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): 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 [2317]

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) 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 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.

NHS England have made following treatment available for defined patients with RR-TB, MDR-TB, pre-XDR and XDR-TB: bedaquiline and/or delamanid as part of an appropriate combination regimen. This updated policy statement includes the additional concurrent use of bedaquiline and delamanid in defined patients who meet the below eligibility criteria. These drugs should be given for the necessary time and either concurrently or sequentially, if required, as determined on a case-by-case basis.

This updated policy applies to the use of longer, individualised TB regimens in patients for whom a WHO recommended regimen, including the bedaquiline (B), pretomanid (Pa), linezolid (L) +/- moxifloxacin (M) BPaLM/BPaL treatment regimen, cannot be

constructed. Some of the recommendations sit outside of the current licenses for bedaquiline and delamanid but are supported by a number of studies and clinical consensus.

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 use of bedaquiline and/or delamanid as part of an individualised treatment regimen as described in this clinical commissioning policy statement will be available for all ages, in line with the pre-existing evidence review and updated clinical consensus.	This policy statement is expected to positively impact patients with RR-TB, MDR-TB, pre-XDR TB or XDR-TB and will be available to individuals of all ages in line with the eligibility criteria in the clinical commissioning policy statement. 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 frequent reported co-morbidity was diabetes (11.9%) (Gov.uk, 2021). The second most frequent co-morbidity was	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised 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.

	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).	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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised 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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen.
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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised 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).
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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised 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. 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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised 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-TB and XDR-TB. Care and treatment should seek to understand any religious and/or cultural beliefs to seeking care, 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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Care and treatment should seek to understand any potential barriers to seeking care, 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 statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Care and treatment should seek to understand any potential barriers to seeking care, 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. Treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen will be available for patients of all ages in line with the eligibility criteria.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Care and treatment should seek to understand any potential barriers to seeking care, 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. 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 seeking care, 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).	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. 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 seeking care, 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).	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. 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. All reasonable efforts should be made to mitigate this. 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 seeking care, 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	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Additionally, TB case managers should undertake a risk assessment to

	5.3% of patients with TB in England in 2021 (Gov.uk, 2021).	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. 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 seeking care, 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. 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 seeking care, 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. 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 seeking care, 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Care and treatment should seek to understand any potential barriers to seeking care, 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 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Wherever possible, follow-up 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 seeking care, 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.	All patients who meet the eligibility criteria outlined in the policy statement will be offered treatment with bedaquiline and/or delamanid as part of an individualised treatment regimen. Care and treatment should seek to understand any potential barriers to seeking care, 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, pending approval of this policy statement at Clinical Panel Gateway 2.	January 2024
2	**Patient Representation**	PPV representation has been sought in the development of this policy statement.	
3			

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		

Consultation and involvement findings	The updates to this clinical commissioning policy statement were developed on the basis of Clinical Consensus in accordance with the updated WHO 2022 guidelines.	
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 update to this clinical commissioning policy statement incorporates the concurrent use of bedaquiline and delamanid as part of an individualised treatment regimen for defined patients with RR-TB, MDR-TB, pre-XDR TB or XDR-TB for whom a WHO-approved treatment regimen cannot be constructed. Additional changes have been made to reflect the 2022 WHO updated guidelines for the treatment of patients with RR-TB, MDR-TB, pre-XDR TB and XDR-TB. This is expected to have a positive impact on health equity as it provides an additional treatment option for patients with RR-TB, MDR-TB, pre-XDR TB or XDR TB for whom a WHO approved regimen cannot be constructed.

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:	