

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

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

- 1. Name of the proposal (policy, proposition, programme, proposal or initiative): Dabrafenib and trametinib in the treatment of BRAF-mutated anaplastic thyroid cancer (Adults). URN 2110.**
- 2. Brief summary of the proposal in a few sentences**

This Clinical Commissioning Policy outlines the commissioning criteria for the use of dabrafenib and trametinib in people with BRAF-mutated anaplastic thyroid cancer (ATC) (Adults).

ATC is a rare, aggressive form of thyroid cancer that typically presents late and often with metastases. The disease is associated with an extremely poor prognosis, with a median survival of about 3 months following diagnosis (Lin et al, 2019). ATC is almost universally fatal within one year of diagnosis.

People usually have a high symptom burden related to invasion of local structures by progressive disease, such as pain, noisy or difficulty in breathing, shortness of breath, hoarseness and a persistent cough. These symptoms lead to a poor quality of life and patients typically die of difficulty breathing due to airway compromise.

There is currently no specific treatment for ATC and most patients are managed with best supportive care and palliative radiotherapy. A small proportion of patients that are medically fit may have palliative chemotherapy; typically, with a platinum/taxane combination administered intravenously, however, response rates are usually poor (less than 15%) and duration of response is short. Less than 5% of people with BRAF mutated ATC have tumours which are suitable for surgical resection with curative intent at diagnosis.

The combination of dabrafenib and trametinib is a form of targeted therapy against BRAF-mutated cancers and currently has marketing authorisation for use in the treatment of BRAF-mutated melanoma. Emerging evidence suggests that dabrafenib and



trametinib in the treatment of BRAF-mutated anaplastic thyroid cancer improves survival and may potentially downstage tumours, rendering them amenable to curative resection.

This policy proposes that the combination of dabrafenib and trametinib is made available to treat patients with inoperable BRAF-mutated ATC.

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 |
|--|---|--|
| <p>Age: older people; middle years; early years; children and young people.</p> | <p>ATC is strongly related to age, with the highest incidence rates being in individuals aged above 70 years. Survival rates are also poorer in this population (Lin et al, 2019). As this is a rare subtype of thyroid cancer, no age-specific incidence rates have been reported.</p> <p>Implementation of the policy is considered to have a potential positive impact on this protected characteristic group because:</p> <ul style="list-style-type: none"> • it enables access to an effective treatment for a condition which disproportionately impacts older people. • The treatment may reduce the symptom burden associated with | <p>None – the policy criteria are based on clinical evidence.</p> |

| 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>the condition and, in turn, the need to treat those symptoms.</p> <ul style="list-style-type: none"> In line with the clinical evidence and best practice in the management of cancer in older people (Macmillan “Age old excuse” 2012), the policy criteria include a focus on fitness for treatment using an Eastern Cooperative Oncology Group (ECOG) Performance Status score, rather than age. <p>There are no adverse impacts associated with this policy on this protected characteristic group.</p> | |
| <p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p> | <p>Following a diagnosis of cancer, the individual is defined as having a disability under the Equality Act 2010.</p> <p>Dabrafenib and trametinib are oral medicines which can be administered in an outpatient or community setting. This may support individuals with disabilities to complete their course of treatment if they have difficulties in attending an acute setting for palliative radiotherapy or chemotherapy.</p> | <p>None – the policy criteria are based on clinical evidence.</p> |

| 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 |
|--|--|--|
| | Implementation of the policy is considered to have a potential positive impact on individuals with disabilities. There are no adverse impacts associated with this policy on this protected characteristic group. | |
| Gender Reassignment and/or people who identify as Transgender | No differential impact identified in this population. | None – the policy criteria are based on clinical evidence. |
| Marriage & Civil Partnership: people married or in a civil partnership. | No differential impact identified in this population. | None – the policy criteria are based on clinical evidence. |
| Pregnancy and Maternity: women before and after childbirth and who are breastfeeding. | <p>No differential impact identified in this population.</p> <p>The epidemiology of ATC indicates that it is predominantly a disease which occurs in older individuals and is relatively rare in people of childbearing age.</p> <p>Pregnancy is covered within the Summary of Product Characteristics (SmPC) for both dabrafenib and trametinib and the policy directs clinicians to refer to this when considering the use of and/or using the treatments.</p> | None – the policy criteria are based on clinical evidence. |

