

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):** 2121 Obinutuzumab for systemic lupus erythematosus with secondary non-response to rituximab (adults and post-pubescent children)

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

Systemic lupus erythematosus (SLE, also known as lupus) is a long-term autoimmune condition (a condition where your immune system attacks the body) that causes swelling, soreness, and inflammation in the body. It affects the whole body including the skin, joints and internal organs and results in long-term ill health and premature mortality. Inadequately treated active disease causes damage of the affected organs and systems thus increasing complications, morbidity and can lead to both a higher and earlier death rate. The aim of treatment is to suppress disease activity, prevent organ damage such as kidney failure and improve quality of life.

Obinutuzumab is proposed for use in a particular subset of patients with severe lupus that is no longer responding to treatment with rituximab, the current last line therapy. This is called secondary non-response to rituximab. Obinutuzumab has the potential to be organ sparing or lifesaving in these patients who currently have no other treatment options.

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.	SLE is more common in young women and although the age-adjusted prevalence and incidence rates obtained in epidemiological studies are not homogeneous, the peak age of onset	All patients who meet the proposed policy inclusion criteria would be considered for obinutuzumab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

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	<p>among women seems to be between 15 and 40 years. Importantly however, the median age at diagnosis among women is 37-50 years, reflecting the delayed diagnosis.</p> <p>Lupus with age at onset > 50 years has been shown to have slightly lower disease activity compared with onset below 50 years of age.¹ The age-standardised incidence in the UK is 8.3/100,000/year for females and 1.4/100,000/year for males.²</p> <p>This policy provides a new treatment for those who have limited other options after rituximab failure, and therefore has a potential positive prognostic impact on this group of people. The phenomenon of secondary non-response to rituximab in SLE is an incredibly rare disease and specific epidemiological data relating to this is not known.</p> <p>The clinical experience of the Policy Working Group is that although rare, juvenile SLE (with an onset at <16 years</p>	<p>The policy does not allow access for children who are pre-pubescent, because there is no data to confirm safety in this sub-group of patients.</p>

¹ Verstappen S. Epidemiology of Lupus. LUPUS UK. 2022. Accessed on 1/6/22. Available at: <https://www.lupusuk.org.uk/medical/lupus-diagnosis-treatment/introduction-to-lupus/epidemiology-of-lupus/#:~:text=It%20is%20more%20difficult%20to,per%20100%2C000%20persons%20per%20year>.

² Tidy C. Patient. 2020. Accessed on 1/6/22. Available at: <https://patient.info/doctor/systemic-lupus-erythematosus-pro>

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
	old) does tend to be more severe, with high rates of rituximab use. This was also raised in stakeholder testing for rituximab. This could mean that higher proportions of this younger age population could benefit from obinutuzumab if post-pubescent.	
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Having a disability is not a risk factor for developing SLE, however, SLE often leads to disability. One American study has found that 1 in 3 people have been temporarily disabled by SLE and 1 in 4 people with SLE receive disability benefits ³ . A LUPUS UK membership survey found almost three-quarters of individuals had problems that limit their ability to carry out their usual daily activities. Only 15% of individuals worked full time with over 50% receiving some form of benefits and almost one-half of retirees retiring on medical grounds ⁴ . This policy provides a new treatment for	This policy outlines that obinutuzumab provision should be initiated and reviewed by a specialist SLE multi-disciplinary team of professionals who are responsible for ongoing patient care. The decision for obinutuzumab provision is dependent on shared decision making with the patient, their physician and multi-disciplinary team (MDT) assessment of suitability, which considers an individual's long-term health conditions and their unique circumstance, concurrent health needs, co-morbidities and potential for preventing disability in terms of primary, secondary and tertiary prevention (e.g., prevention of end stage renal failure (ESRF) and dependence on dialysis and transplant listing).

³ Daly R, Al Sawah S, Foster S, et al. FRI0420 Health Related Quality of Life in Lupus Differs by How Patients Perceive their Health and How Often They Experience Flares: Findings from a Cross-Sectional Online Survey in the United States. *Annals of the Rheumatic Diseases* 2015;74:578-579. Accessed on 1/6/22. Available at: https://ard.bmj.com/content/74/Suppl_2/578.3

⁴ Morgan C, Bland AR, Maker C, Dunnage J, Bruce IN. Individuals living with lupus: findings from the LUPUS UK Members Survey 2014. *Lupus*. 2018 Apr;27(4):681-687. doi: 10.1177/0961203317749746. Epub 2018 Jan 8. PMID: 29310537; PMCID: PMC5888773.

