NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

1. Name of the proposal (policy, proposition, programme, proposal or initiative): Sirolimus for the treatment of patients with extracranial slow-flow vascular formations (2316)

2. Brief summary of the proposal in a few sentences

This policy outlines the commissioning criteria for sirolimus for the treatment of patients with extracranial slow-flow vascular malformations.

Slow-flow vascular malformations are inborn errors of formation of blood vessels caused by genetic mutations. The types of blood vessels affected in slow-flow vascular malformations include veins, lymphatics and capillaries. Supportive and medical measures are often not effective in providing satisfactory outcomes to patients with significant symptoms and thus invasive procedures are the mainstay of treatment. These invasive procedures can be potentially life changing and life threatening. Unfortunately, a small subset of patients will not respond to invasive interventions and remain refractory to treatment. Currently, no licensed medication exists to treat these patients. Sirolimus inhibits the mTOR pathway which is overactive as a result of genetic mutations in patients with certain slow-flow vascular malformations and has demonstrated encouraging clinical effectiveness in the literature. The policy recommends that sirolimus is available to patients with slow-flow vascular malformations who meet the inclusion criteria.

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.	Slow-flow vascular malformations can occur at any age and affect 1-1.5% of the population including babies, children, and young adults (Behravesh et al 2016). Unfortunately, many patients are refractory to standard care and can develop life-threatening consequences. The availability of sirolimus provides a therapy for patients who are refractory to standard care, regardless of age.	The inclusion criteria in the policy are for all ages, maximising equitable access to treatment.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Having a disability is not a risk factor for developing slow-flow vascular malformations. However, those with a disability may be impacted by access to treatment. Sirolimus is delivered by specialist centers and may require patients to travel to receive treatment. Current standard treatment also requires travel to specialist centers. Sirolimus requires regular monitoring via blood tests. It is acknowledged that sirolimus trough levels are not performed in every laboratory, and therefore people with disabilities may face increased travel costs to attend hospitals for blood tests and follow up. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address	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 living with disabilities. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

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
	the consequences of refractory slow-flow vascular malformations (including complications).	
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be risk factors for slow-flow vascular malformations. This policy is expected to have a positive effect on the overall survival and overall outcomes of all eligible patients, regardless of gender reassignment and being transgender. However, these patients may face barriers to getting a diagnosis.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.
Marriage & Civil Partnership: people married or in a civil partnership.	Marriage status is not known to be a risk factor for slow-flow vascular malformations. This policy will promote access to sirolimus regardless of marriage status.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Slow-flow vascular malformations can affect individuals of childbearing age and therefore has the potential for significant impact on pregnancy and maternity. <u>Pregnancy</u>	The Summary of Product Characteristics (SmPC) advises against the use of sirolimus in pregnancy. Any pregnant woman not treated with sirolimus will continue to receive best standard of care in line with current clinical practice. Breast-feeding should be discontinued during treatment with sirolimus.

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 are no or limited amount of data from the use of sirolimus in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Sirolimus should not be used during pregnancy unless clearly necessary. Effective contraception must be used during sirolimus therapy and for 12-weeks after sirolimus has been stopped. <u>Breast-feeding</u> Following administration of radiolabeled sirolimus, radioactivity is excreted in the milk of lactating rats. It is unknown whether sirolimus is excreted in human milk. Because of the potential for adverse reactions in breast-fed infants from sirolimus, breast-feeding should be discontinued during treatment. <u>Fertility</u> Impairments of sperm parameters have been observed among some patients treated with sirolimus. These effects have been reversible upon discontinuation of sirolimus in most cases. <u>Impact</u>	The SmPC advises individuals of childbearing potential must use effective contraception during 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
	Aside from the positive impact this would have on individuals in general who would be eligible to receive this treatment, sirolimus may have an adverse impact on pregnant women in whom treatment may cause toxicity to the foetus both from a physical and mental health perspective. It may also have an adverse impact on the mental and psychological health of individuals who wish to conceive.	
Race and ethnicity[1]	No significant difference in incidence has been observed according to race and ethnicity for slow-flow vascular malformations. This policy offers sirolimus maintenance regardless of race or ethnicity, and therefore is anticipated to have a positive impact.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.

[1] 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
Religion and belief: people with different religions/faiths or beliefs, or none.	Religion is not known to be a risk factor for slow-flow vascular malformations. This policy will promote access to sirolimus regardless of religion.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.
Sex: men; women	No significant difference in incidence has been observed according to sex for slow-flow vascular malformations. This policy offers patients with slow-flow vascular malformations sirolimus maintenance regardless of sex.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be a risk factor for slow-flow vascular malformations. This policy will promote access to sirolimus regardless of sexual orientation.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.

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[2]	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 may have a potential adverse impact on looked after children and young people, because: 1. Looked-after children and young people may face additional barriers to accessing therapeutics. Therefore, they may have less chance of meeting the policy eligibility criteria to receive sirolimus. 2. If eligible for treatment, looked after young people will require someone to bring them to appointments, provide consent for treatment, and guide administering of sirolimus, which may be more difficult than for children with a permanent guardian or carer.	The adverse impact of this policy on looked after children and young people is acknowledged; there are currently no recommendations to address this identified impact.
Carers of patients: unpaid, family members.	Carers may be indirectly affected by this policy. If the use of sirolimus is successful, it has the potential to improve the health status of the individual.	This policy recommends that the suitability of sirolimus as an intervention is assessed by the MDT. This includes considering the support, care and follow-up mechanisms a patient would require undergoing the intervention in order to reduce any impact on this group. In addition, the MDT will need to consider the individual patient and carer needs.

