

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)¹:** Clinical Commissioning Policy Statement - Use of Adalimumab for refractory chronic non-bacterial osteomyelitis / osteitis (CNO) (all ages) [1926]
2. **Brief summary of the proposal in a few sentences**

A national Policy Working Group was established to review the case for commissioning Adalimumab for refractory Chronic non-bacterial osteomyelitis (CNO). CNO is a rare auto-inflammatory condition that causes severe bone pain arising from inflammation of bone(s). CNO primarily affects children but can persist into adulthood or present in adult life. It covers a wide spectrum of disease ranging from time-limited mild inflammation affecting a single bone to severe chronically active or recurrent inflammation affecting multiple bones. A rapid three paper review of the available evidence was conducted to inform the decision. Although the study results were promising, they were not sufficient to support the recommendation for the routine commissioning of adalimumab for refractory CNO. Further research is recommended in this area, particularly consideration of clear outcome measures.

Conclusion - **Adalimumab is not recommended** to be available as a treatment option through routine commissioning for refractory chronic non-bacterial osteomyelitis/ osteitis.

¹ Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.



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.	This policy applies to all ages. Children are more likely to have CNO and this policy means they will not have access to adalimumab for CNO. This does not change the commissioning position as they currently do not have access to this.	Further research is encouraged in this area to help build up the evidence base. This will enable a more informed commissioning decisions in the future when this policy position is reviewed.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	CNO may result in a degree of disability in severe disease with bone deformity and chronic pain. This may continue into adult life. This policy may have a negative impact on people with a disability caused by CNO.	NHSE will encourage further research into this area to help build up the evidence base. This will allow us to make more informed commissioning decisions in the future when this policy is reviewed.
Gender Reassignment and/or people who identify as Transgender	N/A	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	N/A	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	N/A	N/A

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
Race and ethnicity ²	CNO can affect people of any race and ethnicity, so this policy will not affect any group disproportionately.	N/A
Religion and belief: people with different religions/faiths or beliefs, or none.	N/A	N/A
Sex: men; women	CNO can affect people of any gender, so this policy will not affect any group disproportionately.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	N/A	N/A

² 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.

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.

Groups who face health inequalities³	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	This policy does not positively or negatively impact on this group who experience health inequalities above the age-related aspects outlined above.	N/A
Carers of patients: unpaid, family members.	N/A	N/A
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	N/A	N/A
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	N/A	N/A
People with addictions and/or substance misuse issues	N/A	N/A
People or families on a low income	N/A	N/A
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	N/A	N/A
People living in deprived areas	N/A	N/A

³ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities³	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
People living in remote, rural and island locations	N/A	N/A
Refugees, asylum seekers or those experiencing modern slavery	N/A	N/A
Other groups experiencing health inequalities (please describe)	N/A	N/A

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 Established a Policy Working Group	Policy Working Group consisting of clinicians, a patient representative and NHS England agreed with the policy.	Jan 2020
2 Stakeholder testing	The Policy Statement was sent for stakeholder testing for a two-week period in June 2020. Thirteen responses were received. Eleven respondents submitted comments in relation to the EHIA. Five did not support the EHIA raising concerns that there was inequity in access to adalimumab between indications and concerns regarding variation in local access. It	11th to 25th June 2020

		was noted that a national policy position would reduce variation.	
3	Clinical Priorities Advisory Group (CPAG)	CPAG members reviewed the EHIA alongside policy proposition documentation. CPAG supported the EHIA.	December 2020

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	Public Health England conducted a brief review of the 3 best available papers on adalimumab for CNO.	Small studies, no randomised controlled trials, outcome measures not defined well.
Consultation and involvement finding	Stakeholder engagement.	
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Policy Working Group consisted of expert clinicians within the field of rheumatology as well as a patient representative.	

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	Stronger evidence required with regards to whether adalimumab is effective for refractory CNO.	High quality, nationally driven studies. Also potentially through the evaluative commissioning scheme at NHS England. An application has been developed for consideration for after publication of this policy.
2		
3		

10. Summary assessment of this EHIA findings

This proposal is a not for routine commissioning policy for a treatment which is not currently commissioned in England for chronic non-bacterial osteomyelitis. We anticipate that there will be not be a significant impact on health inequalities, but will reduce the current variation in access to the intervention by the adoption of a Not Routinely Commissioned position.

11. Contact details re this EHIA

Team/Unit name:	Internal Medicine
Division name:	Specialised Commissioning
Directorate name:	Finance, Performance and Planning
Date EHIA agreed:	13/11/20
Date EHIA published if appropriate:	