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	those who have limited other treatment options after rituximab failure, and therefore has a potential positive impact on this group of people. Moreover, it may limit potential development of disability through the reduction in disease activity and steroid burden.	
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be risk factors for SLE with secondary non-response to rituximab. The effects of SLE on those who identify as transgender are not well known. However, exogenous hormone therapy such as oestrogen could potentially impact disease. However, making obinutuzumab available may provide a treatment option for those who identify as transgender, who may not have any other options available.	All patients who meet the inclusion criteria would be considered for obinutuzumab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Marriage & Civil Partnership: people married or in a civil partnership.	This policy will promote access to obinutuzumab regardless of marriage status. Marriage status is not known to be a risk factor for SLE with secondary non-response to rituximab.	The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS).
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	As a disease which predominantly affects women in child-bearing years, SLE has a significant impact on pregnancy and	There is no safety data on obinutuzumab in pregnancy.

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>maternity. Many women with SLE may struggle to conceive, experience miscarriage or pre-term birth because of poorly controlled disease. Advice from health professionals often encourages women against conceiving until disease has been controlled for 6 months. Pregnancy and breastfeeding are also a time when many women may choose against disease controlling medication because of a lack of safety data at this time. This may lead to increased flares or complications.</p> <p>This policy provides a new treatment for those who have limited other options after rituximab failure, and therefore has a potential positive impact on women who wish to conceive. Moreover, it may limit potential development of complications during this time through the reduction in disease activity.</p>	<p>The policy suggests that individuals' suitability and balance of risks against clinical need is assessed and discussed by a specialised Rheumatology and/or Renal specialist MDT. This combined expertise could assist with the clinical challenges of considering obinutuzumab use in pregnancy and/or during breastfeeding for this complex cohort as SLE with secondary non-response to rituximab (which by definition is not controlled) places an individual and also child at increased risk of complications.</p>
Race and ethnicity ⁵	In the UK, lupus is more prevalent among people of Afro-Caribbean origin, followed	All patients who meet the inclusion criteria would be considered for obinutuzumab treatment. The policy

⁵ 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

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	<p>by Asians and then Caucasians. The highest incidence rates are seen in those of African-Caribbean descent, 31.4/100,000/year compared to 6.7/100,000/year for those of white European descent.⁶</p> <p>Ethnicity does not seem to purely affect the rate of occurrence of disease but also the clinical presentation, as black patients with lupus seem to be more commonly affected by discoid skin lesions, cellular casts in the urine and serositis. There is evidence that lupus nephritis is more prevalent in African and Hispanic Americans as well as Chinese and other Asians. Mortality attributed to lupus in the US is higher in African American patients and this has been mirrored in British studies. Rates of survival have markedly increased in the developed world in the past few decades, but poorer survival continues to be</p>	<p>is therefore not considered to have an adverse impact on this protected characteristic group. Given the higher prevalence of SLE, greater severity of SLE, adverse socioeconomic, language and cultural factors, and consequently the high rate of secondary non-response to rituximab, availability of Obinutuzumab is of greater importance to patients with non-European ancestry. A lack of availability of this treatment would have greater adverse impact on non-European ancestry groups.</p> <p>This policy aims to offer equitable access to all patients affected by SLE, noting that particular support would need to be targeted at patients from ethnic minority backgrounds with a higher incidence of SLE. This may include the services of an interpreter to help with any language barriers and to ensure that relevant information is accessible to all eligible individuals.</p>

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.

⁶ Tidy C. Patient. 2020. Accessed on 1/6/22. Available at: <https://patient.info/doctor/systemic-lupus-erythematosus-pro>

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	<p>recorded in India and amongst Afro-Caribbean patients.⁷</p> <p>The reasons for worse outcomes in patients with non-European ancestry may include socioeconomic factors or language and cultural factors. In line with the above, a substantial proportion of patients experiencing secondary non-response to rituximab are of non-European ancestry.</p>	
<p>Religion and belief: people with different religions/faiths or beliefs, or none.</p>	<p>This policy will promote access to obinutuzumab regardless of religion. Religion is not known to be a risk factor for SLE with secondary non-response to rituximab.</p>	<p>The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS).</p>
<p>Sex: men; women</p>	<p>SLE occurs primarily in women, in particular during childbearing years, when approximately 90% of those affected are female. Female gender is the strongest host factor in predicting occurrence of SLE. Although still evident in childhood and late-onset SLE, the female predominance rises with puberty,</p>	<p>All patients who meet the inclusion criteria would be considered for obinutuzumab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.</p>

⁷ Verstappen S. Epidemiology of Lupus. LUPUS UK. 2022. Accessed on 1/6/22. Available at: <https://www.lupusuk.org.uk/medical/lupus-diagnosis-treatment/introduction-to-lupus/epidemiology-of-lupus/#:~:text=It%20is%20more%20difficult%20to,per%20100%2C000%20persons%20per%20year>.

