

## NHS England and NHS Improvement: 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):** Nebulised liposomal amikacin for the treatment of non-tuberculous mycobacterial pulmonary disease caused by Mycobacterium Avium Complex (MAC) that is refractory to current treatment options (adults and post pubescent children).[URN: 2111]

2. **Brief summary of the proposal in a few sentences**

The policy aims to offer a treatment option to the cases of adult and post pubescent patients with non-tuberculous mycobacterial pulmonary disease caused by Mycobacterium Avium Complex (MAC) who do not have cystic fibrosis and are refractory to the current guidance based therapy (GBT). It involves the use of nebulised liposomal amikacin in addition to the current oral GBT. Treatment with nebulised liposomal amikacin, as part of a combination antimicrobial regimen, should be continued for 12 months after sputum culture conversion.

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
<b>Age:</b> older people; middle years; early years; children and young people.	The condition is more common in older people (and can also more complicated to manage due to comorbidities) who will	The publication of the policy from NHS England will benefit the affected population by enabling equitable access to a more effective treatment



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
	<p>thus benefit from an improved treatment regime.</p> <p>Pre-pubescent children are not covered by the policy but are also not affected by the condition.</p>	<p>which should also reduce the length of time patients are affected by the condition.</p> <p>Pre-pubescent children are not impacted by the disease.</p>
<p><b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>People with learning disabilities or some mental health conditions may have difficulties using nebulized treatments.</p> <p>Patient groups more affected by the condition are those:</p> <ul style="list-style-type: none"> <li>• With other chronic lung diseases</li> <li>• Who are immunodeficient either genetically or acquired such as people with COPD, HIV and those taking medications which affect immune response.</li> </ul>	<p>People with learning disabilities or some mental health conditions may need extra support to enable the use of a homecare based nebulized treatment regime.</p> <p>The policy enables access to more effective treatment for all patients fulfilling the clinical criteria. Service delivery will be managed by clinicians expert in MAC who will develop local systems to meet patients' needs.</p>
<p><b>Gender Reassignment and/or people who identify as Transgender</b></p>	<p>No issues identified for people with these protected characteristics</p>	
<p><b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.</p>	<p>No issues identified for people with these protected characteristics</p>	
<p><b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.</p>	<p>The condition is uncommon in pregnant and postnatal women. The product characteristic suggest that it is preferable to avoid this product during pregnancy.</p>	<p>Clinical teams will need to develop individualized treatment plans for pregnant women, based on risk. Likewise for breastfeeding women, a joint decision will need to be made as to whether to discontinue</p>

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
	For breastfeeding patients there is no information regarding the presence of amikacin in human milk. However, systemic exposure to inhaled liposomal amikacin following inhalation is expected to be low compared to parenteral administration of amikacin.	breast-feeding or to discontinue inhaled liposomal amikacin therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.
<b>Race and ethnicity</b> <sup>1</sup>	No UK based evidence to show a variation in MAC prevalence by race or ethnicity	
<b>Religion and belief:</b> people with different religions/faiths or beliefs, or none.	No issues identified for people with these protected characteristics	
<b>Sex:</b> men; women	Women tend to be more likely to have NTM disease than men.	The policy enables access to more effective treatment delivered by subject experts for all patients fulfilling the clinical criteria
<b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.	No issues identified for people with these protected characteristics	

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

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<sup>1</sup> Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

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.

Groups who face health inequalities <sup>2</sup>	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
<b>Looked after children and young people</b>	Pre-pubescent children are not covered by the policy but are also not affected by the condition. MAC is very uncommon in young adults	Pre-pubescent children are not impacted by the disease. The policy enables access to more effective treatment for all patients fulfilling the clinical criteria. Service delivery will be managed by clinicians expert in MAC who will develop local systems to meet patients' needs.
<b>Carers of patients:</b> unpaid, family members.	The policy will positively impact carers of patients through the delivery of more effective treatment of a debilitating chronic condition.	The provision of the treatment through homecare arrangements will benefit carers who need to otherwise accompany patients to hospitals for treatment, or who might need to assist patients with selfcare.
<b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&Bs.	May be less likely to have their condition recognised and referred for treatment. Homeless people may face difficulties using the treatment in nebulised form. The treatment needs to be stored in a fridge so homeless people may not have access to a fridge with sufficient capacity to store a sufficient supply of medication.	Publication of the policy from NHS England should raise awareness of the condition within primary care services and charities who care for the homeless populations. Service delivery will be managed by clinicians expert in MAC who will develop local systems to meet patients' needs working with relevant charities, social services, accommodation providers etc..
<b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.	May be less likely to have their condition recognised and referred for treatment.	Publication of the policy from NHS England should raise awareness of the condition in healthcare providers in the criminal justice system.

