

## Equality and Health Impact Assessment

### Dabrafenib and trametinib for the treatment of inoperable BRAF-mutated anaplastic thyroid cancer (OW27)

AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 07/03/2024

1.	AWTTC contact details	Tel: 02921 826900 Email: <a href="mailto:awttc@wales.nhs.uk">awttc@wales.nhs.uk</a>
2.	State the objectives of the project.	Assessment of dabrafenib and trametinib for the treatment of inoperable BRAF-mutated anaplastic thyroid cancer via the One Wales Medicines assessment process
3.	Evidence and background information considered. For example: <ul style="list-style-type: none"> <li>• population data</li> <li>• staff and service users' data, as applicable</li> <li>• needs assessment</li> <li>• engagement and involvement findings</li> <li>• research</li> <li>• good practice guidelines</li> <li>• participant knowledge</li> <li>• list of stakeholders and how stakeholders have engaged in the development stages</li> <li>• comments from those involved in the designing and development stages</li> </ul>	<p>Anaplastic thyroid cancer (ATC) is a very rare form of thyroid cancer that progresses quickly. For those patients with inoperable disease there are few treatment options. Clinicians in Wales submitted dabrafenib and trametinib as a treatment option for ATC with BRAF V600E mutation for consideration through the One Wales process. They consider there is an unmet need in Wales and have identified a cohort of patients who could benefit from this treatment. Therefore, dabrafenib and trametinib was considered suitable for assessment though the One Wales Medicines process.</p> <p>Dabrafenib and trametinib are inhibitors of enzymes called protein kinases. Dabrafenib inhibits BRAF kinases with activating codon 600 mutations (BRAF V600E). Trametinib inhibits MEK-1 and MEK-2 kinases.</p> <p>Combination treatment with dabrafenib and trametinib is routinely commissioned in NHS England and NHS Scotland to treat inoperable ATC. In</p>



<p><a href="#">Population pyramids</a> are available from Public Health Wales Observatory.</p>	<p>Wales, the current route of access for treating ATC with dabrafenib plus trametinib is through the individual patient funding request (IPFR) process.</p> <p>Due to the aggressive nature of this disease metastatic spread is usually present with only 10–15 % of patients having disease confined to the thyroid gland at time of presentation. Therefore, treatment aims to try to slow the growth of the cancer, and to improve symptoms and people’s quality of life. Treatments include radiotherapy, surgery, chemotherapy and immunotherapy, as well as supportive care to manage symptoms. Surgery to resect the cancer is only suitable for a small number of people, and might be recommended if the cancer has not spread outside the thyroid gland.</p> <p>Based on All Wales pathology data, clinicians in Wales estimate between 5 and 10 people are diagnosed with ATC in Wales each year with approximately 50% having the BRAF V600E mutation. Therefore, they estimate that between 2 and 5 patients per year would be eligible for treatment with dabrafenib and trametinib. This is similar to the predicted annual incidence of 1–2 ATC cases per million, which results in an estimated 3–6 patients diagnosed annually with ATC in Wales. Of those diagnosed with ATC, published data indicates that approximately 25-45% will have the BRAF V600E mutation. The proportion of patients that are likely to be inoperable has not been reported but using a measure of the incidence of metastatic disease (for whom a reasonable proportion would be inoperable) the All Wales Therapeutics and Toxicology Centre (AWTTC) estimates that around 1 to 3 patients would be eligible for treatment with dabrafenib and trametinib each year.</p> <p>An evidence status report produced by AWTTC summarising the clinical and cost effectiveness data, budget impact and societal, patient and service impact of dabrafenib and trametinib for this indication will be sent to the company and to clinicians for comment. Clinicians and patient organisation representatives are invited to attend the One Wales Medicines Assessment</p>
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Group (OWMAG) meeting. The constitution of the OWMAG is available [online](#).

