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

Equality and Health Impact Assessment

Gilteritinib as maintenance treatment after allogeneic stem cell transplant for acute myeloid leukaemia with associated FLT3-internal tandem duplication (ITD) mutation if there is evidence of minimal residual disease (MRD) positivity before or after transplant

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: 17/02/2026

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	To assess the use of gilteritinib as maintenance treatment after allogeneic stem cell transplant for acute myeloid leukaemia (AML) with associated FLT3-internal tandem duplication (ITD) mutation in patients who have evidence of minimal residual disease (MRD) positivity pre- or post-transplant. 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 gilteritinib in NHS Wales; evidence of clinical 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. For example: • 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 Population pyramids are available from Public Health Wales Observatory.	An FLT3-internal tandem duplication (ITD) mutation occurs in approximately 25% of all AML cases and is associated with an increased risk of relapse and poor prognosis compared to FLT3 wildtype AML. Allogeneic stem cell transplant in first complete remission is the standard-of-care for these patients. In 2022, the One Wales Medicines process supported the off-label use of the FLT3 inhibitor sorafenib for maintenance treatment post-transplant to reduce the risk of relapse. In 2024, results of the MORPHO clinical trial, which explored use of gilteritinib as maintenance treatment of FLT3-ITD AML post-transplant, showed evidence, in sub-group analysis, for targeting only those patients with detectable MRD either pre- or post-transplant. Clinical experts in Wales prefer gilteritinib to sorafenib for maintenance treatment of FLT3-ITD AML post-transplant, because of fewer adverse effects and better tolerability. Clinical experts say that targeting patients with measurable MRD would limit the cohort of patients eligible for FLT3 inhibitor treatment and reduce the number of patients receiving unnecessary treatment. If gliteritinib were approved for routine use through the One Wales Medicines process, then clinicians in Wales would no longer offer maintenance treatment with sorafenib and the current One Wales decision for sorafenib (OW18) could be discontinued. The request for consideration of gilteritinib through the One Wales Medicines process is backed by the South Wales Blood and Transplant team. Gilteritinib is a type 1 FLT3 and AXL inhibitor. It inhibits receptor signalling and proliferation in cells exogenously expressing FLT3 and specifically induces apoptosis in leukemic cells expressing ITD mutation of FLT3 (SmPC). Gilteritinib is licensed as monotherapy for the treatment of adult patients who have relapsed or refractory AML with a FLT3 mutation. The licensed dose is

		120 mg once daily. In the absence of a response after 4 weeks of treatment the dose may be increased to 200 mg once daily. For maintenance treatment post-transplant clinicians propose a dose of 120 mg once daily for two years, as used in the MORPHO clinical trial. Gilteritinib monotherapy is recommended as an option for treating relapsed or refractory FLT3-mutation-positive acute AML in adults, NICE TA642 (2020). The recommendation states that in the relapsed/refractory setting patients who are treated with gilteritinib and go on to receive an allogeneic stem cell transplant should not restart gilteritinib as maintenance treatment after transplant. Best practice recommendations on MRD-guided interventions for AML have been published by the European Society for Blood and Marrow Transplantation Practice Harmonisation and Guidelines Committee (Sanz et al, 2025). The recommendations state that detectable MRD is a prognostic factor for relapse after HCT. FLT3 inhibitors should be offered as maintenance therapy in patients with FLT3-ITD AML and gilteritinib might be preferred for patients with detectable pre-transplant MRD. The recommended duration of FLT3 inhibitor maintenance therapy is 2 years. However, treatment duration should be individualised based on tolerability and patient-specific factors. For patients with detectable MRD post-transplant recommendations are more general and state that targeted pharmacological agents should be used in patients for whom these therapies are available. In the MORPHO study (Levis et al. (2025) of gilteritinib as post-transplant maintenance for AML with internal tandem duplication mutation of FLT3, 356 patients were randomised to receive placebo (178) or gilteritinib (178). RFS was improved in the gilteritinib arm, however, this did not meet the threshold for significance (hazard ratio [HR], 0.679 [95% confidence interval [CI] 0.459 to 1.005]; p = 0.0518). pre-planned sub-group analysis of patients with