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
	peaking in young adulthood and then declines after the menopause. ⁸	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	This policy will promote access to obinutuzumab regardless of sexual orientation. Sexual orientation is not known to be a risk factor for SLE with secondary non-response to rituximab.	The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS).

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 ⁹	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 should be no direct negative or positive impact on this group as looked after children and young people have not been identified as high-risk group for SLE with secondary non-response to rituximab.	Children with SLE are managed in a specialist Rheumatology child-focused services. As outlined, the safety data for obinutuzumab does not include children, therefore this policy is adult focused, but would allow post-puberty access, for children and young people meeting the inclusion criteria. It is proposed that by use of the specialist Rheumatology MDT to determine suitability for obinutuzumab, individual health, physical, mental, emotional, educational, and developmental needs

⁸ Verstappen S. Epidemiology of Lupus. LUPUS UK. 2022. Accessed on 1/6/22. Available at: <https://www.lupusuk.org.uk/medical/lupus-diagnosis-treatment/introduction-to-lupus/epidemiology-of-lupus/#:~:text=It%20is%20more%20difficult%20to,per%20100%2C000%20persons%20per%20year.>

⁹ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ⁹	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
		of the child are taken into consideration if obinutuzumab was proposed as a treatment option.
<p>Carers of patients: unpaid, family members.</p>	<p>Carers may be indirectly affected by this policy.</p> <p>If the use of obinutuzumab is successful, it has the potential to improve an individual's health status if they can achieve disease control. Individuals in whom the disease is not suppressed have increased morbidity and mortality. Obinutuzumab may decrease the symptoms of SLE and therefore increase an individual's active participation, which may reduce their care needs allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with SLE by reducing the assistance required to complete work, family, and personal tasks.</p> <p>The use of obinutuzumab may require ongoing carer support to facilitate sessions to receive the drug and attend follow-up appointments. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of advanced SLE and are likely to be less</p>	<p>The policy recommends that the suitability of obinutuzumab as an intervention is assessed by the MDT team. This includes considering the support, care, and follow-up mechanisms a patient would require undergoing the intervention.</p> <p>If this policy is adopted, a commissioning plan will set out the pathway of provision for obinutuzumab which will include access at appropriately staffed centres.</p>

Groups who face health inequalities ⁹	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
	than for someone with uncontrolled disease.	
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	<p>This group may be less likely to enter the patient pathway, due to access issues (e.g., not registered with a General Practitioner).</p> <p>The lack of a permanent base for which drug delivery and follow-up appointments could be co-ordinated may be challenging in this cohort of patients.</p> <p>If identified, those who are homeless could be at risk of adverse outcomes, due to lack of access to services, incomplete follow-up as well as environmental conditions which may expose individuals to infection or potentially exacerbate underlying health issues with SLE.</p>	<p>NHS England is producing the obinutuzumab policy to increase access for anyone who may benefit from the intervention.</p> <p>Commissioned providers and their specialised Rheumatology Teams should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for homeless patients and facilitate access to the drug.</p>
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	This policy will promote access to obinutuzumab regardless of criminal status. Being in the criminal justice system is not known to be a risk factor for SLE with secondary non-response to rituximab.	The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS).
People with addictions and/or substance misuse issues	This policy will promote access to obinutuzumab regardless of addiction issues. Addiction and substance misuse	The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS). These issues of addiction and substance

Groups who face health inequalities⁹	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
	is not known to be a risk factor for SLE with secondary non-response to rituximab.	misuse and any impact on drug interactions, compliance and need for carer and inter-agency support and assistance will be considered by the MDT.
People or families on a low income	<p>This policy will promote access to obinutuzumab regardless of economic status. There is mixed data on whether low economic status is a risk factor for SLE, and this is an area which needs more research.</p> <p>. The majority of patients develop lupus early on in adulthood which can affect employment. This has important financial and personal implications as being in paid work increases self-esteem, social inclusion, and self-worth. In a review of 13 studies, it was estimated that 34% of those with SLE were work disabled, with ~50% of people losing their job within 15 years after diagnosis. Various patient characteristics have been found to be associated with work disability, including : being younger, African American, less educated, of lower socio-economic status, less physically functional, longer affected, severely affected, and having other patient reported outcomes such as</p>	<p>NHS England is producing the obinutuzumab policy to increase access for anyone who may benefit from the intervention.</p> <p>Commissioned providers should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to ensure adequate referral, access and attendance support for people or families on a low income.</p>

