

Equality & Health Impact Assessment for

One Wales: Improving access to medicines for patient cohorts

Please read the Guidance Notes in Appendix 1 prior to commencing this Assessment

New and updated text to this October 2022 version is highlighted in yellow.

Please note:

- The completed Equality & Health Impact Assessment (EHIA) must be
 - Included as an appendix with the cover report when the strategy, policy, plan, procedure and/or service change is submitted for approval
 - Published on the UHB intranet and internet pages as part of the consultation (if applicable) and once agreed.
- Formal consultation must be undertaken, as required¹
- Appendices 1-3 must be deleted prior to submission for approval

Please answer all questions:-

1	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	One Wales: Improving access to medicines for patient cohorts
2	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Clinical Diagnostics and Therapeutics. Matthew Temby
3	Objectives of strategy/ policy/ plan/ procedure/ service	To provide access to medicines not usually available in NHS Wales for clearly defined cohorts of patients where no alternative medicine or treatment is available and an unmet need has been identified by service providers.

¹http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,73860407,253_73860411&_dad=portal&_schema=PORTAL

<p>4 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 Observatory² and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need³.</p>	<p>Background</p> <p>The All Wales Medicines Strategy Group (AWMSG) and the National Institute for Health and Care Excellence (NICE) provide Health Technology Assessment (HTA) guidance on the introduction of new licensed medicines within NHS Wales. In the absence of AWMSG/NICE advice the individual patient funding request (IPFR) process may be used by clinicians to access a medicine when it is not routinely funded by the NHS in Wales. Where several patients who may benefit from the medicine are identified, the IPFR process (with its emphasis on the individual patient) may not be considered appropriate and may result in funding variation and differential access across Wales. For such cases AWTTTC, in conjunction with representatives from Welsh Health Specialised Services Committee (WHSSC) and IPFR Panel Co-ordinators developed the One Wales Process which provides a route for access to medicines for clearly defined and specific cohorts of patients rather than individual patients. Medicines and potential patient cohorts (clearly defined and specific) are identified by Health Board IPFR panels, WHSSC, Chief Pharmacists or clinical experts. These healthcare professionals can request that a medicine be considered for One Wales by completing a medicine request form, available on the AWTTTC website: https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/one-wales-medicines-process/</p> <p>AWTTTC also has a central coordinating role in the IPFR process, enabling the identification of potential patient cohorts at an early stage, by using All Wales IPFR data. The final decision as to whether or not the One Wales process should be initiated is proposed by AWTTTC and approved by the AWMSG Steering Committee. The IPFR process has been though the EHIA process: http://www.wales.nhs.uk/sitesplus/documents/862/IPFR_Policy_EQIA.pdf</p> <p>Needs assessment</p> <p>Criteria for the medicine to be considered for the One Wales process are:</p> <ul style="list-style-type: none"> • a clearly identified clinical need for the medicine • commitment by clinicians to collect outcome data • sufficient evidence of clinical efficacy <p>In addition, for licensed medicines:</p> <ul style="list-style-type: none"> • an absence of a negative HTA recommendation from either NICE or AWMSG, • a clear and binding commitment by the marketing authorisation holder to engagement in a future HTA. <p>https://cavuhb.nhs.wales/about-us/our-mission-vision/transformation/population-needs-assessments-for-cardiff-and-vale-of-glamorgan/</p> <p>To date, October 2022, the One Wales Process has been in operation for 6 years. Recommendations have been made for the use of 18 medicines/medicine combinations, of which 17 have had a positive recommendation at some point. At present there are 12 medicines available for patients in Wales through the One Wales process.</p> <p>Population data:</p>
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² <http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf>

³ <http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face>

It is estimated that in 2021 approximately 240 patients in Wales were treated with medicines accessed through the One Wales process. The number of patients treated may change in future years depending upon the disease areas and medicines identified for the One Wales process. One Wales recommendations apply to any patient in Wales which fit the treatment criteria for the specific medicine.

