	As 76.4% cases of TB in the UK are found in people born outside the UK, it is important to be mindful that this may constitute a diverse range of religious or belief groups.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Patients will be treated in MDR-TB Centres, which are TB treating centres with established experience and expertise in managing and supporting patients with MDR- and XDR-TB. This should include every reasonable effort to understand religious and/or cultural beliefs that may present barriers to compliance or uptake of a suitable treatment regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Sex: men; women	Males are over-represented amongst individuals with TB. In 2021, 60.6% (2,682 out of 4,425) of people notified with TB were male; a similar proportion of male individuals with TB between UK-born and non-UK-born populations were observed. The overall male-to-female ratio of 1.5 in England is stable over time and reflects the excess risk in males reported globally. The excess risk in males is observed only in adulthood. The reason for the disparity between the sexes is poorly understood.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).

Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not a recognised risk factor for developing TB compared to the general population.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

There are demographic, social and economic characteristics that can lead to people experiencing social exclusion, stigma and discrimination, resulting in barriers in access to healthcare, poor health outcomes and contributing to increasing health inequalities. The National TB Surveillance System (NTBS) collects data on 6 specific social characteristics, referred to as Social Risk Factors (SRFs) that are commonly reported to increase the risk of TB and are associated with barriers in access to healthcare and poor outcomes. These are; alcohol misuse, drug misuse, homelessness, imprisonment, mental health needs and asylum seeker status.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	Looked after children and young people refers to children under the care of their Local Authority. The BPaLM/BPaL treatment regimen will be available for individuals aged 14 years old or older.	All patients who meet the eligibility criteria outlined in the policy will be offered treatment with the BPaLM/BPaL treatment regimen. This will include individuals aged 14 years old or older, so this policy will not be particularly applicable to this group.

		Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Carers of patients: unpaid, family members.	Carers who have been in prolonged close contact with a case of active TB disease are at increased risk of developing TB. This situation may result if patients with active, untreated TB have poor health literacy or understanding of their condition, due to social, cultural or linguistic barriers, and consequently go on to develop further care needs.	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Additionally, MDR-TB teams and others working with seldom heard groups should use high quality material to raise awareness of TB. The material should be current, culturally and linguistically appropriate and available in a range of media formats (that is, not just in a written format). This material should be modified to meet the specific needs of the audience, if necessary. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	Current or previous homelessness was identified as an SRF in 4.9% of patients with TB in England in 2021 (Gov.uk, 2021).	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Additionally, MDR- TB teams should consider meeting additional non-clinical needs to facilitate holistic

		care, such as providing food and drink, to encourage people to attend for follow-up appointments. Commissioners of TB prevention and control programmes should consider offering homeless people and substance misusers other health interventions when they are screened for TB at a mobile X-ray unit. (Examples may include blood-borne virus [BBV] screening, dentistry and podiatry services.) MDR-TB teams should work closely with mobile X-ray teams and frontline staff in hostels and day centres to ensure appropriate onward referrals and follow-up. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Current or previous prison sentence was identified as an SRF in 4.1% of patients with TB in England in 2021 (Gov.uk, 2021).	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. It is recognised that there is frequently movement within institutions also discharge when the TB centre may not be aware of immediately and subsequent loss of continuity of treatment. A shorter regime will reduce the impact of these. Additionally, MDR-TB teams, prison and immigration removal centre healthcare services should ensure they can communicate effectively with each other and should agree a care pathway for TB to ensure any suspected or confirmed cases are reported to, and managed by, the

		MDR- TB team. MDR-TB teams, in liaison with prison or immigration removal centre healthcare providers, should manage all cases of active TB. Investigations and follow-up should be undertaken within the prison or immigration removal centre, wherever practically possible. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People with addictions and/or substance misuse issues	Current alcohol misuse was identified as an SRF in 4.5% of patients with TB in England in 2021 (Gov.uk, 2021). Current or previous drug misuse was identified as an SRF in 5.3% of patients with TB in England in 2021 (Gov.uk, 2021).	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Additionally, TB case managers should undertake a risk assessment to identify whether the person should have directly observed therapy (DOT) or video observed therapy (VOT). Effective monitoring and supervision, including the use of DOT/VOT where applicable should be considered part of standard care, from the start of treatment, for all hard-to-reach children aged under 16 years (noting that this policy will only affect those aged 14 years old or older). It should also be standard care for anyone who requests it including those with addiction or substance misuse issues. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient.