| 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 |
|---|---|--|
| Race and ethnicity ¹ | No differential adverse impact identified in this population. | None – the policy criteria are based on clinical evidence. |
| Religion and belief: people with different religions/faiths or beliefs, or none. | No differential adverse impact identified in this population. | None – the policy criteria are based on clinical evidence. |
| Sex: men; women | <p>ATC has a higher incidence in females; however, survival rates are similar in male and female individuals.</p> <p>Under this policy, dabrafenib and trametinib will be available to individuals who meet the inclusion criteria irrespective of their sex. Therefore, there is no differential impact on this group.</p> | None – the policy criteria are based on clinical evidence. |
| Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual. | No differential impact identified in this population. | None – the policy criteria are based on clinical evidence. |

4. Main potential positive or adverse impact for people who experience health inequalities summarised

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.

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 inequalities² | 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 | No differential impact identified in this population. ATC is predominantly a disease of older individuals. Dabrafenib and trametinib will be available to young people over the age of 12 years if they meet the clinical criteria outlined in the policy. | None – the policy criteria are based on clinical evidence. |
| Carers of patients: unpaid, family members. | Symptoms of ATC affect breathing and ability to eat and may impair the ability of individuals to carry out their caring duties. Dabrafenib and trametinib provide a treatment option in suitable patients and have been shown to improve symptoms of ATC. Implementation of this policy should have a positive impact on carers, either because they have the condition or because they care for people with the condition. There are no adverse impacts associated with this policy on this group. | None - the policy enables access to the treatment, in line with clinical evidence. |

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 |
|--|---|--|
| <p>Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.</p> | <p>People experiencing homelessness are more likely to face a range of barriers in accessing health and care and are more likely to suffer from a physical health problem (The King's Fund, Feb 2020).</p> <p>Dabrafenib and trametinib are oral medicines and can be administered in an outpatient or community setting. This may help this treatment be easier to adhere to for individuals experiencing homelessness that are diagnosed with the condition.</p> <p>There are no adverse impacts associated with this policy on this group.</p> | <p>None - the policy enables access to the treatment, in line with clinical evidence.</p> |
| <p>People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.</p> | <p>People in the criminal justice system have access to prison healthcare, including referrals to secondary care. Ex-offenders also have access to primary care services.</p> <p>There are no differential impacts identified in this population.</p> | <p>None – the policy criteria are based on clinical evidence.</p> |

| Groups who face health inequalities² | 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 | <p>There is no known association with addictions and/or substance misuse for ATC.</p> <p>There are no differential impacts on this group.</p> | None – the policy criteria are based on clinical evidence. |
| People or families on a low income | <p>Cancer treatment is known to have a financial impact on patients with cancer with 4 in 5 people are affected by financial difficulties and incurring, on average, costs of £570 per month (Macmillan Cancer Care, 2017). These extra costs have been attributed to travel to and from hospital appointments, an increase in household bills from being at home more, paying for extra support such as help at home and the impact of loss of income.</p> <p>Dabrafenib and trametinib are oral medicines which can be administered in an outpatient or community setting. This is anticipated to lead to a reduction in the need for regular hospital visits which is likely to reduce the financial impact of having BRAF mutated ATC.</p> | None - the policy enables access to the treatment, in line with clinical evidence. |

| 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 |
|---|--|--|
| | Implementation of the policy is likely to have a positive impact on individuals with BRAF mutated ATC. There are no anticipated adverse impacts associated with this policy. | |
| People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills). | There are no differential impacts on this group. | None – the policy criteria are based on clinical evidence. |
| People living in deprived areas | <p>Around 50-60 new cases of ATC are diagnosed each year in England, of which 20 are associated with a BRAF mutation. There is no known association with deprivation with ATC.</p> <p>The introduction of an oral medicine, which can be administered in an outpatient or community setting, should result in fewer hospital visits and reduce the costs associated with treatment. Therefore, the policy should have a positive impact on this group. There are no anticipated adverse impacts on this group.</p> | None - the policy enables access to the treatment, in line with clinical evidence. |
| People living in remote, rural and island locations | The introduction of oral medicines, which can be administered in an outpatient or community setting, should result in fewer hospital visits. Therefore, the policy | None - the policy enables access to the treatment, in line with clinical evidence. |