<sup>2</sup> Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities <sup>2</sup>	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
		Service delivery will be managed by clinicians expert in MAC who will develop local systems to meet patients' needs working with prisons, the probation service and charities.
<b>People with addictions and/or substance misuse issues</b>	May be less likely to have their condition recognised and referred for treatment.	Publication of the policy from NHS England should raise awareness of the condition in healthcare providers in the criminal justice system. Service delivery will be managed by clinicians expert in MAC who will develop local systems to meet patients' needs working with addiction and social service providers.
<b>People or families on a low income</b>	People or families on low income will benefit as homecare arrangements will reduce hospital transport costs.	Access to a more effective (and potentially shorter) treatment should improve health and enable employment opportunities.
<b>People with poor literacy or health Literacy:</b> (e.g. poor understanding of health services, poor language skills).	May be less likely to have their condition recognised and referred for treatment, and may also need more help with managing treatment	Publication of policy by NHS England should raise awareness of the condition within health care professionals looking after patients with poor literacy or health literacy. Services will need to develop systems to support people with poor literacy or health literacy with managing the treatment regime.
<b>People living in deprived areas</b>	No issues identified for people who face these health inequalities	
<b>People living in remote, rural and island locations</b>	People who face these health inequalities may be less likely to have their condition recognised and referred for treatment. The provision of homecare arrangements will significantly reduce the need for hospital visits.	Publication of this policy from NHS England should raise awareness of the condition within the healthcare teams looking after people living in remote areas. Services covering these locations will need to develop a service model to support such patient

Groups who face health inequalities <sup>2</sup>	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
		groups to enable management of the treatment regime using homecare provisions.
Refugees, asylum seekers or those experiencing modern slavery	May be less likely to have their condition recognised and referred for treatment. More likely to be living in conditions where home delivery of a nebulised treatment could be difficult.	Publication of the policy from NHS England should raise awareness of the condition within healthcare professionals and charities looking after these patients. Services will need to enable a service model that will support refugees, asylum seekers or those experiencing modern slavery with managing the treatment regime, working with social services, charities and other organisations involved with these population groups. .
Other groups experiencing health inequalities (please describe)	No others identified.	

## 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
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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 There has been communication within the PWG to discuss EHIA	All the points raised by the members of the PWG have been included on the form	Oct 2021 -Feb 2022

2			
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
<b>Published evidence</b>	A limited evidence review was conducted to determine patient groups most affected by MAC	No UK based study could be found. Much of the published literature makes reference to a paucity of evidence in this area.
<b>Consultation and involvement findings</b>		
<b>Research</b>		
<b>Participant or expert knowledge</b> For example, expertise within the team or expertise drawn on external to your team	PWG that included a patient representative, Public Health Consultant, Pharmacists and Respiratory Medicine Consultants, all with expert knowledge on the issue. The PWG also included a patient with current MAC pulmonary disease who has offered her experience and provided suggestions.	

**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?		X	
The proposal may support?	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 The prevalence of MAC by patient groups in the UK	Data collation exercise by services and laboratories currently treating people with the condition.
2	
3	

**10. Summary assessment of this EHIA findings**

This policy will contribute to advancing equality of opportunity and reducing health inequalities.
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**11. Contact details re this EHIA**

Team/Unit name:	Internal Medicine Programme of Care
Division name:	Specialised Commissioning, Health and Justice



Directorate name:	Finance
Date EHIA agreed:	15/02/22
Date EHIA published if appropriate:	