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):** 2268 Dabrafenib for BRAF^{V600E} mutated histiocytic neoplasms

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

Histiocytic neoplasms are very rare and complex blood cancers that can lead to chronic morbidity and death. They can occur at any age, are fatal in 10% of children with high-risk disease at one year and in up to 70% of adults at five years.

There are no standard treatments approved by NICE or NHS England for the treatment of histiocytic neoplasms. All drugs currently used are unlicensed.

The intervention is dabrafenib, an oral BRAF inhibitor. Dabrafenib may be given in the outpatient clinic with intermittent monitoring and offers a potentially life-saving line of therapy for those with high-risk, refractory disease.

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.	Histiocytic neoplasms affect people of all ages, but specific subtypes have higher incidences at certain ages. Infants (children under 1 year) have the highest incidence of Langerhans cell histiocytosis and older adults have the highest incidence of Erdheim Chester disease. This policy is expected to have a positive effect on the overall survival and overall outcomes of both children and adults, with side-effects that are apparent but less harmful of those caused by chemotherapy or untreated progressive disease.	This policy aims to make dabrafenib available for all children and adults. This policy states that initiation of treatment is discussed and agreed by the National Histiocytosis Advisory Panel which is constituted of paediatric and adult specialists qualified to make inclusive decisions for patients of all ages.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Following a diagnosis of cancer, the individual is defined as having a disability under the Equality Act 2010. Furthermore, patients with histiocytic neoplasms are frequently disabled by the consequences of their disease on musculoskeletal, endocrine, pulmonary and neuropsychiatric health. Dabrafenib is taken orally, which enables administration in the outpatient setting. This significantly supports Service Users with disabilities to complete their course of treatment by greatly reducing the	This policy states that initiation of treatment is discussed and agreed by the National Histiocytic Advisory Panel and a specialist MDT. This will enable the appropriate selection of patients who will benefit from the intervention and mean the drug will be stopped in those gaining no benefit or where the side effect profile is too great. This should mean the greatest benefit is gained from improving physical and mental health and reducing the impact of a long-term condition.

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
	frequency required to attend tertiary referral day-case and inpatient services. The policy is expected to have a positive impact on this protected characteristic group by ameliorating symptoms and improving access to treatment.	
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be associated with histiocytic neoplasms in any way. This policy will promote access to dabrafenib regardless of gender reassignment and being transgender.	Not applicable (no impact known). All patients who meet the clinical inclusion criteria would be considered for dabrafenib 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.	Marriage status is not known to be associated with histiocytic neoplasms in any way. This policy will promote access to dabrafenib regardless of marriage status.	Not applicable (no impact known). All patients who meet the clinical inclusion criteria would be considered for dabrafenib 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.	Dabrafenib is contra-indicated in pregnancy and breast-feeding. Women of child-bearing age should normally use non-hormonal contraception during and for 4 weeks after stopping treatment. This is a potential adverse impact of the policy but note that this restriction on use	The potential adverse impact of the policy on this protected characteristic group cannot be reduced without compromising patient safety. Patients of childbearing age should discuss suitable non-hormonal contraception with their clinician for the duration of dabrafenib 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
	in pregnancy and breast-feeding also applies to all other chemotherapy drugs currently in use to treat histiocytic neoplasms. Therefore, the potential adverse impact of the policy is no greater than that of the current standard of care.	
Race and ethnicity[1]	Ethnicity is linked to the incidence of Langerhans cell histiocytosis which is more common in Hispanic and less common in Black ethnic groups, but race and ethnicity have no bearing on eligibility for treatment with Dabrafenib. The policy intends equitable access to this treatment for all racial and ethnic groups	Not applicable (no impact known). All patients who meet the clinical inclusion criteria would be considered for dabrafenib 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.	Religion is not known to be associated with histiocytic neoplasms in any way. This policy will promote access to dabrafenib regardless of religion.	Not applicable (no impact known) All patients who meet the clinical inclusion criteria would be considered for dabrafenib treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

