

Engagement Report

Topic details

Title of policy or policy statement:	Dabrafenib and trametinib for the treatment of BRAF mutated anaplastic thyroid cancer (ATC) (Adults)
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy
URN:	2110

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Anaplastic thyroid cancer (ATC) is a rare, aggressive form of thyroid cancer, which is usually diagnosed at a late stage, when the cancer has spread to the surrounding area and to other parts of the body.

ATC usually occurs in older people and following diagnosis, patients typically survive for an average of three months.

There is currently no specific treatment for ATC. Curative intent surgical resection may be feasible in $\leq 5\%$ of patients if the cancer is detected or diagnosed in the early stages. Most patients are offered supportive treatment, palliative radiotherapy and chemotherapy to help manage their symptoms due to the late stage of their disease.

Chemotherapy is sometimes considered in patients who are considered medically fit enough to tolerate the side effects to try to reduce the volume of the tumour in the absence of more effective treatments. The existing chemotherapy regimen is a platinum/taxane combination which is not curative. Response rates are poor, with less than 15% of tumours shrinking and the duration of response is short.

The proposed new treatment is a combination of two drugs, dabrafenib and trametinib. This is a targeted treatment, where the drugs act against specific cancer cells, such as those with the BRAF mutation. This combination is currently approved in the USA for the treatment of melanoma (a type of skin cancer), certain lung cancers and ATC that carry a BRAF mutation. In the UK, the combination is approved for use in BRAF-mutated melanoma and certain lung cancers with a BRAF mutation.

There is some evidence which shows that using dabrafenib and trametinib to treat locally advanced ATC (when the cancer has spread to the surrounding structures) with the BRAF mutation can reduce the size of the tumour. This means that surgery to remove the tumour and cure the cancer may be possible.

3. Engagement

The Programme of Care agreed that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision was assured by the Patient Public Voice Advisory Group.

Respondents were asked the following consultation questions:

- Do you support the proposition for dabrafenib and trametinib for anaplastic thyroid cancer to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- The impact assessment has been completed to identify the impact of moving from current pathways of care to the one proposed in the draft policy proposition taking into account the anticipated patient numbers, treatment, cost of the treatment and capacity within providers, Do you think that the impact assessment fairly reflects the likely patient numbers, treatment, cost of treatment and the capacity within providers? If not, what do you think is inaccurate?
- The patient pathway describes the patient's journey through the health system to receive current treatment for this condition. Do you think that the policy proposition accurately describes the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential positive and negative impacts on equality and health inequalities which might arise as a result of the proposed policy that have been described?
- Are there any changes or additions you think need to be made to this document, and why?
- Did you comment on the stakeholder testing for this policy proposition?

4. Engagement Results

Copies of the policy proposition, Equality and Health Inequalities Impact Assessment (EHIA), evidence review, and patient impact assessment were sent to the following groups to comment:

- Policy Working Group which was established as per NHS England policy
- The Chemotherapy Clinical Reference Group (CRG), which contains representatives of the relevant Royal Colleges and professional societies, including:
 - British Oncology Pharmacy Association
 - UK Oncology Nursing Society

- o Joint Collegiate Council for Oncology

Registered stakeholders of the Chemotherapy CRG were sent copies of the draft policy proposition documents for comment (n=c690).

The British Thyroid Foundation, Butterfly Thyroid Cancer Trust and British Thyroid Association were personally contacted and invited to participate and provide feedback.

A total of three responses were received from:

- a) The company who manufacture dabrafenib and trametinib
- b) NHS Trust
- c) The British Thyroid Foundation

Respondent (a) advised they were unable to comment on the policy proposition because it relates to an unlicensed use of medicines, but informed NHS England that the evidence review incorporated the interim analysis for the Phase II study (Subbiah et al 2018) and that the updated analysis was published earlier in 2022, containing the full enrolment of 36 patients reporting approximately 4 years of safety follow up data.

Respondents (b) and (c) were both in support of the policy proposition. The proposition was described as offering a treatment option for a condition that currently does not have an effective treatment and has the potential to offer eligible patients some hope of an improvement in symptoms and survival in an otherwise rapidly fatal disease.

In line with the 13Q assessment it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Cancer PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
Additional data, linked to the Phase II study (Subbiah et al 2018), is available for review.	The additional data was published after the Evidence Review was completed. However, in line with NHS England's standard processes for policy development the additional data was reviewed by a Public Health Consultant and a standalone report completed. The conclusion of the review was that the additional data does not alter the recommendations contained within the policy proposition.
Impact Assessment	
No comments	
Current Patient Pathway	

No concerns were raised with the description and presentation of the patient pathway. Respondents noted that the treatment would provide patients with potential improvements in symptoms and survival, in an otherwise rapidly fatal disease.	No response required – respondents supported the policy proposition documentation.
Potential impact on equality and health inequalities	
No issues or concerns were raised by respondents.	No response required – respondents supported the policy proposition documentation.
Changes/addition to policy	
No comments	No response required – respondents supported the policy proposition documentation.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

Following the stakeholder responses received, no changes have been made to the policy proposition.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

There are no remaining concerns.