# 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 Proposition: Canakinumab for patients with Still's disease refractory to anakinra and tocilizumab (adults and children 2 years and over)

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

This is a clinical commissioning policy for the use of canakinumab as 4th line treatment for adults and children 2 years and over with Still's disease.

Still's disease is the term used for two conditions: systemic-onset juvenile idiopathic arthritis (SJIA) in children and adult-onset Still's disease (AOSD) in adults. Still's disease is a rare inflammatory condition that can manifest at any age, usually with symptoms of fever, joint pain, rash, weight loss and muscle aches. Patients with a diagnosis of Still's disease are usually treated with non-steroidal anti-inflammatory drugs (such as ibuprofen) and corticosteroids. If these treatments do not help control symptoms, they can be given disease-modifying anti-rheumatic drugs (such as methotrexate). Often, even this does not help control symptoms and patients are started on newer drugs such as anakinra or tocilizumab. For a very small number of patients, their symptoms may not be controlled by any of these medications, or they may be intolerant to these medications. Currently there are no further treatment options for these patients.

This policy recommends the use of canakinumab for adults and children 2 years and over with Still's disease where their symptoms are not controlled by any of the currently available treatments, which can be life-changing for these severely affected patients.

**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. | Symptoms of Still's disease can manifest at any age. The policy is for the use of canakinumab as 4th line treatment in patients where previous treatment has not been effective, therefore the policy is expected to have a positive impact on adults and children over 2 years.<br><br>There is the small potential for a negative impact on children under 2 years as they are excluded from the policy due to the license, which is for use in children over 2 years. | Although children under 2 years are excluded from the policy due to canakinumab's license, it is unlikely that children under 2 would have exhausted the other treatment options. Treatment is usually expected to be trialed for effectiveness over 3-6 months before consideration for withdrawal of treatment. This can be reviewed if further evidence of safety and efficacy is published for the use of canakinumab in children under 2 and the license changes. |
| **Disability:** physical, sensory and learning impairment; mental health condition; long-term conditions. | Patients with Still's disease that is poorly controlled may have or develop a disease- or treatment-related physical and/or cognitive disability. This policy is expected to have a positive impact on this group as it would improve access to a wider number of available treatments. | Treatment of refractory Still's disease with canakinumab where other treatment options have failed provides another treatment option to help slow down and stop the progression of the disease. |
| **Gender Reassignment and/or people who identify as Transgender** | There is no identified impact of this policy on this protected characteristic. | 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 |
|---|---|---|
| **Marriage & Civil Partnership:** people married or in a civil partnership. | There is no identified impact of this policy on this protected characteristic. | N/A |
| **Pregnancy and Maternity:** women before and after childbirth and who are breastfeeding. | This policy may have a negative impact on women who are pregnant or may become pregnant while taking canakinumab. It is recommended that women who may become pregnant use effective contraception during treatment with canakinumab and for up to 3 months after the last dose. There is limited data for the use of canakinumab in women who are pregnant. It is also unknown whether canakinumab is excreted in human milk. | Pregnancy, the ability to become pregnant, or breast-feeding are not exclusion criteria for canakinumab. However, the risks and benefits must be discussed with the patient, understanding that there are very few trials of canakinumab in these groups. |
| **Race and ethnicity**[2] | It is unclear whether this policy will have an impact on patients based on their race or ethnicity. It is not known if AOSD or AOSD prognosis is significantly influenced by ethnicity. It is not known if SJIA is significantly influenced by ethnicity. | The policy suggests canakinumab as a 4th line treatment for patients that have not responded adequately to other treatments. |

[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.

| 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 |
|---|---|---|
| | There is some evidence that in a US adult population, patients of Asian origin had a significantly increased chance of in-hospital death compared to white people (Mehta 2019). | |
| **Religion and belief:** people with different religions/faiths or beliefs, or none. | There is no identified impact of this policy on this protected characteristic. | N/A |
| **Sex:** men; women | Most studies agree that there is no difference in the sex ratio between males and females with Still's disease.<br><br>One study of people with adult-onset Still's disease in Japan (Wakai 1997) reported a sex ratio (female to male) of 2.1, though this may be specific to this study or Japan. Another small study of people with adult-onset Still's disease in Turkey reported a sex ratio (female to male) of 3.2.<br><br>There is no identified impact of this policy based on sex | The policy proposition suggests canakinumab as a 4th line treatment for patients that have not responded adequately to other treatments. |
| **Sexual orientation:** Lesbian; Gay; Bisexual; Heterosexual. | There is no identified impact of this policy on this protected characteristic. | N/A |