| 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 |
|--|---|--|
| | <p>should have a positive impact on this group.</p> <p>There are no anticipated adverse impacts on this group.</p> | |
| Refugees, asylum seekers or those experiencing modern slavery | <p>There are no differential impacts on this group.</p> <p>The policy will apply to eligible patients diagnosed with ATC who are already accessing health care.</p> | None – the policy criteria are based on clinical evidence. |
| Other groups experiencing health inequalities (please describe) | No other disproportionately impacted populations have been identified. | None – the policy criteria are based on clinical evidence. |

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 | Stakeholder testing was undertaken with clinical staff, professional groups, patients, patient groups and industry groups who have expressed an interest in chemotherapy to offer a wide range of opinions and backgrounds The three thyroid cancer specific groups (The British Thyroid Foundation, Butterfly Thyroid Cancer Trust and British Thyroid Association) were contacted to seek feedback to the policy. | May 2022 |
| 2 | Policy working group | The policy working group that has developed the policy is made up of specialist clinicians, a public health consultant, a pharmacist and a commissioner. | Throughout the policy development process |
| 3 | PPV Advisory Group | The PPVAG were consulted on the stakeholder engagement findings and the need to undertake further consultation – which was not indicated in this case. | May 2022 |

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 |
|----------------------------------|--|---|
| <p>Published evidence</p> | <p>An external review of available clinical evidence was undertaken to inform this policy.</p> <p>Cream, J. et al 2020 Delivering health care to people who sleep rough, The Kings Fund https://www.kingsfund.org.uk/sites/default/files/2020-02/Delivering-health-care-people-sleep-rough.pdf</p> <p>The Equality Act 2010. [Online]. London: The Stationery Office. [Accessed 7th May 2022) Available https://www.legislation.gov.uk/ukpga/2010/15/contents</p> <p>Lin B, Ma H, Ma M, et al. The incidence and survival analysis for anaplastic thyroid cancer: a SEER database analysis. Am J Transl Res. 2019;11(9):5888-5896.</p> <p>MacMillan 2012. Age old excuse report https://www.macmillan.org.uk/documents/getinvolved/campaigns/ageoldexcuse/ageoldexcusereport-macmillancancersupport.pdf</p> <p>Summary of Product Characteristics (SmPC), [Online], Available from https://www.ema.europa.eu/en/glossary/summary-product-characteristics</p> | <p>No evidence on cost-effectiveness of the intervention.</p> <p>No evidence of improvement on quality of life or performance status scores, however the PWG agrees that the evidence of downstaging of tumours is a proxy for improvement in quality of life (given that symptoms from invasion of adjacent structures is a key driver of deterioration in quality of life).</p> |

| Evidence Type | Key sources of available evidence | Key gaps in evidence |
|--|---|---|
| Consultation and involvement findings | Stakeholder engagement has taken place and a report of the findings is available. | Of the 3 thyroid cancer specific charities, only 1 submitted a response. This is a potential gap. |
| Research | No pending research is known about. | Not applicable. |
| Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team | Through the Cancer Programme of Care and its Clinical Reference Group structures supporting the policy working group with its expert knowledge regarding anaplastic thyroid cancer and chemotherapy/targeted therapy. | Not applicable. |

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? | | | |
| The proposal may support? | x | x | |
| Uncertain whether the proposal will support? | | | 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 None noted. | N/A |
| 2 | |
| 3 | |

10. Summary assessment of this EHIA findings

The policy is likely to provide an overall positive impact on patients with inoperable BRAF-mutated ATC. Those who suffer from debilitating symptoms and poor quality of life will have a treatment option that has the potential to downstage tumours (rendering some potentially operable) and prolong survival, with improved quality of life. This policy ensures access to an effective and acceptable treatment option that may improve adherence and therefore outcomes in certain populations that are more likely to face health inequalities.

11. Contact details re this EHIA

| | |
|-------------------------------------|-----------------------------------|
| Team/Unit name: | National Cancer Programme of Care |
| Division name: | Specialised Commissioning |
| Directorate name: | Finance |
| Date EHIA agreed: | |
| Date EHIA published if appropriate: | |