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):

2. Brief summary of the proposal in a few sentences

Idiopathic Multicentric Castleman Disease (iMCD) is a rare disorder of uncontrolled lymph node growth. It causes lymph node enlargement, organomegaly and constitutional symptoms such as weight loss and night sweats. It tends to follow a responding and relapsing pattern. There is currently no nationally commissioned standard of care for treatment of iMCD, with management of the condition being delivered at a local level with discrepancy between local centres. The usual course of treatment involves corticosteroids, rituximab and chemotherapy agents.

Siltuximab is a monoclonal antibody that blocks the action of interleukin-6 (IL-6) which is a major driver of the cytokine storm that causes the symptoms of iMCD. It has been proposed as a treatment for newly diagnosed iMCD, or patients with recurrent iMCD who have previously received treatment but not with siltuximab.

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.	Although incidence and prevalence of iMCD in the UK is unknown, Based on ONS 2019 estimation of population in	This policy aims to make siltuximab available for all adult patients with iMCD if clinically eligible.

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
	England (56.3million) the estimated incidence in England is 138 cases per year and prevalence 355 cases. IMCD is a disease predominantly of adults with a reported age at presentation of 49-66 years.[1] Distribution according to gender appears similar. There is limited data on the diagnosis of iMCD in children, although it can affect those at any age. The policy focuses on adults with iMCD as it is more common in the adult population.	Siltuximab is only licenced for use in adults. As outlined, the safety data for siltuximab does not include pre-pubescent children. Therefore, this policy is adult focused, but would allow post-puberty access, for children and young people meeting the inclusion criteria, as per Commissioning Medicines for Children in Specialised Services Policy (commissioning-medicines-children-specialised-services.pdf (england.nhs.uk)).
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Having a disability is not a risk factor for developing iMCD. iMCD can, in extreme cases, cause multi-organ failure with renal insufficiency, which can lead to the need for dialysis dependency or even death.[2]	This policy outlines that siltuximab provision should be initiated and reviewed by a specialist multi-disciplinary team of professionals who are responsible for ongoing patient care. The decision for siltuximab provision is dependent on shared decision making with the patient, their physician and MDT assessment of suitability, which considers an individual's long-term health conditions and their unique

[1] Lomas, O., Streetly, M., Pratt, G., Cavet, J., Royston, D., Schey, S. and Ramasamy, K., 2021. The management of Castleman disease. British Journal of Haematology, 195(3), pp.328-337.
[2] Ehsan N, Zahra F. Castleman Disease. [Updated 2022 Feb 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK576394/

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
		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 and dependence on dialysis and transplant listing).
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be risk factors for iMCD. The effects of iMCD on those who identify as transgender are not well known. However, exogenous hormone therapy such as oestrogen could potentially impact disease. However, making siltuximab 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 siltuximab 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 siltuximab regardless of marriage status. Marriage status is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	There is very limited data of iMCD affecting pregnant patients, as it mainly tends to occur in the late 40s-60s. This policy provides a new treatment for those with iMCD, and therefore has a	There is no safety data on siltuximab in pregnancy. However, the Summary of Product Characteristics provides clear advice to women considering siltuximab before and after childbirth and who are breastfeeding.[3]

[3] https://www.ema.europa.eu/en/documents/product-information/sylvant-epar-product-information_en.pdf

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
	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. It is also important to note that siltuximab provides another option for women of childbearing age who are concerned about their fertility. They might otherwise receive treatment with medications such as chemotherapy which can negatively impact fertility and are also teratogenic.	
Race and ethnicity[4]	This policy will promote access to siltuximab regardless of ethnicity. Ethnicity is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Religion and belief: people with different religions/faiths or beliefs, or none.	This policy will promote access to siltuximab regardless of religion. Religion is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

[4] 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
Sex: men; women	There has not been any evidence to show disease predominance in either sex. This policy will promote access to siltuximab regardless of sex. Sex is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	This policy will promote access to siltuximab regardless of sexual orientation. Sexual orientation is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

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[5]	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 iMCD.	As outlined, the safety data for siltuximab does not include pre-pubescent children, therefore this policy is adult focused, but would allow post-puberty access, for children and young people meeting the inclusion criteria, as per Commissioning Medicines for Children in Specialised Services Policy

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

Groups who face health inequalities[5]	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
		(commissioning-medicines-children-specialised-services.pdf (england.nhs.uk)). It is proposed that by use of the specialist haematology MDT to determine suitability for siltuximab, individual health, physical, mental, emotional, educational and developmental needs of the child are taken into consideration if siltuximab was proposed as a treatment option.
Carers of patients: unpaid, family members.	Carers may be indirectly affected by this policy. If the use of siltuximab 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. Siltuximab may decrease the symptoms of iMCD 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 iMCD by reducing the assistance required to complete work, family, and personal tasks.	The policy recommends that the suitability of siltuximab 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. If this policy is adopted, a commissioning plan will set out the pathway of provision for siltuximab which will include access at appropriately staffed centres.

