

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: Addition of rituximab to first-line standard chemotherapy for CD20 positive B-cell precursor acute lymphoblastic leukaemia (Adults) [NHS England URN: 1748].

2. Brief summary of the proposal in a few sentences

B-cell precursor acute lymphoblastic leukaemia is type of acute lymphoblastic leukaemia (ALL), which is a very rare and aggressive cancer of the blood and bone marrow. Although the condition is most common in children, teenagers and young adult, it can affect people of any age (Cancer Research UK, 2018). It is estimated that approximately 300 adults are diagnosed with ALL per year.

Chemotherapy is the main treatment option for people with ALL, however, some people may also need treatment with a targeted cancer medicine and/or a stem cell transplant. The duration of treatment for the condition is around two to three years and consists of several months of intensive multi-drug chemotherapy, followed by low intensity maintenance therapy. The chemotherapy regimen (the treatment plan) used is based on clinical trial evidence and protocols have been designated based on the age of the patient, as well as their individual fitness to undergo intensive treatment.

In children, cure rates for ALL are over 80%, however, in adults the treatment of ALL has proven to be more challenging and five-year overall survival is between 29% to 41% (Horvat et al, 2018). This is because leukaemias in adults are more resistant in chemotherapy and there is a reduced treatment tolerance (Linker et al 2002, Rowe 2005). Most of the deaths in adults with ALL are attributed to disease relapse and significant treatment related complications (Horvat et al, 2018).

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

The policy recommends that rituximab be given in addition to the current chemotherapy regimens used for people with newly diagnosed ALL in adults. The proposal specifically focuses on adults being treated on intensive treatment regimes in line with the available clinical evidence. It is considered that the addition of this treatment reduces disease relapse rates, in what is considered a challenging group of patients to treat.

The policy has been developed in line with the findings of an evidence review and in accordance with NHS England's standard Methods for clinical commissioning policies.

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.	<p>ALL is a rare cancer which is more prevalent in children than adults. In the UK, there were 832 reported new cases of ALL in 2015 and 300 of these were in adults (Cancer Research UK, 2018).</p> <p>In children, cure rates for ALL are at 80%, however, five-year overall survival in adults is between 29% to 41% (Horvat et al, 2018).</p> <p>The policy specifically focuses on for the treatment of adults with ALL, being treated on intensive treatment protocols. This is in line with the available clinical</p>	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to 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>evidence which demonstrates that the introduction of rituximab results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who suffer from disease relapse.</p> <p>For this reason, implementation of the proposition is considered to have a potential positive impact on adults with this rare condition.</p>	
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	<p>Being diagnosed with cancer is defined as a disability under the Equality Act 2010. A review of available clinical evidence demonstrates that the introduction of rituximab results in adults' results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who suffer from disease relapse. For this reason, implementation of the policy is considered to have a potential positive impact.</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p>
Gender Reassignment and/or people who identify as Transgender	Not applicable	Not applicable.
Marriage & Civil Partnership: people married or in a civil partnership.	Not applicable.	Not applicable.

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
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Not applicable.	Not applicable.
Race and ethnicity ²	Not applicable.	Not applicable.
Religion and belief: people with different religions/faiths or beliefs, or none.	Not applicable.	Not applicable.
Sex: men; women	<p>ALL is more common in males than females with 58% of cases occurring in males and 42% of cases in females (Cancer Research UK, 2020).</p> <p>A review of available clinical evidence demonstrates that the introduction of rituximab results in adults' results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who suffer from disease relapse. For this reason, implementation of the policy is considered to have a potential positive impact.</p>	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.

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
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Not applicable.	Not applicable.

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	The policy is specifically for adults with ALL and for this reason is not considered to impact this group.	Not applicable.
Carers of patients: unpaid, family members.	The policy is considered to positively benefit carers of patients. This is because a review of available clinical evidence demonstrates that the introduction of rituximab results in adults' results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who suffer from disease relapse and will allow people with this condition to live longer, free from their cancer.	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.

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
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	People experiencing homelessness are more likely to suffer from a physical health problem and access to healthcare is known to be a problem for this group (Crisis, 2011). However, this policy is only for people diagnosed with disease and therefore no additional impact on this group is anticipated.	Not applicable.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	People involved in the criminal justice system would be able to access treatment through prison healthcare services. No specific impact is expected on this group as a result of implementation of the proposition.	Not applicable.
People with addictions and/or substance misuse issues	Not applicable.	Not applicable.
People or families on a low income	Cancer treatment is known to have a financial impact on patients with cancer with 4 in 5 people are affected by financial difficulties and incurring, on average, costs of £570 per month (Macmillan Cancer Care, 2017). A review of available clinical evidence demonstrates that the introduction of rituximab results in adults' results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.