## 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 inequalities[3] | 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** | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **Carers of patients:** unpaid, family members. | There is evidence that caregivers of patients with systemic juvenile idiopathic arthritis have reduced mental wellbeing, productivity and increased expenses. There is an expected positive impact on this group from treatment with canakinumab in severely affected patients who are refractory to other treatment options. | The policy suggests canakinumab as a 4th line treatment for patients that have not responded adequately to other treatments. A further treatment option improves the chance that the patient will experience fewer symptoms, reducing the burden on the carer. |
| **Homeless people.** People on the street; staying temporarily with friends /family; in hostels or B&Bs. | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **People involved in the criminal justice system:** offenders in prison/on probation, ex-offenders. | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **People with addictions and/or substance misuse issues** | There is no identified impact of this policy on this group who face health inequalities. | N/A |

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

| Groups who face health inequalities[3] | 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 or families on a low income** | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **People with poor literacy or health Literacy:** (e.g. poor understanding of health services poor language skills). | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **People living in deprived areas** | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **People living in remote, rural and island locations** | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **Refugees, asylum seekers or those experiencing modern slavery** | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| **Other groups experiencing health inequalities (please describe)** | There are no further direct negative or positive impacts of this policy on any other groups experiencing health inequalities. | 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 | ~~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 engagement (planned) | There has been a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods. | 8 September 2021 to 22 September 2021 |
| | | | |
| **2** | Policy working group | The policy working group that has developed the policy is made up of specialist clinicians, a patient public voice representative, a public health consultant, a pharmacist and a commissioner to offer a wide range of opinions and backgrounds. | Throughout the policy development process |
| | | | |
| **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** | Balci MA, Pamuk ON, Pamuk GE, Uzundere FK, Donmez S. (2015) Epidemiology and outcome of adult-onset Still's disease in the northwestern Thrace region in Turkey. Clinical and Experimental Rheumatology. 33:818-823.<br><br>Feist E, Mitrovic S, Fautrel B. (2018) Mechanisms, biomarkers and targets for adult-onset Still's disease. Nature Reviews Rheumatology. 14:603-618.<br><br>Gerfaud-Valentin M, Jamilloux Y, Iwaz J, Seve P. (2014) Adult-onset Still's disease. Autoimmunity Reviews. 13(7): 708-722.<br><br>Gurion R, Lehman TJA, Moorthy LN. (2012) Systemic arthritis in children: a review of clinical presentation and treatment. International Journal of Inflammation. 2012:271569.<br><br>Mehta BY, Ibrahim S, Briggs W, Efthimiou P. (2019) Racial/ethnic variations in morbidity and mortality in adult-onset Still's disease: an analysis of national dataset. Seminars in Arthritis and Rheumatism. 49(3):469-473.<br><br>Shenoi S, Horneff G, Cidon M, Ramanan AV, Kimura Y, Quartier P, Foeldvari I, Zeft A, Lomax KG, Gregson J, Abma T, Campbell-Hill S, Weiss J, Patel D, Marinsek N, Wulffraat N. (2018) The burden of systemic juvenile idiopathic arthritis for patients and caregivers: an international survey and retrospective chart review. Clinical and Experimental Rheumatology. 36:920-928.<br><br>Wakai K, Ohta A, Tamakoshi A, Ohno Y, Kawamura T, Aoki R, Kojima M, Lin Y, Hashimoto S, Inaba Y, Minowa M, Aizawa S, Ichikawa Y, Miyasaki N. (1997) Estimated prevalence and incidence of adult-onset Still's disease: findings by a nationwide epidemiological survey in Japan. Journal of Epidemiology. 7(4):221-225. | |
| **Consultation and involvement findings** | Awaited | |

| Evidence Type | Key sources of available evidence | Key gaps in evidence |
|---|---|---|
| **Research** | Not applicable | |
| **Participant or expert knowledge** | Through the Blood and Infection Programme of Care and its Clinical Reference Group structures supporting the policy working group with its expert knowledge regarding the epidemiology and treatment of Still's disease. | |

**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 | |
| Uncertain whether the proposal will support? | X | | X |

**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? | | |
| The proposal may support? | X | X |
| 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 | None noted | N/A |
| 2 | | |
| 3 | | |

## 10. Summary assessment of this EHIA findings

There is a potential negative impact identified for patients with Still's disease under 2 years as they are excluded from this policy. However, as the treatment is being proposed as 4th line, it is unlikely that the child will have received all available treatment before reaching the requirements for the use of canakinumab. Although pregnancy is not an exclusion criterion for the use of canakinumab, a discussion with the patient must take place of the risks and benefits, acknowledging that very little is known about the use of canakinumab during pregnancy due to a lack of studies. The policy supports the use of canakinumab as 4th line treatment for adults and children 2 years and over with Still's disease. This policy and the clinical criteria defined within it are based on the result of an external evidence review.

## 11. Contact details re this EHIA

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|---|---|
| Team/Unit name: | |
| Division name: | |
| Directorate name: | |
| Date EHIA agreed: | |
| Date EHIA published if appropriate: | |