[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
Sex: men; women	Histiocytic neoplasms are more common in males that females. LCH in children is about twice as common in boys and ECD in adults is about four-times more common in men. Sex has no bearing on eligibility for treatment with Dabrafenib (with the exception for pregnancy and breast-feeding). The policy intends equitable access to this treatment for both sexes.	Not applicable (no impact known). All patients who meet the clinical inclusion criteria would be considered for dabrafenib treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be associated with histiocytic neoplasms in any way. The policy will promote access to dabrafenib regardless of sexual orientation.	Not applicable (no impact known). All patients who meet the clinical inclusion criteria would be considered for dabrafenib 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[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	The incidence of Langerhans cell histiocytosis is significantly higher in children and highest in infants (children under 1 year old). This policy is expected to have a positive effect on the overall survival and overall outcomes of looked after children and young people, with side-effects that are apparent but less harmful of those caused by chemotherapy or untreated progressive disease. Dabrafenib is taken orally, which enables administration in the outpatient setting. This significantly supports looked after children and young people to complete their course of treatment by greatly reducing the frequency required to attend tertiary referral day-case and inpatient	The National Histiocytosis Advisory Panel includes physicians who manage children and young people. The individual health, physical, mental, emotional, educational, and developmental needs of the patient will be taken into consideration if dabrafenib was proposed as a treatment option. The availability of an oral treatment is likely to have a positive impact on this inequality group. Commissioned providers and their specialised cancer teams should work with other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for looked after children and young people and facilitate access to the drug, as well as clinical monitoring and follow-up appointments.

[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
	services and is likely to increase compliance in this group.	
Carers of patients: unpaid, family members.	Dabrafenib has the potential to improve an individual's health status and reduce morbidity. Dabrafenib may reduce the care needs of patients, allowing them to participate more in activities of daily living. Additionally, as an oral medication, dabrafenib will reduce hospital attendance for intravenous infusions, thereby potentially relieving pressures on carers. This policy may benefit carers who support patients with histiocytic neoplasms by reducing the assistance required to complete work, family and personal tasks and reduce the need for emergency or unscheduled care or prolonged admissions to address the consequences of advanced neoplasms.	All patients who meet the clinical inclusion criteria would be considered for dabrafenib treatment. The policy recommends that the suitability of dabrafenib as an intervention is assessed by the National Histiocytosis Advisory Panel. This includes considering the support, care, and follow-up mechanisms a patient would require undergoing the intervention. The availability of an oral treatment is likely to have a positive impact on this inequality group.
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. In addition, chronic ill-health such as that caused by histiocytic neoplasms, is associated with homelessness. They may also find it	All patients who meet the clinical inclusion criteria would be considered for dabrafenib treatment. The availability of an oral treatment is likely to have a positive impact on this inequality group. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low

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
	more difficult to maintain engagement with a course of treatment. Dabrafenib is taken orally, which enables administration in the outpatient setting. This potentially supports Service Users to complete their course of treatment by greatly reducing the frequency required to attend tertiary referral day-case and inpatient services and is likely to increase compliance in this group.	Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS). Commissioned providers and their specialised cancer 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.	Dabrafenib is taken orally, which enables administration in the outpatient settings. This potentially supports Service Users to complete their course of treatment if they are involved in the criminal justice system. This policy will promote access to dabrafenib regardless of criminal status.	All patients who meet the clinical inclusion criteria would be considered for dabrafenib treatment. The availability of an oral treatment is likely to have a positive impact on this inequality group. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS).
People with addictions and/or substance misuse issues	Addiction and substance misuse is an increased risk in patients with histiocytic neoplasms who often experience a high level of chronic pain. Dabrafenib is taken orally, which enables administration in the outpatient setting. This potentially supports Service Users by greatly reducing the frequency	The policy will facilitate access to dabrafenib through a National Histiocytosis Advisory Panel. Members of the panel are skilled in the management of chronic pain, opiate addiction, and potential drug interactions. These issues of addiction and substance misuse and any impact on drug interactions, compliance and need for carer and inter-agency support and assistance will be

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
	required to attend tertiary referral day-case and inpatient services is likely to increase compliance in this group. This policy will promote access to dabrafenib in the context of holistic care and attention to addiction issues.	carefully considered in making treatment recommendations. The availability of an oral treatment and access to specialist guidance is likely to have a positive impact on this inequality group.
People or families on a low income	Overall incidence of a specific histiocytic neoplasm subtype is significantly higher in more deprived areas, as well as being associated with worse outcomes[3] (Liu et al, 2022). The policy acknowledges this and therefore potentially aims to reduce burden of disease in this group positively. Dabrafenib is taken orally, which enables administration in the outpatient setting. This potentially supports Service Users to complete their course of treatment by greatly reducing the frequency required to attend tertiary referral day-case and inpatient services and is likely to increase compliance in this group.	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. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme (LIS) and the Healthcare Travel Costs Scheme (HTCS).

