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Equality and Health Impact Assessment

Ziconotide (Prialt®) for the treatment of severe chronic pain in patients who require intrathecal analgesia in Wales

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: 30/4/2025

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	<p>AWTTC will prepare a report for an All Wales Medicines Strategy Group (AWMSG) health technology assessment for the use of ziconotide (Prialt®) in NHS Wales for the treatment of severe chronic pain in adults who require intrathecal analgesia.</p> <p>This is a resubmission, after a non-recommendation by AWMSG in July 2008, when the case for cost-effectiveness was not proven. The resubmission considers the use of a starting dose of ziconotide that is lower than the licensed dose, and using a slower titration rate, as recommended by clinical guidelines, and has an approved patient access scheme discount.</p> <p>The AWMSG Secretariat Assessment Report produced by AWTTC will summarise the clinical effectiveness of ziconotide, how it would be used in NHS Wales, cost effectiveness and budget impact, and equity of access across Wales and the rest of the UK. The views of patient organisations relevant to this condition will also be requested and clinicians will be asked for comments. The New Medicines Group (NMG), a sub-group of AWMSG will</p>



		meet to consider the assessment and agree a recommendation for AWMSG. Clinicians, company representatives and patient organisation representatives are invited to attend the AWMSG meeting to consider this assessment.
3.	<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>Patients with severe chronic pain who need intrathecal analgesia are usually given off-label morphine. The British Pain Society and the Polyanalgesic Consensus Conference (PACC) recommend intrathecal delivery of ziconotide as an option for the first-line treatment of chronic malignant or non-malignant pain.</p> <p>Clinicians in Wales have raised an unmet need for a treatment for patients who have pain that is not controlled with intrathecal morphine or cannot tolerate the side effects of morphine.</p> <p>Ziconotide reduced pain scores in three short pivotal studies comparing it with placebo (a large, randomised controlled trial [RCT] and two smaller supportive RCTs), and in several long-term studies, including studies of lower doses.</p> <p>The company and AWTTC considered that ziconotide should be considered under the AWMSG's criteria for appraising medicines for severe conditions.</p>
4.	Who will this project affect?	People in Wales who have severe chronic pain and require intrathecal anaesthesia, 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</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) for the medicine or the British National Formulary.</p>	<p>Dose adjustment is not required in older adults. However, it should be taken into account that renal and/or hepatic insufficiency is more common in patients aged 65 years and older.</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).
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
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	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).
	status or being in a civil partnership.		
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.	Ziconotide is not recommended for women who are pregnant or who want to become pregnant, or in women of child-bearing potential who are not using contraception. Please refer to the SmPC . The manufacturer of ziconotide advises that it is unknown whether ziconotide or its metabolites are excreted in human milk, and a risk to newborns or infants cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue or abstain from ziconotide therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the patient.	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 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).
<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>	N/A	N/A
<p>5.7 People with a religion or belief or with no religion or belief.</p> <p>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);	<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



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by).
· both sexes (bisexual). Stonewall			
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. ·	Treatments are provided by regional centres, which could affect whether patients (and their carers) can access them? Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back. Patients might have issues with meeting these costs of travel and of being given time out of work to receive treatment?	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).
	There might be an impact on a person's ability to work due to the severity of disease. Making treatments available might increase a person's chance to regain employment as their symptoms improve.		
5.11 People according to where they live.	Treatments are provided by regional centres, which could affect whether patients (and their carers) can access them? Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back.	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• People who are homeless or those who experience homelessness: people on	We would expect a positive impact on carers or family members who look after people with severe chronic pain who need intrathecal analgesia as there would be an additional treatment available which can reduce side effects and provide a further option when other	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>the street; those staying temporarily with friends/family; those in hostels/B&Bs</p> <ul style="list-style-type: none">• 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	<p>treatments do not provide adequate pain relief or when side effects are not tolerated.</p>		
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) <i>Refer to where the mitigation is included in the document, as appropriate.</i>
6.1 People being able to access the service offered.	Treatments are provided by regional centres, which could affect whether patients (and their carers) can access them? Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back.	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.	Treatments are provided by regional centres, which could affect whether patients (and their carers) can access them? Patients who work might be negatively affected if they have to travel to a treatment centre, wait for treatment and then travel back.	Patient organisation summaries will only be available where patient confidentiality is ensured.	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) <i>Refer to where the mitigation is included in the document, as appropriate.</i>
	<p>Patients might have issues with meeting these costs of travel and of being given time out of work to receive treatment?</p> <p>Patients who respond to the treatment may be more likely to be in employment if their pain is better controlled.</p>		
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.		
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.		
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.		

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>The positive aspects of controlling the severe pain may impact people's ability to work and have a positive impact on carers and their families. The treatment is provided at regional centres which requires some patients to travel further and to incur costs which may be difficult for patients on a lower income or unemployed.</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"> · AWTTC to prepare the AWMSG Secretariat Assessment Report (ASAR). · New Medicines Group (NMG) meet to consider and make a recommendation to AWMSG. · AWMSG meet to consider and make a recommendation to Welsh Government about the use of ziconotide in Wales. 	<p>AWTTC</p>	<p>Feb–May 2025</p> <p>Mar 2025</p> <p>May 2025</p>	<p>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; ASAR prepared.</p> <p>NMG made recommendation. AWTTC made changes to the ASAR based on company response.</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?	AWMSG meet to consider the NMG's recommendation and all the evidence presented by AWTTC. AWMSG to agree recommendation for Welsh Government.	AWMSG	May 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.