<https://www.ons.gov.uk/census/2011census/2011censusdata/2011censusdatacatalogue/populationstatisticsfortheuk>

<https://statswales.gov.wales/Catalogue/Population-and-Migration/Population/Estimates/Local-Authority/populationestimates-by-localauthority-year>

Research

AWTTC gather the evidence demonstrating the potential for the medicine to address the clinical need. For licensed medicines the marketing authorisation holder is expected to provide evidence of clinical efficacy. For all medicines AWTTC perform a comprehensive literature search and gather evidence published in the public domain. Along with input from clinical experts evidence is collated into an Evidence Summary Report (ESR) which informs the One Wales Assessment Group (OWAG), previously known as the Interim Pathways Commissioning Group (IPCG) for their decision-making discussions.

Examples of evidence status reports can be found on the AWTTC website:

<https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/one-wales-medicines-process/one-wales-medicines-interim-decisions/>

Involvement and engagement of stakeholders

The ESR is considered by the OWAG which directly advises the Chief Executive Management Team (CEMT), the final decision-makers with regard to One Wales medicines. Membership of OWAG is primarily drawn from all IPFR Panels in Wales and reports to CEMT. Whenever possible, all of the IPFR panels are represented at every meeting (with deputies attending when the main member is unavailable). In addition to IPFR panel members the group also has lay representation, a health economist, finance director, representative from Association of the British Pharmaceutical Industry (ABPI) Cymru Wales and a clinical pharmacologist.

Patient organisations are invited to attend the One Wales Assessment Group meeting (in person or via TEAMS, tele- or video conference) or they may submit a statement or patient story to the Group to provide the Group with a better understanding of the patient/carer perspective.

A clinical expert is invited to the OWAG meeting to observe proceedings and answer questions to enable members to gain a better understanding of the clinical context.

Meeting minutes and current membership of OWAG can be found on the AWTTC website:

<https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/one-wales-medicines-process/one-wales-medicines-assessment-group-owmag/>

Guidelines

For medicines recommended which are off-label (medicines used outside of their terms of licence) the One Wales advice refers prescribing clinicians to the General Medical Council guidelines for prescribing unlicensed medicines:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>

	<p>All current One Wales recommendations are available on the AWTTTC website: https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/one-wales-medicines-process/one-wales-medicines-interim-decisions/ IPFR annual reports are produced by AWTTTC and include a report on One Wales activities, all annual reports can be found here: https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/individual-patient-funding-request-ipfr/ipfr-annual-reports/</p>
<p>5 Who will be affected by the strategy/ policy/ plan/ procedure/ service</p>	<p>The policy affects:</p> <ul style="list-style-type: none"> • Defined patient cohorts in Wales who require treatment not normally available in NHS Wales. • Clinicians treating these patients who may prescribe One Wales medicines without completing IPFR applications. • IPFR panels in Wales have fewer medicine IPFR requests. • Pharmacists are required to make the One Wales medicines available on health board formularies and keep formularies up to date accordingly.