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
	suffer from disease relapse. For this reason, implementation of the policy is considered to have a potential positive impact, allowing people to live free of their cancer for longer.	
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	The policy is specifically for people with a confirmed cancer diagnosis and already accessing healthcare. For this reason, there is no specific impact for people in this group.	Not applicable.
People living in deprived areas	There is evidence for a small association between ALL and deprivation for males in England, making this one of the few cancers where incidence rates are lower for more deprived males. There is no evidence for an association between the incidence of ALL and deprivation for females (Cancer Research UK, 2020). For this reason, this policy is not considered to impact on people living in deprived areas.	
People living in remote, rural and island locations	Not applicable.	Not applicable.
Refugees, asylum seekers or those experiencing modern slavery	Not applicable.	Not applicable.
Other groups experiencing health inequalities (please describe)	Not applicable.	Not applicable.

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 Public consultation on the draft proposition	<p>The introduction of the treatment was first recommended for not routine commissioning, and the draft proposition underwent a 30-day public consultation.</p> <p>There were eight responses to public consultation, of which four respondents did not provide any specific comments on the promotion of equality and reduction of health inequalities. The remaining four respondents raised the following concerns:</p> <ul style="list-style-type: none">• That the use of rituximab in this indication was common practice internationally and as such, had already become incorporated in the practice of some cancer centres in England. Respondents felt that this could result in an inequity of access and create a post-code lottery.• This policy specifically focused on treatment regimes in adults with this acute lymphoblastic leukaemia (ALL). Respondents stated that more novel treatments were being developed for younger patients, potentially disadvantaging older people with this disease who would not get access to the same treatments.	May – July 2019

		As a result of the much wider feedback from public consultation, the draft proposition (and the supporting clinical evidence) was reviewed by the Specialised Services Clinical Panel, and a revised proposition has been developed now recommending use of the treatment.	
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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	<p>Cancer Research UK, 2018. Available at: https://www.cancerresearchuk.org/about-cancer/acute-lymphoblastic-leukaemia-all/about</p> <p>Cancer Research UK, 2020. Available at: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/leukaemia-all/incidence</p> <p>Crisis, 2011 Available at:- https://www.crisis.org.uk/media/237321/crisis homelessness a silent killer 2011.pdf https://www.crisis.org.uk/ending-homelessness/homelessness-knowledge-hub/health-and-wellbeing/</p> <p>Macmillan Cancer Support, 2017 https://www.macmillan.org.uk/_images/MAC16493%20Money%20and%20Cancer%20policy%20report_tcm9-314796.pdf</p>	There is little evidence on the causes and risk factors associated with ALL as the disease is rare.
Consultation and involvement findings	<p>See comments in Section 5 regarding previous consultation.</p> <p>The revised proposition has been tested with stakeholders to confirm their support and has proceeded through the usual process. The EHIA was tested as part of the engagement process.</p>	
Research	Not applicable.	

Evidence Type	Key sources of available evidence	Key gaps in evidence
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The National Cancer Programme of Care, through its Clinical Reference Group structures and the support Policy Working Group for this specific group, has expert knowledge regarding the incidence and treatment of ALL.	

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?			
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?		X
The proposal may support?	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	Not applicable.	Not applicable.

10. Summary assessment of this EHIA findings

ALL is a rare cancer. The cancer predominantly affects children where cure rates are usually high, however, the cancer can occur at any age. In adults, ALL is more challenging to treat, and overall survival is much lower than in the younger age groups.

The policy recommends that rituximab should be added to the current standard of care for adults with ALL undergoing treatment with intensive chemotherapy.

The policy and clinical criteria defined in the policy are based on the findings of an evidence review which demonstrated that the introduction of rituximab results in adults' results in an improvement in event free survival by 13%; this ultimately will result in a reduction in the number of people who suffer from disease relapse and will allow people with this condition to live longer free from their cancer.

For this reason, adoption of the policy is considered to improve health outcomes for people with protected characteristics (based on age, disability, and sex). The policy may also potentially impact groups who face health inequalities (carers of patients) due to possible improvements in quality of life.

11. Contact details re this EHIA

Team/Unit name:	National Cancer Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Finance, Planning and Performance

Date EHIA agreed:	September 2020
Date EHIA published if appropriate:	September 2020