

## Equality and Health Impact Assessment

### **Nivolumab and ipilimumab for the neoadjuvant treatment of patients with resectable macroscopic stage III melanoma with $\geq 1$ pathologically proven lymph node metastasis and up to 3 in-transit metastases.**

**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: 21/11/2025**

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.	<p>To assess the use of nivolumab and ipilimumab for the neoadjuvant treatment of patients with resectable macroscopic stage III melanoma with <math>\geq 1</math> pathologically proven lymph node metastasis and up to 3 in-transit metastases.</p> <p>AWTTC will conduct a literature search for evidence and prepare an evidence status report (ESR) for an assessment under the One Wales Medicines process. The ESR will summarise: current use of nivolumab and ipilimumab in NHS Wales; evidence of clinical effectiveness; safety considerations; budget impact; and equity of access across Wales and the rest of the UK.</p> <p>AWTTC will request the views of relevant patient organisations and send the ESR to the company (marketing authorisation holder) and to clinicians in Wales for comment. Clinicians, company representatives and patient organisation representatives will be invited to attend the meeting of the One</p>



		Wales Medicines Assessment Group (OWMAG) to consider the ESR. The OWMAG constitution is available <a href="#">online</a> .
<b>3.</b>	<p>Evidence and background information considered. For example:</p> <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><a href="#">Population pyramids</a> are available from Public Health Wales Observatory.</p>	<p>Melanoma is a type of skin cancer arising from melanocytes within the skin. In <a href="#">stage III melanoma</a>, melanoma cells have spread into the skin, lymph vessels, or lymph glands. <a href="#">In-transit metastases</a> are melanoma cells that have spread more than 2 cm from the primary melanoma but not as far as the nearest lymph node. General <a href="#">symptoms</a> of advanced melanoma include weight loss, loss of appetite, and fatigue.</p> <p>Patients with malignant melanoma harbour either a BRAF V600 mutation-positive, or BRAF mutation wild type tumour. According to clinicians, the BRAF gene mutation test is currently a routine test that's undertaken across NHS Wales, and 40% of the Welsh population harbour the BRAF V600 mutation.</p> <p>The <a href="#">incidence</a> of stage III melanoma of the skin gradually increased in Wales between 2011 and 2022. The five-year unstandardised net <a href="#">survival</a> for stage III melanoma of the skin diagnoses in Wales between 2017-2021 was 77.7% (for people aged 15 – 99 years old).</p> <p>The current treatment pathway for resectable macroscopic stage III melanoma in Wales is resection surgery, followed by adjuvant immunotherapy. The Cancer Network Immunotherapy Group have identified an unmet need for a neoadjuvant treatment option in NHS Wales, which would be treatment sparing for some patients.</p>
<b>4.</b>	Who will this project affect?	People in Wales who develop resectable macroscopic stage III melanoma with ≥1 pathologically proven lymph node metastasis and up to 3 in-transit metastases, and their families and carers.

## 5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

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></p> <p>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 Summary of Product Characteristics (SmPC) for <a href="#">nivolumab</a> and <a href="#">ipilimumab</a> for the medicine or the British</p>	<p>Any patient-facing resources produced will be provided on the AWTTC website in accessible formats that can be printed.</p>	<p>N/A</p>



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	<p>National Formulary for <a href="#">nivolumab</a> and <a href="#">ipilimumab</a>. Healthcare professionals should follow relevant 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>) ]</p>		
<p><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.</p>	<p>We do not expect a potential negative, or unequal, impact on people with a disability.</p>	<p>All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will also be produced in easy read formats in Welsh and English.</p>	<p>N/A</p>



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<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.	N/A	N/A
<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.	N/A	N/A
<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.	Nivolumab is not recommended for women who are pregnant or who want to become pregnant, unless the clinical benefit outweighs the risk. Please refer to the <a href="#">SmPC</a> .	Prescribers should take account of the Summary of Product Characteristics (SmPC) when prescribing any medicines for women who are	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



