

Equality and Health Impact Assessment

Infliximab to treat immune checkpoint inhibitor (ICI) therapy-induced severe or life-threatening (grade 3–4) pneumonitis that has not responded to first-line treatment with corticosteroids

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: 6/10/2025

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	To assess the use of infliximab to treat grade 3–4 steroid-refractory pneumonitis induced by immune checkpoint inhibitor (ICI) therapy. 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 infliximab in NHS Wales; evidence of clinical effectiveness and cost effectiveness; safety considerations; budget impact; and equity of access across Wales and the rest of the UK. 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 Wales Medicines Assessment Group (OWMAG) to consider the ESR. The OWMAG constitution is available online .
3.	Evidence and background information considered.	Pneumonitis is a rare immune-related adverse event caused by immune checkpoint inhibitor (ICI) treatment for cancer. Depending on the type of IC



<p>For example:</p> <ul style="list-style-type: none">• population data• staff and service users' data, as applicable• needs assessment• engagement and involvement findings• research• good practice guidelines• participant knowledge• list of stakeholders and how stakeholders have engaged in the development stages• comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory.</p>	<p>inhibitor used, or the incidence of pneumonitis ranges from 1% of patients to 5% of patients, and up to 10% for PD(L)1 and CTLA-4 inhibitors used in combination. Around 33% of patients with ICI pneumonitis will develop grade 3 (severe) or 4 (life-threatening, require intubation or tracheotomy) pneumonitis; around 12% of patients will die.</p> <p>The European Society for Medical Oncology (ESMO) guideline, and other treatment guidelines for ICI pneumonitis, state that ICI therapy should be discontinued and steroid treatment started; if the pneumonitis does not respond to steroids within 48–72 hours, it is defined as steroid-refractory and treatment with a second-line immunosuppressant should be started, such as: infliximab, tocilizumab, intravenous immunoglobulin (IVIG), mycophenolate mofetil (MMF) or cyclophosphamide.</p> <p>Clinicians in Wales are currently developing a guideline on the treatment of ICI-induced pneumonitis. They have used infliximab off-label and second-line to treat ICI-induced pneumonitis through non-formulary requests, and have requested that AWMSG assess this use of infliximab under the One Wales Medicines process.</p> <p>Clinicians in Wales estimate that 24 patients per year are expected to develop steroid-refractory ICI-induced pneumonitis, and 12 of them would be eligible for infliximab treatment.</p> <p>Infliximab is an anti-tumour necrosis factor-alpha (anti-TNF) antibody licensed to treat a range of chronic immune-mediated inflammatory conditions: Crohn's disease, rheumatoid arthritis, psoriasis and ulcerative colitis. A course of three infusions would usually be given to treat ICI-induced pneumonitis. Similar courses of infliximab are currently used off-label to treat ICI-induced enterocolitis, and ICI-induced myocarditis, after recommendations by One Wales Medicines Assessment Group.</p>
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		Evidence of the efficacy of infliximab in treating grade 3–4 steroid-refractory ICI pneumonitis comes from retrospective case series and systematic reviews. Real-world evidence is available from some patients in Wales who have received infliximab to treat steroid-refractory pneumonitis.
4.	Who will this project affect?	People in Wales who develop grade 3 or 4 pneumonitis during ICI therapy for cancer, 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>5.1 Age For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> • under 18 years; • between 18 and 65 years; • over 65 years. 	<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 the medicine or the British National Formulary.</p>	<p>N/A</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).
	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 (MHRA guidance on off-label or unlicensed use of medicines)]		
5.2 Persons with a disability as defined in the Equality Act 2010 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.	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
5.3 People of different genders: Consider men, women, people undergoing gender reassignment. N.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
5.4 People who are married or who have a civil partner.	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
5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	We do not expect a potential negative, or unequal, impact on women who are expecting a baby, are breastfeeding, or are on a break from work after having a baby.	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 there is a change to the current



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	<p>Infliximab should only be used during pregnancy if clearly needed. Please refer to the SmPC.</p> <p>Infliximab could be considered for use during breast-feeding.</p> <p>The SmPC advises that women of childbearing potential should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last infliximab treatment.</p>		advice for pregnant and breastfeeding women.
<p>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</p> <p>The Runnymede Trust</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>	Note in the project document that people of different race and ethnicities can have varying responses to medicines.	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
<p>5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief.</p> <p>Implications of religious beliefs on selection of medicines (BMJ)</p> <p>In practice: guidance on religion, personal values and beliefs (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 or 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>	N/A	N/A
<p>5.8 People who are attracted to other people of:</p> <ul style="list-style-type: none">• the opposite sex (heterosexual);• the same sex (lesbian or gay);• both sexes (bisexual). <p>Stonewall</p>	<p>We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.</p>	N/A	N/A
<p>5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.</p>	<p>We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language.</p> <p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh</p>	<p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.</p>	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	language standards, including easy read booklets.		
5.10 People according to their income related group.	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.	N/A	N/A
5.11 People according to where they live.	We do not expect a potential negative, or unequal, impact on people based on where they live.	N/A	N/A
5.12 Consider others who face health inequalities, such as: <ul style="list-style-type: none">• Looked after and accommodated children and young people• Carers: paid/unpaid, family members	We do not expect a potential negative, or unequal, impact on people who face health inequalities.	N/A	N/A



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">• People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&Bs• People involved in the criminal justice system: offenders in prison or on probation, ex-offenders• People with addictions and substance misuse problems• People who have poor literacy• People living in remote, rural and island locations			
5.13 Consider any other groups and risk factors relevant to this project.	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)
6.1 People being able to access the service offered.	We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.	N/A	N/A
6.2 People being able to improve or maintain healthy lifestyles.	We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles.	N/A	N/A
6.3 People in terms of their income and employment status.	We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status.	N/A	N/A
6.4 People in terms of their use of the physical environment.	We do not expect a potential negative, or unequal, impact on people's use of the physical environment.	N/A	N/A
6.5 People in terms of social and community influences on their health.	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
6.6 People in terms of macro-economic, environmental and sustainability factors.	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.

<p>7.1 Please summarize the potential positive and/or negative impacts of the project.</p>	<p>No negative impacts identified. We might expect a potential positive impact on people who develop steroid-refractory, ICI-induced pneumonitis, and their families and carers.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
<p>7.2 What are the key actions identified as a result of completing the EqHIA?</p>	<ul style="list-style-type: none"> • Consult with clinical experts in Wales, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website. • AWTTC to prepare an Evidence Summary Report (ESR) • One Wales Medicines Assessment Group (OWMAG) meet to consider and agree a recommendation. <p>AWMSG meet to ratify OWMAG's recommendation.</p>	<p>AWTTC</p>	<p>Sep 2025- Dec 2025</p>	



	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?	No			
7.4 What are the next steps?	AWTTC to write an evidence summary report for consideration by the One Wales Medicines Assessment Group (OWMAG).	AWTTC	Oct 2025	
7.5 Review of project and EqHIA		AWTTC	[TBC]	

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