*References:*

- *European Medicines Agency. Assessment Report: Mekinist®. Procedure No.: EMEA/H/C002643. Aug 2018. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/mekinist> . Accessed Jan 2024.*
- *European Medicines Agency. Assessment Report: Tafinlar®. Procedure No.: EMEA/H/C002604. Aug 2018. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/tafinlar> . Accessed Jan 2024.*
- *NHS England. Clinical Commissioning Policy: dabrafenib and trametinib in the treatment of patients with BRAF-mutated anaplastic thyroid cancer (2110) [221006P]. Oct 2022. Available at: <https://www.england.nhs.uk/publication/clinical-commissioning-policy-dabrafenib-and-trametinib/> . Accessed Jan 2024.*
- *Healthcare Improvement Scotland. National Cancer Medicines Advisory Group (NCMAG) Programme. NCMAG107 Dabrafenib plus trametinib. Advice document v1.0. Oct 2023. Available at: NCMAG advice documents (healthcareimprovementscotland.scot). Accessed Jan 2024.*
- *Macmillan Cancer Support. Anaplastic thyroid cancer. Jun 2021. Available at: <https://www.macmillan.org.uk/cancer-information-and-support/thyroid-cancer/anaplastic> . Accessed Jan 2024.*
- *Cleere EF, Prunty S, and O'Neill JP. Anaplastic thyroid cancer: improved understanding of what remains a deadly disease. The Surgeon. Feb 2024. Epub Oct 2023.;22(1):e48-e53.*
- *Nagaiah G, Hossain AKM, Mooney CJ et al. Anaplastic thyroid cancer: a review of epidemiology, pathogenesis, and treatment. Journal of Oncology. 2011;2011:Article ID 542358. Available at: <https://www.hindawi.com/journals/jo/2011/542358/> .*



**AWTTC**

All Wales Therapeutics & Toxicology Centre  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

4.	Who will this project affect?	Patients and staff
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### 5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on their 'protected characteristics'.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<p><b>5.1 Age</b> For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"><li>• under 18 years;</li><li>• between 18 and 65 years;</li><li>• over 65 years.</li></ul>	<p>We do not expect a potential negative, or unequal, impact on people based on their age.</p> <p>[Note: For prescription medicines we expect the prescriber to have prescribed or advised their use within the terms of their UK marketing authorisations. Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring needs for the medicine. These are explained in the <a href="#">Summary of Product Characteristics (SmPC)</a> for the medicine or the <a href="#">British National Formulary</a>. Healthcare professionals should follow relevant</p>	<p>None</p>	<p>none</p>



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines. This includes considering the contraindications, warnings, monitoring requirements and other safety recommendations for the medicine ( <a href="#">MHRA guidance on off-label or unlicensed use of medicines</a> ) ]		
<b>5.2 Persons with a disability as defined in the Equality Act 2010</b> Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.	We do not expect a potential negative, or unequal, impact on people with a disability.	All related documents published on the AWTTC website will meet accessibility requirements.  Any patient-facing materials will be also be produced as easy read booklets in Welsh and English.	



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by).</b>
<b>5.3 People of different genders:</b> Consider men, women, people undergoing gender reassignment. <b>N.B.</b> Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender.	We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment.	none	none
<b>5.4 People who are married or who have a civil partner.</b>	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.	none	none
<b>5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.</b> They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Women of childbearing potential must use effective methods of contraception during therapy and for 2 weeks following discontinuation of dabrafenib and 16 weeks following the last dose of	Prescribers should take account of the Summary of Product Characteristics (SmPC) when prescribing any medicines for women who are pregnant, or who are breastfeeding.	The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment. This will be identified for consideration of any change to the advice at the next review if



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	<p>trametinib when given in combination with dabrafenib. Dabrafenib may decrease the efficacy of oral or any systemic hormonal contraceptives and an effective alternative method of contraception should be used. <a href="#">SmPC</a></p> <p>Dabrenfib and trametinib are not usually recommended for women who are pregnant or who want to become pregnant. Please refer to the dabrafenib <a href="#">SmPC</a> and trametinib <a href="#">SmPC</a></p> <p>The manufacturer of dabrafenib and trametinib advises that a decision must be made whether to discontinue breastfeeding or discontinue treatment, taking in to account the benefit of breast-feeding for the child and the benefit of</p>		<p>there is a change to the current advice for pregnant and breastfeeding women.</p>





