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

Equality and Health Impact Assessment

Emicizumab (Hemlibra) for routine prophylaxis of bleeding episodes in people with haemophilia A (congenital factor VIII [factor 8] deficiency) without factor VIII inhibitors who have moderate disease (FVIII between 1% and 5%) with severe bleeding phenotype

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: 18/03/2026

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	AWTTC will prepare an evidence summary report (ESR) for a limited AWSMG assessment for the use of emicizumab in the routine prophylaxis of bleeding episodes in people with haemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors who have moderate disease (factor VIII between 1% and 5%) with severe bleeding phenotype. The All Wales Medicines Strategy Group's Scrutiny Panel reviewed an assessment request from Roche, the company that holds the UK licence for emicizumab. The panel considered that the medicine was suitable for a limited assessment by the Licensed One Wales Medicines Assessment Group (LOWMAG). The panel agreed that the case for clinical effectiveness of emicizumab is established and does not need further review. Therefore, the limited assessment will give an overview of current use, equity of access and the expected budget impact only.

		AWTTC's ESR will focus on: evidence from a submission from Roche, feedback from clinicians in Wales, and an estimation of the budget impact. AWTTC will also request the views of patient organisations relevant to this condition. AWTTC will send the ESR to the company and to clinicians for comment. Clinicians, company representatives and patient organisation representatives are invited to attend the LOWMAG meeting. The LOWMAG 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.	Haemophilia A is a rare genetic condition, usually in males, which affects the blood's ability to clot due to missing or defective clotting factor protein called factor VIII (FVIII). According to the International Society on Thrombosis and Haemostasis (ISTH), prophylaxis is indicated in people with moderate haemophilia A without inhibitors and with a severe bleeding phenotype. There is no single definition for the term 'severe bleeding phenotype' but according to NHS England this includes adults with joint damage and any joint bleeds in a year, or more than 3 to 4 bleeds in a year, or currently on prophylaxis with FVIII for more than 12 weeks, and all children with baseline FVIII levels of 1–3 IU/dL. People with moderate haemophilia A are currently treated with prophylaxis FVIII replacement treatment. However, around one third of people who receive FVIII replacement therapy will develop FVIII inhibitors, which make the replacement FVIII ineffective. Clinical experts from the Cardiff Haematology Centre state that some adults with moderate haemophilia A with severe bleeding phenotype decline FVIII prophylaxis and receive treatment with FVIII on-demand only (that is, in the presence of bleeding or after trauma).

		The International Society on Thrombosis and Haemostasis (ISTH) clinical practice guideline for treatment of congenital haemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology strongly recommends that people with severe and moderately severe (that is, with a severe bleeding phenotype even if FVIII plasma levels are ≥2 IU/dL) haemophilia A without inhibitors are given prophylaxis over episodic treatment of bleeding events. The guideline conditionally recommends that either prophylaxis with emicizumab or prophylaxis with FVIII concentrates should be given and acknowledges that emicizumab may offer a lower treatment burden for patients due to its weekly, biweekly, or four-weekly schedule and subcutaneous administration. Emicizumab is an alternative prophylaxis treatment for haemophilia A and can be used in all age groups. It is licensed for the routine prophylaxis of bleeding episodes in patients with haemophilia A with FVIII inhibitors and for people without FVIII inhibitors who have either severe (FVIII < 1%) or moderate (FVIII ≥ 1% and ≤ 5%) haemophilia A with a severe bleeding phenotype. Patients in Wales and England with haemophilia A with FVIII inhibitors, or without inhibitors but with severe disease, already have routine access to emicizumab prophylaxis through commissioning by the NHS Wales Joint Commissioning Committee (NWJCC) and by NHS England respectively. This assessment considers the remaining subpopulation of haemophilia patients: people with moderate haemophilia A without FVIII inhibitors and with a severe bleeding phenotype for which no all-Wales guidance is available. In England, routine access to emicizumab for this subpopulation has recently been enabled in England by NHS England. The pharmaceutical company (Roche) suggests an estimated 6–12 patients in Wales per year might be eligible for treatment with emicizumab for the

		indication considered, and that between 8–10 patients might be prescribed emicizumab. Clinical experts from the Haematology Centre at Cardiff and Vale UHB estimates that 20 patients (which includes those on recombinant FVIII prophylaxis and those who have declined FVIII prophylaxis and are treated on-demand) would be eligible for this treatment within the Bleeding Disorders Network Wales, with a predicted 50% uptake of emicizumab.
4.	Who will this project affect?	People in Wales with people with moderate Haemophilia A without FVIII inhibitors and with a severe bleeding phenotype; 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
5.3 People of different genders:	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).
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.	people based on their gender, or on people undergoing gender reassignment. Haemophilia A is more likely to affect males.		
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.	The manufacturer of emicizumab advises that women of childbearing potential receiving emicizumab should use effective contraception during, and for at	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

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	least 6 months after cessation of emicizumab treatment. Please refer to the SmPC. The manufacturer also advises that emicizumab should be used during pregnancy only if the potential benefit for the mother outweighs the potential risk to the fetus taking into account that, during pregnancy and after parturition, the risk for thrombosis is increased and that several pregnancy complications are linked to an increased risk for disseminated intravascular coagulation (DIC). Please refer to the SmPC. The SmPC also states that a decision must be made whether to stop breastfeeding or to discontinue/abstain from emicizumab therapy, taking into account the benefit of	pregnant, or who are breastfeeding.	the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
	breastfeeding for the child and the benefit of therapy for the woman.		
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.	Any patient information leaflets produced will be available in Welsh and English.	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. 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

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
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, 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. These will be provided on the AWTTC website in accessible formats that can be printed.	N/A
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	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).
	recommendations through this project will not affect people depending on their income-related group.		
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: • 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	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).
• 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) *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 fill in the action plan.**

7.1 Please summarize the potential positive and/or negative impacts of the project.	We have not identified any negative impacts. There might be a positive impact for all patients in Wales who are eligible for treatment if the medicine is recommended to be routinely available in Wales; due to the genetics of haemophilia A, we may expect a positive impact for males who are much more likely to have this condition and thus require treatment.

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?	• AWTTC to consult with clinical experts in Wales, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website or questionnaire by email • AWTTC to prepare an Evidence Summary Report (ESR) • Licensed One Wales Medicines Assessment Group (LOWMAG) meet to consider and make a recommendation to AWMSG. • AWMSG meet to consider and endorse the LOWMAG	AWTTC	January–March 2026 April 2026 May 2026	

	Action	Lead(s)	Timescale	Actions taken *(state who by)*
	recommendation to Welsh Government about the use of emicizumab in Wales.			
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?	No			
7.4 What are the next steps?	AWTTC conduct a limited assessment and submit an evidence summary report to the Licensed One Wales Medicines Assessment Group (LOWMAG).	AWTTC	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.