		A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People or families on a low income	In 2021, the rate of TB was 13.1 per 100,000 in the 10% of the population living in the most deprived areas compared with only 2.5 per 100,000 in the 10% of the population living in the least deprived areas, with a clear trend of a decreasing rate of TB with decreasing deprivation.	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. This will potentially require fewer follow-up appointments at specialist MDR-TB centres, which may be more difficult to reach for people in low-income families due to associated travel costs. Wherever possible appointments should be offered to patients at the specialist centre closest to where they live or via a hub-and-spoke model with VOT. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Cases of TB in England are more common in those born outside of the UK. Additionally, the most common SRF was asylum seeker status at 5.4%. This means that many service users may have a poor understanding of health services, and/or poor language skills.	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Additionally, MDR-TB teams and others working with hard-to-reach groups should use high quality material to raise awareness of TB. The material should be current, culturally and linguistically appropriate and available in a range of media formats (that is, not just in a written format). This material should

		be modified to meet the specific needs of the audience, if necessary. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People living in deprived areas	In 2021, the rate of TB was 13.1 per 100,000 in the 10% of the population living in the most deprived areas compared with only 2.5 per 100,000 in the 10% of the population living in the least deprived areas, with a clear trend of a decreasing rate of TB with decreasing deprivation.	The BPaLM/BPaL treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
People living in remote, rural and island locations	Between 2020 and 2021, there were increases in the proportion of people with at least one SRF in the West Midlands, Yorkshire and the Humber and the North East (61.5, 32.8 and 33.7% increase respectively). There were decreases in the South West (41% decrease), East Midlands (21% decrease) and the East of England (14% decrease). London and the North East consistently had the highest proportions, with	The BPaL/BPaLM treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. This will potentially require fewer follow-up appointments at specialist MDR-TB centres, which may be more difficult to reach for people living in remote or rural locations. Wherever possible, follow-up appointments should be offered to patients at the

	the North East having the highest proportion in 2021 at 24.0% compared with 17.6% in London and 9.9% in the South East, which consistently had the lowest proportion.	specialist centre closest to where they live or via a hub-and-spoke model with VOT. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Refugees, asylum seekers or those experiencing modern slavery	The most common SRF was asylum seeker status at 5.4%, but as no information or unknown is recorded for a large proportion of those born outside of the UK (61.5%) this should be interpreted with caution. However, in the non-UK-born population with recorded data, the proportion of asylum seekers is 9.3%. Younger people had the highest prevalence of asylum seeker status.	The BPaL/BPaLM treatment regimen is expected to have a positive impact on this group of patients, as it comprises a reduced polypharmacy burden and shorter treatment duration than longer, individualised treatment regimens. Care and treatment should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery to optimise benefit for the patient. A useful tool to consider this for any group of patients is the Health Equity Assessment Tool (HEAT).
Other groups experiencing health inequalities (please describe)		

References:

TB incidence and epidemiology in England, 2021. Available at: https://www.gov.uk/government/publications/tuberculosis-in-england-2022-report-data-up-to-end-of-2021/tb-incidence-and-epidemiology-in-england-2021 (Accessed: 06 June 2023).

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes x	No	Do Not Know

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	**Stakeholder Testing**	Stakeholder testing took place in January 2024 for 14 days, following approval of this policy at Clinical Panel Gateway 2.	Jan 24
2	**Patient Representation**	PPV representation has been sought in the development of this policy.	

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	Independent evidence review undertaken by Solutions for Public Health	
Consultation and involvement findings		
Research		
Participant or expert knowledge		

For example, expertise within the team or expertise drawn on external to your team		

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?	x	x	x
Uncertain whether the proposal will support?			

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	x	x
The proposal may support?		
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		
3		

10. Summary assessment of this EHIA findings

In summary, the BPaLM/BPaL regimen is proposed for the treatment of patients aged 14 years old or older with RR-TB, MDR-TB and pre-XDR TB. The 6–9-month BPaLM/BPaL treatment regimen represents a shorter, more patient-centred model for the management of patients with RR, MDR and pre-XDR TB, with a reduced polypharmacy burden. This is expected to have a positive impact on health equity, particularly for individuals in vulnerable groups who may have difficulty accessing healthcare resources.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	CFO
Date EHIA agreed:	
Date EHIA published if appropriate:	