

Equality and Health Impact Assessment

Venetoclax (Venclyxto) with azacitidine to treat relapsed or refractory acute myeloid leukaemia (AML) in adults after at least one round of intensive chemotherapy before or after allogeneic haematopoietic stem cell transplant (HSCT), and when intensive chemotherapy is now not appropriate

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: 09/07/2025

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	<p>To assess the use of venetoclax with azacitidine to treat relapsed or refractory acute myeloid leukaemia (AML) in adults after at least one line of intensive chemotherapy before or after allogeneic haematopoietic stem cell transplant (HSCT) where intensive chemotherapy is not appropriate.</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 venetoclax 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.</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 Wales Medicines Assessment Group (OWMAG) to consider the ESR. The OWMAG constitution is available online.</p>



<p>3.</p>	<p>Evidence and background information considered. 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>AML is an aggressive cancer of the blood and bone marrow characterised by the overproduction of immature myeloid cells (blasts). Severe infections, anaemia and haemorrhage develop over a few weeks and can be fatal if untreated. Symptoms include: looking pale or washed out; losing weight; breathlessness; frequent infections; unusual bruising or bleeding.</p> <p>Current treatment options for relapsed or refractory AML are limited and poorly tolerated. Standard care is intensive salvage chemotherapy or palliative treatments. Clinical experts in Wales have identified an unmet need for a treatment option that is better tolerated and improves quality of life with reduced hospital stay. Treatment with venetoclax with azacitidine may provide a bridge to allogeneic haematopoietic stem cell transplant (HSCT).</p> <p>In 2021, there were 85 new cases of AML in Wales, an incidence of 3 new cases per 100,000 population. The incidence is higher in older people, with a median age at diagnosis of 72 years. Survival rates are higher for younger patients and decrease with age.</p> <p>Treatment with venetoclax and azacitidine would be reserved for patients:</p> <ul style="list-style-type: none">• who are not eligible for gilteritinib treatment (licensed for patients with FLT3 mutation); or• for whom intensive chemotherapy is not suitable (e.g. due to co-morbidities or frailty); or• who experience unacceptable toxicity with intensive chemotherapy; <p>and</p> <ul style="list-style-type: none">• whose disease is not refractory to venetoclax-based therapy. <p>Venetoclax is a selective inhibitor of B-cell lymphoma BCL-2, activating apoptosis effectors and cell death. Azacitidine acts by multiple mechanisms including cytotoxicity on abnormal haematopoietic cells in the bone marrow and hypomethylation of DNA. Venetoclax and azacitidine are administered on a 28-day cycle.</p>
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There are no UK guidelines for the treatment of relapsed or refractory AML. Clinical experts have informed AWTTC that the UK AML clinical network have asked NHS England commissioning services to consider venetoclax with azacitidine. Venetoclax with azacitidine is recommended as a treatment option for relapsed or refractory AML in the February 2025 version of the US National Comprehensive Cancer Network (NCCN) guidelines.

A retrospective study reports the use of venetoclax with azacitidine in relapsed and refractory AML patients treated in centres in the UK, this is the main study to inform the assessment. Supporting evidence is provided by 10 additional multiple and single centre retrospective studies conducted outside of the UK.

[Venetoclax-based non-intensive combinations for relapsed/refractory acute myeloid leukaemia real-world data from a UK-wide programme](#) is a retrospective study by Wood et al. (2025). Data for patients treated between 2017 and 2022 were collected from 11 NHS trusts and health boards in the UK. Overall response was strongly associated with survival from 2 months after initiation, median OS was 15.9 months (95%CI 12.0–18.9) in responders versus 3.8 months (95% CI 2.3–5.4) in non-responders. Non-responders received a median of two cycles and responders received a median of five cycles.

Patients with relapsed or refractory AML have poor outcomes and there is currently no standard of care.