Groups who face health inequalities[5]	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
	The use of siltuximab may require ongoing carer support to facilitate sessions to receive the drug and attend follow-up appointments.	
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	This group may be less likely to enter the patient pathway, due to access issues (e.g., not registered with a General Practitioner). 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. 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 iMCD.	NHS England is producing the siltuximab policy to increase access for anyone who may benefit from the intervention. Commissioned providers and their specialised Haematology/ Immunology 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, as well as clinical monitoring and follow-up appointments.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	This policy will promote access to siltuximab regardless of criminal status. Being in the criminal justice system is not known to be a risk factor for iMCD.	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
People with addictions and/or substance misuse issues	This policy will promote access to siltuximab regardless of addiction issues.	The policy will facilitate access to siltuximab if approved (as it is not currently available in the NHS). These issues of addiction and substance

Groups who face health inequalities[5]	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
	Addiction and substance misuse is not known to be a risk factor for iMCD.	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	This policy will promote access to siltuximab regardless of economic status. Economic status is not known to be a risk factor for iMCD. However, 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. By providing an extra treatment option, this policy may have a positive impact on this patients group.	NHS England is producing the siltuximab policy increase access for anyone who may benefit from the intervention. 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.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This group may find it hard to understand their condition and the benefits and risks associated with different treatment options.	Shared decision making should be used. This can be through various mediums including verbal as well as written shared decision-making tools, translated and Easy Read materials. The provision of siltuximab involves face-to-face assessment and delivery with verbal instruction. This can assist those with poor health or literacy skills. It is proposed that the developmental stage and a holistic assessment of an individual is undertaken to

Groups who face health inequalities[5]	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
		assess their suitability and understanding of compliance barriers for siltuximab.
People living in deprived areas	This policy attempts to ensure there is equal access to treatment regardless of location, it will reduce variation in practice. Deprivation is not known to be a risk factor for iMCD.	The policy will increase geographic access of Haematology centres to siltuximab 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. This will help to ensure, where practicable, treatment is proved as close to the home location of the patient as possible, with priority given to those in deprived areas who may find it challenging to arrange travel, or that travel arrangements are provided by ICBs.
People living in remote, rural and island locations	This policy attempts to ensure there is equal access to treatment regardless of location. As siltuximab requires intravenous infusion, this may be difficult for people living in remote, rural or island locations as it may require travel to the nearest delivering centre.	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 siltuximab regardless of economic status. Being a refugee, asylum seeker or	All patients who meet the inclusion criteria would be considered for siltuximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

Groups who face health inequalities[5]	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
	experiencing modern slavery are not known to be risk factors for iMCD.	
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

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	The policy underwent a two-week period of stakeholder testing between 1 December and 15 December 2022 with registered stakeholders for the Chemotherapy and Specialised immunology and allergy services Clinical Reference Groups (CRGs).	**December 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
Published evidence	An external review of available clinical evidence was undertaken to inform this policy.	Cost effectiveness of treatment Use of siltuximab in patients with ECOG-PS score ≥3
Consultation and involvement findings	The overall response from the stakeholders was that they agreed with equality and health inequalities impact assessment. It was noted that one stakeholder raised concerns of excluding pre-pubescent children from the policy.	The policy is restricted to adults and post-pubescent access as there is no evidence of safe use of siltuximab in children.
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 iMCD specialists, a public health specialist, a pharmacist and a patient and public voice 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?	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		
2		
3		

10. Summary assessment of this EHIA findings

This policy aims to make siltuximab available for all adult patients with iMCD if clinically eligible. The policy focuses on adults with iMCD and excludes pre-pubescent children with iMCD as siltuximab is not licenced for use in children, and there is no evidence to support its safe use in children. This policy will extend the use of siltuximab in iMCD to post-pubescent children and adolescents via the Commissioning Medicines for Children in Specialised Services Policy (commissioning-medicines-children-specialised-services.pdf (england.nhs.uk)). It is not thought to adversely impact on any other individuals from protected characteristic groups. The policy could provide a treatment option for patients who are currently experiencing the consequences of iMCD which has currently limited or no treatment options to control the disease. This policy is informed by the evidence base and the clinical expertise of the policy working group.

A national commissioned policy will reduce variation in clinical practice promoting an equity of care nationally for those in which this intervention is indicated. At present some trusts have agreed to fund the treatment for the occasional patient but other trusts have not agreed to do so.

11. Contact details re this EHIA

Team/Unit name:	Cancer Programme of Care
Division name:	Specialised Commissioning
Directorate name:	NHS England
Date EHIA agreed:	
Date EHIA published if appropriate:	