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

Equality and Health Impact Assessment

Guanfacine for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years for whom stimulants are not suitable, not tolerated or have been shown to be ineffective

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: 25/02/2025

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	AWTTC will prepare a report for a limited AWSMG assessment for the use of guanfacine (Intuniv®) modified-release tablets in NHS Wales for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Guanfacine must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures. This is a reassessment of guanfacine after a negative recommendation by AWMSG in June 2016, when the case for cost-effectiveness was not proven. The reassessment is happening because three health boards have added guanfacine to their formularies so that it can be routinely used as a treatment option for ADHD within its licensed indication. This has created an inequity of access to guanfacine within NHS Wales, which clinicians from other health boards have raised as an issue, because they are unable to routinely prescribe guanfacine to suitable patients in their localities who would otherwise receive it in some other parts of Wales, in England and in Scotland.

		As the AWMSG Scrutiny Panel considered that the case for clinical effectiveness is established, this will not be re-examined in the re-assessment. The evidence status report produced by AWTTC will summarise its current use in NHS Wales, equity of access across Wales and the rest of the UK, and budget impact only. The views of patient organisations relevant to this condition will also be requested. The evidence summary report will be sent to the company and to clinicians for comment. Clinicians, company representatives and patient organisation representatives are invited to attend the Licensed One Wales Medicines Assessment Group (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.	The management of ADHD consists of a multi-faceted approach combining behavioural therapy and where appropriate pharmacotherapy that addresses the individual needs of a patient. Current UK guidelines recommend psychostimulant medicines as first-line treatment, which must be part of a comprehensive treatment programme. The use of non-stimulant medicines is recommended in children and adolescents who cannot tolerate or do not respond to stimulants. Guanfacine (Intuniv®) is a non-stimulant medicine, with a different mechanism of action to the existing licensed treatments and is positioned joint 3rd line in the treatment pathway with atomoxetine, the only other licensed non-stimulant treatment for ADHD. It is routinely available for patients in Scotland via a Scottish Medicines Consortium recommendation. The use of guanfacine is recommended in NICE guideline NG87; in England, patients can access guanfacine through local trust protocols. The current AWMSG advice from May 2016 states that guanfacine is not recommended for use in NHS Wales for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

		Despite the AWMSG negative recommendation, some health boards in Wales decided to routinely fund guanfacine as a joint 3rd line non-stimulant treatment option in-line with the NICE NG87 guideline. AWTTC has received repeated requests from clinicians and formulary pharmacists from the other health boards to re-look at the AWMSG recommendation, because they consider that access to guanfacine in Wales has become inequitable, that it is a useful option in the treatment pathway fulfilling an unmet clinical need for a small sub-group of patients and that the AWMSG recommendation is out-of-step with the approach taken by other nations in the UK and the available published clinical evidence. The company holding the marketing authorisation for guanfacine has not sent an updated submission for re-assessment. However, the 2025 change to the AWMSG assessment process allows AWMSG to re-assess a medicine, if considered appropriate by AWMSG's Scrutiny Panel, without the need for an updated submission from the company. In clinical practice, clinicians say that guanfacine is mainly given after atomoxetine has proved ineffective or led to worsening of symptoms. Clinicians report from experience that guanfacine appears to be more effective and better tolerated than atomoxetine in certain sub-groups of children with ADHD. These are generally children with co-morbidities including: autistic spectrum complex (ASC), learning disabilities, disordered sleep and hyperkinesis. Some clinicians have reported that guanfacine has been 'life-changing' for some of their patients, allowing return to full-time schooling, being able to access coping strategies and participate in family events. Clinicians generally think that guanfacine is a useful option for a small sub-group of children and young people with ADHD particularly those with other co-morbidities; and that the limits on guanfacine prescribing in some

		parts of NHS Wales results in an unmet clinical need, although anticipated use would be limited. The most frequently reported adverse reactions include: somnolence (40.6%), headache (27.4%), fatigue (18.1%), abdominal pain upper (12.0%), and sedation (10.2%). The most serious adverse reactions commonly reported include hypotension (3.2%), weight increase (2.9%), bradycardia (1.5%) and syncope (0.7%). Before starting treatment, a patient's cardiovascular status including heart rate and blood pressure parameters, family history of sudden cardiac death or unexplained death, should be assessed to identify patients at increased risk of hypotension, bradycardia, and QT-prolongation or risk of arrhythmia. Clinicians in Wales estimate that about 1 in 10 children or young people with ADHD requiring treatment with medication may benefit from guanfacine. Most children receive between 1 mg and 4 mg daily and typically remain on guanfacine for 3–7 years, although some may remain on it indefinitely and into adult life. Evidence from phase III studies (SPD503-315, SPD503-316 and SPD503-318) showed that guanfacine was more effective than placebo at improving ADHD symptoms in children and adolescents, although a beneficial effect on social functioning was not consistently shown. There has been subsequent clinical evidence published that demonstrates efficacy of guanfacine in children and adolescents with ADHD.
4.	Who will this project affect?	Children and young people aged 6–17 years with ADHD requiring treatment with medication, 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. Guanfacine is only licensed for use in patients aged 6 years to 17 years. [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	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)
	Characteristics (SmPC) for the medicine or the British National Formulary.		
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. A positive recommendation might have a positive impact on children and young people with ADHD who have autistic spectrum complex (ASC) or learning disabilities.	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.	
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

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Actions taken (and who by)
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.	Guanfacine is not recommended during pregnancy and in women of child-bearing potential not using contraception. Please refer to the SmPC. The manufacturer of guanfacine advises that a decision must be made whether to stop breastfeeding or to discontinue and/or abstain from guanfacine therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the mother.	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.
5.6 People of a different race, nationality, colour, culture or ethnic origin including nonEnglish speakers, gypsies	We do not expect a potential negative, or unequal, impact on people of a different race,	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)
and travellers, migrant workers. The Runnymede Trust	nationality, colour, culture or ethnic origin. People of different race and ethnicities can have varying responses to medicines.		
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 English, in line with the Welsh	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.	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. We would expect a positive recommendation to	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)
	remove any inequity in access to guanfacine because of where patients live in Wales.		
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

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) *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.	No potential negative impacts identified.

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 or by questionnaire via 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 recommendation to Welsh Government about the use of guanfacine in Wales.	AWTTC	Feb-May 2025 Feb-Mar 2025 Apr 2025 May 2025	

	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 Licensed One Wales Medicines Assessment Group (LOWMAG). LOWMAG meet to consider and make a recommendation to AWMSG. AWMSG meet to consider and endorse the LOWMAG recommendation to Welsh Government about the use of guanfacine in Wales.	AWTTC	Mar-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.