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

Note, only One Wales recommendations which identify specific groups of people or are for diseases which affect specific groups are mentioned in this section.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
<p>6.1 Age For most purposes, the main categories are:</p> <ul style="list-style-type: none"> • under 18; • between 18 and 65; and • over 65 	<p>Adalimumab is recommended for treatment of paediatric patients with non-anterior uveitis. For patients under 18 years old an improvement in symptoms due to accessing the medicine due to One Wales advice. Negative impacts may be the potential for adverse effects of the medicine.</p>	<p>Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects. One Wales advice refers the prescribing clinician to the GMC guidelines for prescribing of off-label or unlicensed medicines. Provision of criteria for starting and stopping treatment with adalimumab to ensure treatment is prescribed appropriately and does not continue if adverse effects outweigh the benefits. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.</p>	<p>The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AW TTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.</p>
	<p>Arsenic trioxide is recommended for the treatment of acute promyelocytic leukaemia in adult patients unsuitable for anthracycline-based therapy. These patients are too frail to receive standard</p>	<p>Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects. One Wales advice refers the</p>	<p>The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AW TTC who collate the outcome data to inform the annual review to ensure that the medicine</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	treatment due to the adverse effects and tend to be more elderly. The majority will be over 65 although occasionally a younger patient may require this treatment. Patients benefit from a potentially curative treatment where the standard treatment is not suitable. Adverse effects may be experienced.	prescribing clinician to the GMC guidelines for prescribing off-label or unlicensed medicines. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.	is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.
	Opicapone has been recommended for treatment of Parkinson's disease, this disease most commonly affect older people although occasionally younger patients may be affected. Parkinson's is a degenerative disease, this medicine can prolong the time before more invasive interventions are required to control the disease. Patients may experience adverse effects.	Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects. Provision of criteria for starting and stopping treatment with opicapone to ensure treatment is prescribed appropriately and does not continue if adverse effects outweigh the benefits. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective.	The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AWTTTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.
	Sorafenib is used as a maintenance treatment for people eligible for haematopoietic cell transplant (HCT) to reduce their risk of relapse and increase their overall survival. It would not be used in people who are not eligible for HCT, this may be based on age, fitness and co-morbidities. In	The NICE pathway provides information on alternative treatment options. Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects. One Wales advice refers the	The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AWTTTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	<p>these cases. People would receive alternative treatment to HCT. Patients may experience adverse effect whilst on sorafenib. This treatment is off label and therefore has not been licensed in this treatment group. Safety is therefore less well defined in this patient group.</p>	<p>prescribing clinician to the GMC/appropriate guidelines for prescribing off-label or unlicensed medicines. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.</p>	<p>review decisions.</p>
	<p>Vonicog alfa is recommended for the treatment of Von Willebrands (VW) disease in children. This medicine has a licence for use in adults and is currently available through WHSSC commissioning. The risk of transmission of infections through plasma-borne VW factor derivatives was considered to be an unacceptable risk for children and young persons and represented an inequality for this patient group.</p>	<p>Access through One Wales allows this patient group to be treated and WHSSC will be producing a policy in accordance with the agreed start stop criteria. Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects One Wales advice refers the prescribing clinician to the GMC/appropriate guidelines for prescribing off-label or unlicensed medicines. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.</p>	<p>On license for paediatric patients this treatment will remain available through WHSSC commissioning. The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AW TTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.</p>
<p>6.2 Persons with a disability as defined in the Equality Act 2010</p>	<p>Paediatric patients suffering from uveitis may have some sight loss prior to treatment. Adalimumab can improve</p>	<p>It is the prescribing clinician's responsibility to ensure that patients</p>	<p>The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AW TTC</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	sight or prevent/slow further loss of sight. Treatment can also reduce the need for concomitant use of other medications. Patients may experience adverse effects.	and their guardians receive accessible information about the impact of the treatment.	who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.
<p>6.3 People of different genders: Consider men, women, people undergoing gender reassignment</p> <p>NB 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</p>	<p>Bevacizumab is recommended for the treatment of advanced ovarian cancer and as such only affects female patients or patients undergoing gender re-assignment who have ovarian tissue.</p> <p>Patients with advanced ovarian cancer have a short life expectancy and the treatment can increase overall survival by several months where no other treatment is available. As expected the treatment can cause adverse effects.</p>	<p>Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects.</p> <p>One Wales advice refers the prescribing clinician to the GMC guidelines for prescribing off-label or unlicensed medicines.</p> <p>Provision of criteria for starting and stopping treatment with bevacizumab to ensure treatment is prescribed appropriately and does not continue if adverse effects outweigh the benefits.</p> <p>The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.</p>	<p>The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AWTTTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.</p>