		detectable MRD either pre- or post transplant (n = 180) demonstrated significantly improved RFS with gilteritinib compared with placebo (HR 0.515; 95% CI, 0.316 to 0.838; p = 0.0065). Those without detectable MRD showed no benefit (HR, 1.213 [95% CI, 0.616 to 2.387]; p = 0.575). A health-related quality of life (HRQoL) study of gilteritinib vs. placebo post-transplant for FLT3-ITD acute myeloid leukemia (Hamilton et al. 2024) investigated the effects on HRQoL in patients in the phase 3 MORPHO clinical trial. Assessments used were: Functional Assessment of Cancer Therapy (FACT)-Bone Marrow Transplantation (BMT) measure, FACT-Leukemia (FACT-Leu) measure, and the EuroQOL-5 Dimensions (EQ-5D-5L). HRQoL was measured at post-transplant randomisation; day 29; months 3, 6, 12, 18, 24; and/or end of therapy. There were no differences in HRQoL scores between the treatment groups at any time point. Sub-group analysis comparing MRD positive and negative patients also demonstrated no differences between groups. A retrospective analysis compared efficacy and safety of gilteritinib to sorafenib maintenance in FLT3-ITD AML post-transplant (Yeh et al 2024). A total of 55 patients were treated with gilteritinib (n = 26) or sorafenib (n = 29) after transplant. There was no significant difference in progression-free survival between groups. The summary of product characteristics (SmPC) for gilteritinib describes adverse effects reported in patients with relapsed or refractory AML. The most frequent serious adverse effects were: acute kidney injury (6.6%); diarrhoea (4.7%); ALT increased (4.1%); dyspnoea (3.4%); AST increased (3.1%) and hypotension (2.8%). The SmPC also highlights several clinically significant adverse reactions including differentiation syndrome (2.2%), electrocardiogram QT prolonged (0.9%) and posterior reversible encephalopathy syndrome (0.6%). Regular electrocardiograms and monitoring of blood chemistry, including creatinine kinase are recommended

		prior to initiation of treatment and for the duration of treatment. According to clinical experts these tests are routine and do not differ from monitoring with the use of sorafenib as post-transplant maintenance treatment. Clinical experts reported that of 18 patients treated with sorafenib in Wales over the past five years, none were able to tolerate 400 mg bd of sorafenib, and doses were reduced to 200 mg bd. Nine patients discontinued treatment due to skin or gastro-intestinal toxicities and were unable to restart. Clinical experts consider gilteritinib to be more potent and better tolerated than sorafenib. Therapy targeted by MRD measurements would mean only those patients expected to derive benefit would receive maintenance treatment. Sorafenib is associated with significant toxicity resulting in dose interruptions and discontinuations. Unplanned hospital visits and additional monitoring are required for those patients who experience toxicity. Experts expect dose interruptions and unplanned hospital visits to be reduced if using gilteritinib used instead of sorafenib. Clinicians in Wales highlight the limited capacity in haematology units and the additional burden that unplanned visits and monitoring place on the service. A better tolerated treatment option such as gilteritinib is expected to reduce the frequency and duration of unscheduled care.
4.	Who will this project affect?	People in Wales who have an allogeneic stem cell transplant for AML with associated FLT3-internal tandem duplication (ITD) mutation and evidence of minimal residual disease positivity before or after transplant, 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).
5.1 Age For most purposes, the main categories are people aged: • under 18 years; • between 18 and 65 years; • over 65 years.	We do not expect a potential negative, or unequal, impact on people based on their age. [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.	Any patient-facing resources produced will be provided on the AWTTC website in accessible formats that can be printed.	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 also be produced in easy read formats 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.	We do not expect a potential negative, or unequal, impact on women who are expecting a baby, are breastfeeding, or are	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

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	on a break from work after having a baby. Gilteritinib is not recommended during pregnancy and in women of childbearing potential who are not using effective contraception. Please refer to the SmPC. The manufacturer of gilteritinib advises that breastfeeding should be discontinued during treatment with gilteritinib and for at least two months after the last dose. Please refer to the SmPC.	pregnant, or who are breastfeeding.	consideration of any change to the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women.
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.	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).
	People of different race and ethnicities can have varying responses to medicines.	Any patient information leaflets produced will be available in Welsh and English.	
5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief. Implications of religious beliefs on selection of medicines (BMJ) In practice: guidance on religion, personal values and beliefs (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. Some medicines are made from certain animal products and people might not want to take them because of religion or belief.	N/A	N/A
5.8 People who are attracted to other people of: • 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,	We do not expect a potential negative, or unequal, impact on	Any patient-facing materials will be produced in Welsh and	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).
information leaflets, or service plans and design.	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.	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.	
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

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
5.12 Consider others who face health inequalities, such as: • 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
5.13 Consider any other groups and risk factors relevant to this project.			

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).

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) *Refer to where the mitigation is included in the document, as appropriate.*
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

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) *Refer to where the mitigation is included in the document, as appropriate.*
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 then fill in the action plan.**

7.1 Please summarize the potential positive and/or negative impacts of the project.	We did not identify any potential negative impact.

Action plan for mitigation or improvement and implementation

	Action	**Lead(s)**	**Timescale**	**Actions taken** *(state who by)*
7.2 What are the key actions identified as a result of completing the EqHIA?	• 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. • AWMSG meet to ratify OWMAG's recommendation.	AWTTC	Feb–Sep 2026 Feb–Sep 2026 Oct 2026 Nov 2026	

	Action	Lead(s)	Timescale	Actions taken *(state who by)*
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	Mar-Sep 2026	
7.5 Review of project and EqHIA		AWTTC	[TBC]	

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