The only potentially curative treatment for these patients is allogeneic HSCT and this is only available to those patients who achieve remission with further therapy (and have an available donor). Current treatment options are intensive salvage chemotherapy with relatively poor response rates. These treatments are also highly toxic and, as a result, large numbers of patients



		<p>have few or no further treatment options due to age, treatment toxicity or co-morbidity.</p> <p>Venetoclax with azacitidine represents a less toxic, more easily delivered treatment option for relapsed or refractory AML in patients who otherwise have a life expectancy of only 2–3 months. The combination is an oral tablet and subcutaneous injection; there is no need for indwelling lines. Salvage chemotherapy requires inpatient admission for seven days up to several weeks. Venetoclax with azacitidine is administered as an outpatient treatment so patients can remain at home; it can be delivered by local hospitals so travel to tertiary treatment centres is reduced.</p>
4.	Who will this project affect?	Adults in Wales who have AML that has relapsed or is refractory to at least one line of intensive chemotherapy before or after an allogeneic HSCT, and for whom intensive chemotherapy is not appropriate.



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</p> <p>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), or the British National Formulary, for venetoclax and azacitidine.</p>	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).
	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



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	<p>Venetoclax is not recommended for women who are pregnant or who want to become pregnant, or for women of childbearing potential who are not using highly effective contraception. Please refer to the SmPC. Women should avoid becoming pregnant while taking venetoclax and for at least 30 days after ending treatment. The manufacturer of venetoclax advises that breastfeeding should be discontinued during treatment with venetoclax.</p> <p>Women of childbearing potential have to use effective contraception during and for at least 6 months after azacitidine treatment; please refer to the SmPC. Men should be advised not to father a child while</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).
	receiving treatment and must use effective contraception during and for at least 3 months after treatment. Azacitidine should not be used during pregnancy, especially during the first trimester, unless clearly necessary. Breast-feeding is contraindicated during azacitidine therapy.		
5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers. The Runnymede Trust	We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin. People of different race and ethnicities can have varying responses to medicines.	Note in the project document that people of different race and ethnicities can have varying responses to medicines.	N/A
5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief.	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.	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).
Implications of religious beliefs on selection of medicines (BMJ) In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)	Some medicines are made from certain animal products and people might not want to take them because of religion or belief.		
5.8 People who are attracted to other people of: <ul style="list-style-type: none">• the opposite sex (heterosexual);• the same sex (lesbian or gay);• both sexes (bisexual). Stonewall	We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.	N/A	N/A
5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.	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.	N/A
5.10 People according to their income related group.	We do not expect a potential negative, or unequal, impact on	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).
	<p>people based on their income-related group.</p> <p>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.</p> <p>Venetoclax with azacitidine is administered on an outpatient basis so patients can remain at home, it can be delivered by local hospitals so travel to tertiary treatment centres is reduced.</p>		
5.11 People according to where they live.	<p>We do not expect a potential negative, or unequal, impact on people based on where they live.</p> <p>Venetoclax with azacitidine is administered on an outpatient basis so patients can remain at</p>	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).
	home, it can be delivered by local hospitals so travel to tertiary treatment centres is reduced.		
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• 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	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).
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.	Patient organisation summaries will only be available where patient confidentiality is ensured.	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	N/A	N/A



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)
	macroeconomic, environmental and sustainability factors.		

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 potential negative impacts identified. We might expect a potential positive impact on people with AML who might benefit from treatment with venetoclax and azacitidine.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken (state who by)
<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. 	<p>Rosie Spears</p> <p>Rosie Spears</p> <p>Andrew Champion (Chair)</p>	<p>15/07/2025-2/09/2025</p> <p>11/08/2025-29/09/2025</p> <p>06/10/2025</p>	<p>Clinicians and company emailed by Rachel Vickery on 15/07/2025 for initial comment/input. ESR sent to clinicians and company on 17/09/2025 by Rachel Vickery for comment. Comments received and actioned, ESR revised as necessary.</p> <p>Report completed and sent to OWMAG members one week ahead of meeting – Rosie Spears</p>

	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
	AWMSG meet to ratify OWMAG's recommendation.		05/11/2025	
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?				
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	Jul-Aug 2025	Complete 30/09/2025
7.5 Review of project and EqHIA		AWTTC	[TBC]	

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