How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	therapy for the woman. Please refer to the dabrafenib <a href="#">SmPC</a> and trametinib <a href="#">SmPC</a>		
<b>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</b>  <a href="#">The Runnymede Trust</a>	We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin.	none	none
<b>5.7 People with a religion or belief or with no religion or belief.</b> The term 'religion' includes a religious or philosophical belief.  <a href="#">Implications of religious beliefs on selection of medicines (BMJ)</a>  <a href="#">In practice: guidance on religion, personal values and beliefs</a> (General Pharmaceutical Council)	We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief.	none	none
<b>5.8 People who are attracted to other people of:</b> <ul style="list-style-type: none"><li>the opposite sex (heterosexual);</li><li>the same sex (lesbian or gay);</li></ul>	We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.	none	none



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<ul style="list-style-type: none"><li>• both sexes (bisexual).</li></ul> <a href="#">Stonewall</a>			
<b>5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.</b>	We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language. Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	
<b>5.10 People according to their income related group.</b>	None expected. This is an oral treatment with similar monitoring requirements to conventional therapy.		
<b>5.11 People according to where they live.</b>	None expected. This is an oral treatment with similar monitoring requirements to conventional therapy. Current treatment options, such as radiotherapy and chemotherapy have a low response rate and additional		



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	toxicities. Both require treatment in a hospital setting.		
<b>5.12 Consider others who face health inequalities, such as:</b> <ul style="list-style-type: none"><li>• Looked after and accommodated children and young people</li><li>• Carers: paid/unpaid, family members</li><li>• People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&amp;Bs</li><li>• People involved in the criminal justice system: offenders in prison or on probation, ex-offenders</li><li>• People with addictions and substance misuse problems</li><li>• People who have poor literacy</li><li>• People living in remote, rural and island locations</li></ul>	We do not expect a potential negative, or unequal, impact on others who face health inequalities		



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by).</b>
<b>5.13 Consider any other groups and risk factors relevant to this project.</b>	None identified		

## 6. HIA - How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
<b>6.1 People being able to access the service offered.</b>	We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.		
<b>6.2 People being able to improve or maintain healthy lifestyles.</b>	We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles.		
<b>6.3 People in terms of their income and employment status.</b>	We will consider the impact of the disease on a person's employment status. Patient organisations, the committee's lay members and clinicians have the opportunity to inform the group about how the disease affects the employment of patients and the effects of treatment.	Patient organisation summaries will only be available where patient confidentiality is ensured.	



<b>How will the project impact on, or affect:</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/ mitigation</b>	<b>Actions taken (and who by)</b> <i>Refer to where the mitigation is included in the document, as appropriate.</i>
<b>6.4 People in terms of their use of the physical environment.</b>	We do not expect a potential negative, or unequal, impact on people in terms of their use of the physical environment.		
<b>6.5 People in terms of social and community influences on their health.</b>	We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health.		
<b>6.6 People in terms of macro-economic, environmental and sustainability factors.</b>	We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors.	The pharmaceutical industry aligns medicine manufacturing with sustainability practices and in line with the policy on <a href="#">climate change-international federation of pharmaceutical manufacturers association.</a>	



**7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.**

<b>7.1 Please summarize the potential positive and/or negative impacts of the project.</b>	None expected. This is an oral treatment with similar monitoring requirements to conventional therapy.
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**Action plan for mitigation or improvement and implementation**

	<b>Action</b>	<b>Lead(s)</b>	<b>Timescale</b>	<b>Actions taken (state who by)</b>
<b>7.2 What are the key actions identified as a result of completing the EqHIA?</b>	<ul style="list-style-type: none"> <li>consult with clinical experts in Wales;</li> <li>consult with patient organisations, patients and carers in Wales (or the UK);</li> <li>invite comments through the AWTTC website.</li> </ul>	AWTTC	March-April 2024	
<b>7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?</b>	No			
<b>7.4 What are the next steps?</b>	<ul style="list-style-type: none"> <li>Process continues unchanged</li> <li>Publish report of this impact assessment on the AWTTC website.</li> <li>Monitor and review</li> </ul>			



	<b>Action</b>	<b>Lead(s)</b>	<b>Timescale</b>	<b>Actions taken (<i>state who by</i>)</b>
<b>7.5 Review of project and EqHIA</b>		AWTTC	April 2025	

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.