Engagement Report

Topic details

Title of policy or policy statement:	Pembrolizumab in combination with dabrafenib and trametinib for patients with BRAF mutated anaplastic thyroid cancer (Adults)
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy
URN:	2418

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 and aggressive form of thyroid cancer, which is a cancer of an organ that releases hormones in the neck. ATC usually presents at an advanced stage or as an emergency as symptoms, such as a neck mass, dysphagia (difficulty swallowing), dysphonia (difficulty controlling the voice), hoarseness and shortness of breath, are only evident once the tumour is a significant size and compressing on local, vital structures. ATC predominantly affects older patients and therefore, patients often present with multiple comorbidities and are unfit for treatment. As a result, ATC has a poor prognosis with median survival being only 3.16 months (Lin et al 2019).

Patients diagnosed with ATC are referred to a specialist thyroid cancer multidisciplinary team. As ATC is usually diagnosed at a late stage and tumours are close to vital structures, ATC is rarely operable. Treatment for ATC is therefore most commonly delivered by a thyroid oncologist. A small number of patients may be suitable for palliative chemotherapy or radiotherapy to help them with symptoms or limit disease progression. However, the benefit for patients undergoing these treatments is marginal. For ATCs that carry a BRAF mutation, targeted therapies can be used. The introduction of dual therapy with dabrafenib and trametinib has significantly improved ATC prognosis. However, patients eventually develop resistance to this treatment combination leading to disease progression.

The policy proposition recommends the use of pembrolizumab in combination with dabrafenib and trametinib, of which the latter two drugs are already commissioned by

NHS England. Pembrolizumab works by stopping ATC's ability to evade the host's immune system. This slows uncontrolled cell division and tumour growth. Pembrolizumab is typically administered as an infusion once every 3 to 6 weeks and is given alongside dabrafenib and trametinib, rather than alone. Emerging evidence shows that pembrolizumab, in combination with dabrafenib and trametinib, improves short-term survival, compared to dual therapy alone (Hamidi et al 2024, Iver et al 2018).

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent a two-week stakeholder testing between the 20th June 2025 to 4th July 2025 with registered stakeholders from:

- Chemotherapy Clinical Reference Group
- Royal College of Radiologists
- Royal College of Physicians
- British Thyroid Association
- UK Thyroid Study Group
- Butterfly Thyroid Cancer Trust

Respondents were asked the following consultation questions:

- Do you support the proposal for routine commissioning based on the evidence review and within the criteria set out in the proposal?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Summary present a true reflection of the patient and carers lived experience of this condition?
- Do you have any further comments on the proposal?
- Please declare any conflict of interests relating to this document or service area.

The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided 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 has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

The policy proposition received 4 stakeholder responses:

- 3 Patients
- 1 Clinician

Given the rarity of ATC, this number, as well as the range of stakeholders represented, this was deemed a sufficient response. In addition, the policy working group included the Chief Executive of the Butterfly Thyroid Cancer Trust as the PPV representative. That individual is also a trustee of the British Association of Endocrine and Thyroid Surgeons. All stakeholders that responded supported the policy proposition and felt that this offered patients a positive change.

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	
All stakeholders agreed that all the relevant evidence had already been identified.	No further action required.
Policy Proposition	
All stakeholders supported the policy proposition and noted that the policy would have a positive impact on patients.	No further action required.
Two stakeholders highlighted that this additional chemotherapy option is a particularly positive change given the limited treatment options for ATC.	No further action required.
Impact Assessment	
All stakeholders agreed with the Equality and Health Impact Assessment (EHIA) and Patient Impact Assessment (PIA).	No further action required.
Current Patient Pathway	
There were no comments about the patient pathway.	No further action required.
Potential impact on equality and health inequalities	
One stakeholder commented that the impact on equality and health inequalities was well documented, however the Health Equity Assessment Tool (HEAT) could be incorporated.	The EHIA and HEAT tool are based on similar principles where the potential (positive or negative) impact of the policy on groups who face health inequalities is assessed systematically and then later evaluated. The same groups are assessed in the EHIA and HEAT tools. The EHIA is the tool that is

	used as outlined in the published Methods: National clinical policies.
Changes/addition to policy	
No changes were suggested to the policy proposition.	No further action required.

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

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

- **Policy Proposition:** No amendments made.
- **EHIA:** No amendments made.
- **PIA:** No amendments made.

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

No.