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	<p>It is advised that patients use effective contraception while being treated with nivolumab and for at least 5 months following the last dose of nivolumab, if they are a woman who could become pregnant.</p> <p>The manufacturer of both nivolumab and ipilimumab advises that it is not known whether nivolumab or ipilimumab gets into breast milk. A risk to the breast-fed infant cannot be excluded and patients should consult their doctor for further advice.</p> <p>Ipilimumab is not recommended for women who are pregnant or who want to become pregnant, unless the clinical benefit outweighs the risk. Please refer to the <a href="#">SmPC</a>.</p>	<p>pregnant, or who are breastfeeding.</p>	<p>the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women.</p>



<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>
<p><b>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</b></p> <p><a href="#">The Runnymede Trust</a></p>	<p>We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin.</p> <p>People of different race and ethnicities can have varying responses to medicines.</p>	<p>Note in the project document that people of different race and ethnicities can have varying responses to medicines.</p> <p>Any patient information leaflets produced will be available in Welsh and English.</p>	
<p><b>5.7 People with a religion or belief or with no religion or belief.</b></p> <p>The term 'religion' includes a religious or philosophical belief.</p> <p><a href="#">Implications of religious beliefs on selection of medicines (BMJ)</a></p> <p><a href="#">In practice: guidance on religion, personal values and beliefs</a> (General Pharmaceutical Council)</p>	<p>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.</p> <p>Some medicines are made from certain animal products and people might not want to take them because of religion or belief.</p>		
<p><b>5.8 People who are attracted to other people of:</b></p> <ul style="list-style-type: none"><li>• the opposite sex (heterosexual);</li><li>• the same sex (lesbian or gay);</li></ul>	<p>We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.</p>		



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<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. These will be provided on the AWTTC website in accessible formats that can be printed.	
<b>5.10 People according to their income related group.</b>	We do not expect a potential negative, or unequal, impact on people based on their income-related group.  In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income-related group.		



<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>5.11 People according to where they live.</b>	<p>We do not expect a potential negative, or unequal, impact on people based on where they live.</p> <p>Some patients may require fewer appointments because of the reduced need for treatment after surgery, which could positively impact those who must travel long distances to attend appointments.</p>		
<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></ul>	<p>We do not expect a potential negative, or unequal, impact on people who face health inequalities.</p> <p>Some patients may not require treatment after surgery, which could positively impact patients with caring responsibilities by reducing the time burden associated with hospital visits and potential adverse effects</p>		



<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>
<ul style="list-style-type: none"><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>	associated with treatment after surgery.		
<b>5.13 Consider any other groups and risk factors relevant to this project.</b>	N/A	N/A	N/A

## 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.

How will the project impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by)
<b>6.1 People being able to access the service offered.</b>	<p>We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.</p> <p>Some patients may not require treatment after surgery, which could positively impact patients by reducing both the number of hospital appointments and the potential side effects associated with further therapy.</p>	N/A	N/A
<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.	N/A	N/A
<b>6.3 People in terms of their income and employment status.</b>	We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status.	N/A	N/A
<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	N/A	N/A



<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>
	people's 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.	N/A	N/A
<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.	N/A	N/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>	No negative impacts identified. We might expect a potential positive impact on people who develop resectable macroscopic stage III melanoma with $\geq 1$ pathologically proven lymph node metastasis and up to 3 in-transit metastases, and their families and carers.
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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 (<i>state who by</i>)</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, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website.</li> <li>• AWTTC to prepare an Evidence Summary Report (ESR)</li> <li>• One Wales Medicines Assessment Group (OWMAG) meet to consider and agree a recommendation.</li> </ul> <p>AWMSG meet to ratify OWMAG's recommendation.</p>	AWTTC	November 2025 – March 2026	

	<b>Action</b>	<b>Lead(s)</b>	<b>Timescale</b>	<b>Actions taken (<i>state who by</i>)</b>
<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>	AWTTC to write an evidence summary report for consideration by the One Wales Medicines Assessment Group (OWMAG).	AWTTC	Dec 2025 – Jan 2026	
<b>7.5 Review of project and EqHIA</b>		AWTTC	Feb 2027	

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