Groups who face health inequalities ⁹	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>pain, fatigue, anxiety, and neurocognitive involvement.¹⁰</p> <p>Moreover, those from disadvantaged socio-economic groups may experience more barriers in accessing treatment. Travel to hospital for infusions, time out of work and arrangements for childcare can be more difficult and may represent a disproportionate expenditure.</p> <p>By providing an extra treatment option, this policy may have a positive impact on this patients group.</p>	
<p>People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).</p>	<p>This group may find it hard to understand their condition and the benefits and risks associated with different treatment options.</p> <p>One study has shown that a lower educational level can be associated with poorer adherence to medication in SLE and it is possible that by offering an IV treatment which is needed very</p>	<p>Shared decision making is mandated within this policy and so clinicians will need to ensure that patients are well informed, this can be through various mediums including verbal as well as written shared decision-making tools, translated and Easy Read materials. The provision of obinutuzumab involves face-to-face assessment and delivery with verbal instruction, this can assist those with poor health or literacy skills.</p> <p>It is proposed that the developmental stage and a holistic assessment of an individual is undertaken to</p>

¹⁰ Verstappen S. Epidemiology of Lupus. LUPUS UK. 2022. Accessed on 1/6/22. Available at: <https://www.lupusuk.org.uk/medical/lupus-diagnosis-treatment/introduction-to-lupus/epidemiology-of-lupus/#:~:text=It%20is%20more%20difficult%20to,per%20100%2C000%20persons%20per%20year>.

Groups who face health inequalities ⁹	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
	infrequently, adherence might be improved ¹¹ .	assess their suitability and understanding of compliance barriers for obinutuzumab.
People living in deprived areas	<p>A national commissioning policy attempts to ensure there is equal access to treatment regardless of location, it will reduce variation in practice.</p> <p>Deprivation is not known to be a risk factor for SLE with secondary non-response to rituximab.</p>	The policy will increase geographic access of Rheumatology centres to obinutuzumab which is not currently available. Patients adverse socio-economic circumstance and impact on treatment delivery, monitoring and follow-up will be considered by the MDT.
People living in remote, rural and island locations	<p>A national commissioning policy attempts to ensure there is equal access to treatment regardless of location.</p> <p>As obinutuzumab requires IV infusion, this may be difficult for people living in remote, rural or island locations as it may require travel to the nearest delivering centre.</p>	If adopted, a commissioning plan will provide guidance for local service arrangements, which may include specialist oversight, to improve travel access for patients but with the necessary arrangements in place for reimbursement.
Refugees, asylum seekers or those experiencing modern slavery	This policy will promote access to obinutuzumab regardless of economic status. Being a refugee, asylum seeker or experiencing modern slavery are not	The policy will facilitate access to obinutuzumab if approved (as it is not currently available in the NHS).

¹¹ Prados-Moreno S, Sabio JM, Pérez-Mármol JM, Navarrete-Navarrete N, Peralta-Ramírez MI. Adherence to treatment in patients with systemic lupus erythematosus. Med Clin (Barc). 2018 Jan 12;150(1):8-15. English, Spanish. doi: 10.1016/j.medcli.2017.05.035. Epub 2017 Jun 29. PMID: 28669516.

Groups who face health inequalities⁹	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
	known to be risk factors for SLE with secondary non-response to rituximab.	
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 Stakeholder testing (planned)	There was a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods.	15 th -28 th November 2022
2 Public consultation	Not formally required	
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	An external review of available clinical evidence was undertaken to inform this policy.	Comparative evidence with other therapies. Cost effectiveness of the intervention. Factors to identify subgroups of patients who may benefit more than others. The impact of socio-economic factors on the development of SLE with secondary non-response to rituximab.
Consultation and involvement findings	The stakeholder testing results have been reviewed and amendments to the policy have been made accordingly. No further consultation was required by PPVAG.	
Research	No pending research is known	Not applicable
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which included SLE specialists, a public health specialist and patient and public voice representatives.	

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	X	
The proposal may support?			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 N/A	
2	
3	

10. Summary assessment of this EHIA findings

This policy does not unfairly discriminate those with a protected characteristic. The policy could provide a treatment option for patients who are currently experiencing the consequences of secondary non-response to rituximab in SLE which has currently limited or no treatment options to control the disease. These patients have a large unmet therapeutic need for an effective intervention post-rituximab and may experience the consequences of uncontrolled SLE, with high morbidity and increased mortality. This policy is informed by the evidence base and the clinical expertise of the policy working group.

A national commissioned policy aims to reduce variation in clinical practice promoting an equity of care nationally for those in which this intervention is indicated.