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

Groups who face health inequalities[2]	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
	This policy may benefit carers who support patients with slow-flow malformations by reducing the assistance required to complete work, family, and personal tasks. Sirolimus maintenance may therefore increase an individual's active participation, which may reduce their care needs allowing them to participate more in activities of daily living. Sirolimus requires regular monitoring via blood tests. It is acknowledged that sirolimus trough levels are not performed in every laboratory, and therefore carers may face an increased burden, supporting attendance for blood tests and follow up. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of refractory slow-flow vascular malformations (including complications).	Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
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 physical health problems and access to healthcare is difficult for this group (Crisis, 2011). This policy offers patients with slow-flow vascular malformations sirolimus maintenance regardless of homelessness.	Commissioned providers and their specialised vascular teams should work with the patient and other relevant agencies to mitigate risk for homeless patients and facilitate access to the drug, as well as clinical monitoring and follow-up appointments.

Groups who face health inequalities[2]	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
	However, those who are homeless may be impacted by access to treatment. Sirolimus is delivered by specialist centers and may require patients to travel to receive treatment. Current standard treatment also requires travel to specialist centers. Sirolimus requires regular monitoring via blood tests. It is acknowledged that sirolimus trough levels are not performed in every laboratory, and therefore people who are homeless may face increased travel costs to attend hospitals for blood tests and follow up. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of refractory slow-flow vascular malformations (including complications).	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Being in the criminal justice system is not known to be a risk factor for slow-flow vascular malformations. This policy will promote access to sirolimus regardless of criminal status.	All patients who meet the inclusion criteria would be considered for sirolimus treatment. There should not be any adverse impact on this protected characteristic group through creating this policy.

Groups who face health inequalities[2]	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 with addictions and/or substance misuse issues	Addiction and substance misuse is not known to be a risk factor for slow-flow vascular malformations. People with addiction/and or substance misuse issues might find it harder to maintain engagement with services. This policy will promote access to sirolimus regardless of addiction issues.	The policy will facilitate access to sirolimus for extracranial slow-flow vascular malformations. The issues of addiction and substance misuse and any impact on drug interactions, compliance and need for carer and inter-agency support should be considered by a specialist MDT.
People or families on a low income	Chronic disease is known to have a financial impact on patients and many people are affected by financial difficulties. Sirolimus requires regular monitoring via blood tests. It is acknowledged that sirolimus trough levels are not performed in every laboratory, and therefore people or families on a low income may face increased travel costs to attend hospitals for blood tests and follow up.	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 of families on a low income. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Individuals with poor literacy/health literacy may not have access to the same information and resources as those more literate. This may limit their agency and ability to access sirolimus.	The existence of a clear referral process into an MDT should enable access to this drug. Shared decision making should be used using appropriate mediums including verbal, written

Groups who face health inequalities[2]	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
		shared decision-making tools, translated, and Easy Read materials. The provision of treatment should be provided in a way to assist those with poor health literacy skills. A holistic assessment of an individual should be undertaken by the prescribing physician to assess their suitability and understanding of compliance barriers for sirolimus.
People living in deprived areas	Deprivation is not known to be a risk factor for slow-flow vascular malformations, however, may be a factor for delayed diagnosis. Sirolimus requires regular monitoring via blood tests. It is acknowledged that sirolimus trough levels are not performed in every laboratory, and therefore people living in deprived areas may face increased travel costs to attend hospitals for blood tests and follow up. Patients' adverse socio-economic circumstances and impact on treatment delivery, monitoring and follow-up should be considered by the MDT.	The existence of a clear referral process into an MDT should enable access to the drug. Patients' socio-economic circumstance will be considered by an appropriately constituted MDT. This will help to ensure treatment is proved as close to the home location of the patient as possible. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)

Groups who face health inequalities[2]	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	Sirolimus is typically offered by specialist centres that are usually located in larger, urban areas. Sirolimus also requires regular monitoring, and it is known that sirolimus trough levels may not be done in all laboratories. This may limit access to people living in remote, rural and island locations as they will have to travel regularly for monitoring.	Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
Refugees, asylum seekers or those experiencing modern slavery	Being a refugee, asylum seeker or experiencing modern slavery are not known to be risk factors for slow-flow vascular malformations. This policy will promote access to sirolimus regardless of economic status.	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 refugees, asylum seeker or experiencing modern slavery. Providing centres need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme: Healthcare Travel Costs Scheme (HTCS) - NHS (www.nhs.uk)
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 (planned)	This involved clinical staff, professional groups, patients, patient groups and industry groups who expressed an interest in this topic area.	6th August-1st September 2024
2	Policy working group	The involved input from a range of clinical staff who have experience in treating both adults and children with slow-flow vascular formations.	
3	Public Consultation (planned)		

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.	No evidence was found on cost effectiveness.
Consultation and involvement findings		N/A
Research	No pending research is known	N/A
Participant or expert knowledge	A Policy Working Group was assembled which included specialists in vascular anomalies, a public health specialist, a	N/A

Evidence Type	Key sources of available evidence	Key gaps in evidence
For example, expertise within the team or expertise drawn on external to your team	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	
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	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	Cost Effectiveness	Further research is required

2		
3		

10. Summary assessment of this EHIA findings

This assessment should summarise whether the findings are that this policy will or will not make a contribution to advancing equality of opportunity and/or reducing health inequalities, if no impact is identified please summarise why below. No specific risk factors were identified for extracranial slow-flow vascular malformations. It was noted that these vascular malformations can occur at all ages and equally in both sexes. A policy for sirolimus for refractory malformations is anticipated to offer an improvement in the outcomes of these patients. There are no anticipated adverse impacts of commissioning sirolimus for this population.

11. Contact details re this EHIA

Team/Unit name:	Internal Medicine Programme of Care
Division name:	Specialised Commissioning
Directorate name:	System Development Group
Date EHIA agreed:	
Date EHIA published if appropriate:	