[3] "The (age-standardised incidence rate) ASR was 1.50 per million for those who resided in the least deprived areas, compared to 1.86 for those who resided in the most deprived areas (IRR 1.27, 95% CI 0.99–1.62; p = 0.06). The estimated increase in relative incidence per deprivation quintile (deprivation quintile fitted as a continuous variable), assuming a linear trend, was 6% (IRR 1.06, 95% CI 1.01–1.13; p = 0.03, adjusted for age, sex and region). When compared to the model with deprivation quintile fitted as a categorical variable, there was no evidence of departure from a linear trend (p = 0.31). There was variation in incidence with region, but small numbers meant there was greater uncertainty in the estimates thus preventing further assessment." (Liu et al, 2022)

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 poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Poor literacy or health literacy is an increased risk in patient with histiocytic neoplasms who may experience neurocognitive disturbances. The intervention offers the first reported treatment potentially capable of reversing neurocognitive deficits in histiocytosis. Although this group may find it hard to understand their condition and the benefits and risks associated with different treatment options, the policy has a very high potential positive impact on this inequality group**.**	Commissioned providers should foster shared decision making using appropriate mediums including verbal, written 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 or 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 dabrafenib.
People living in deprived areas	Overall incidence of a specific histiocytic neoplasm subtype is significantly higher in more deprived areas, as well as being associated with worse outcomes (Liu et al, 2022). The policy acknowledges this and therefore potentially aims to reduce burden of disease in this group positively. Dabrafenib is taken orally, which enables administration in the outpatient setting. This potentially supports Service Users to complete their course of treatment if they have difficulties in travelling to an acute	The existence of a clear referral process into an MDT should enable access to the drug. The policy will increase geographic access of providers of dabrafenib which is not currently available. Patients' socio-economic circumstance will be considered by an appropriately constituted MDT. This will help to ensure treatment is provided as close to the home location of the patient as possible. Access to travel arrangements provided by Integrated Care Boards (ICBs) needs to be part of this. This policy may also confer additional benefit to patients on top of available support schemes that help towards the cost of travel for treatment, including the NHS Low Income Scheme

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
	setting for treatment and is likely to increase compliance in this group.	(LIS) and the Healthcare Travel Costs Scheme (HTCS).
People living in remote, rural and island locations	This may have a positive impact on people in this category as dabrafenib is taken orally, which enables administration in the outpatient setting. This potentially supports Service Users by greatly reducing the frequency required to attend tertiary referral day-case and inpatient services and is likely to increase compliance in this group.	The existence of a clear referral process into an MDT should enable access to the drug. The policy will increase geographic access of providers of dabrafenib which is not currently available. 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	Being a refugee, asylum seeker or experiencing modern slavery are not known to be associated with histiocytic neoplasms in any way. This policy will promote access to dabrafenib regardless of refugee 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.
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

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	PPV Representation	A PPV representative was on the working group of this policy	**March – July 2024**
2	Stakeholder Testing	Stakeholder testing for this policy took place for 14 days in July/August 2024, following a successful outcome at Clinical Panel	**July/August 2024**
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 Larger and longer-term studies on the effect of the intervention.
Consultation and involvement findings	This policy was sent out for a 14-day period of stakeholder testing.	
Research	No pending research is known	Cost effectiveness of treatment Larger and longer-term studies on the effect of the intervention based in the UK.
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 sarcoidosis specialists, a range of medical clinicians, 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	
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	Cost effectiveness of intervention versus usual care	research
2	Clearer understanding of the demographics of patients with ECD, RDD and JXG.	research

10. Summary assessment of this EHIA findings

This policy aims to provide a treatment option for patients of all ages who are currently experiencing the consequences of histiocytic neoplasms. It is not thought to adversely impact on any other individuals from protected characteristic groups. As a policy commissioned nationally, this aims to potentially promote equity of access and treatment across the country, thereby reducing the variation of outcomes for people with histiocytic neoplasms.

11. Contact details re this EHIA

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