	Denosumab for the treatment of osteoporosis in men at risk of fracture. This medicine was only available for treatment of women with osteoporosis in NHS Wales until the One Wales decision was endorsed. This	<p>Refer the prescribing clinician to the Summary of Product Characteristics for information on known adverse effects.</p> <p>Provision of criteria for starting and stopping treatment with denosumab</p>	<p>The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AWTTTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	recommendation provides a treatment option for men for whom other treatments are unsuitable. Adverse effects may have a negative impact on patients	to ensure treatment is prescribed appropriately and does not continue if adverse effects outweigh the benefits. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.	Chief Executive Management Team are responsible for the final endorsement of review decisions.
	Abiraterone is recommended for the treatment of non-metastatic and locally advanced high-risk hormone sensitive prostate cancer. This provides an oral treatment option and has shown greater efficacy than androgen deprivation therapy alone in this patient group. Offering a potential curative option for some patients. It has additional monitoring requirements that are carried out through clinic appointments. This treatment would be available for any person with a prostate gland that meets the clinical definition as described in the STAMPEDE study.	Despite the additional monitoring requirements, it is considered to be less burdensome than current chemotherapy-based treatment options for those patients living remotely and would need to travel for treatment. There is also the option for homecare delivery. Provision of criteria for starting and stopping treatment with abiraterone has been developed to ensure treatment is prescribed appropriately and does not continue if adverse effects outweigh the benefits. The process monitors patient outcomes as part of the annual review process to ensure that the medicine is effective and safe.	The monitoring of patient outcomes is the responsibility of prescribing clinicians in all health boards. Clinicians report to AWTTTC who collate the outcome data to inform the annual review to ensure that the medicine is effective and safe. The NHS Wales Chief Executive Management Team are responsible for the final endorsement of review decisions.
6.4 People who are married or who have a civil partner.	There does not appear to be any impact at this time on individuals from this particular protected characteristic.	There are no mitigation or recommendations necessary at this time	There is no action necessary at this time.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
<p>6.5 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.</p>	<p>There does not appear to be any impact at this time on individuals from this particular protected characteristic.</p>	<p>There are no mitigation or recommendations necessary at this time. Prescribers should take account of the summary of product characteristics when prescribing any medicines for women who are expecting a baby or are breastfeeding.</p>	<p>There is no action necessary at this time.</p>
<p>6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers</p>	<p>There does not appear to be any impact at this time on individuals from this particular protected characteristic. There are no diseases to date that disproportionately affect people of a specific race. In the future a medicine may be considered for a condition which does affect one particular race more than others.</p>	<p>There are no mitigation or recommendations necessary at this time</p>	<p>There is no action necessary at this time.</p>
<p>6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief</p>	<p>There does not appear to be any impact at this time on individuals from this particular protected characteristic.</p>	<p>There are no mitigation or recommendations necessary at this time</p>	<p>There is no action necessary at this time.</p>
<p>6.8 People who are attracted to other people of:</p> <ul style="list-style-type: none"> • the opposite sex (heterosexual); • the same sex (lesbian or 	<p>There does not appear to be any impact at this time on individuals from this particular protected characteristic.</p>	<p>There are no mitigation or recommendations necessary at this time</p>	<p>There is no action necessary at this time.</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
gay); <ul style="list-style-type: none"> both sexes (bisexual) 			
<p>6.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design</p> <p>Well-being Goal – A Wales of vibrant culture and thriving Welsh language</p>	<p>There is a video which explains the One Wales process for patients and clinicians, this is available in both Welsh and English language on the AW TTC website. Both versions are subtitled.</p>	<p>AWTTC will work towards providing the option for patient groups to communicate in the Welsh medium in the future.</p>	<p>A patient group currently may submit a summary in Welsh which AW TTC can get translated into English language for the OWMAG members as required.</p>
	<p>OWMAG correspondence and meetings are conducted exclusively in English language, this has the potential to disadvantage members who communicate using the Welsh language.</p>	<p>Ensure language preferences are considered for OWMAG members and offer communication in Welsh language.</p>	<p>In January 2022 OWMAG members were consulted as to language preferences. All current members expressed a preference for English language communication. On joining the group new members will be asked which is their preferred language.</p>
<p>6.10 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health</p>	<p>For patients in Wales all prescription medicines are provided free of charge, positive recommendations through One Wales will not impact individuals depending upon their income related group. Where a medicine has a negative recommendation following the One Wales process an IPFR may be made on behalf of the patient, this is not dependent upon the patient income</p>	<p>Negative One Wales advice is reviewed annually and if new evidence becomes available the medicines may be re-considered and potentially recommended. AW TTC continue to monitor IPFR requests and may re-consider a medicine previously declined for consideration through the One Wales process (unless it has a</p>	<p>The Chief Executive Management Team are responsible for endorsing a One Wales decision following the reconsideration of a medicine.</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	<p>group.</p> <p>If the medicine is declined through IPFR then the patient may choose to self-fund, this would be dependent upon the income related group of the patient.</p> <p>For medicines not considered suitable for the One Wales process due to a negative HTA the only route for access is IPFR then self-funding.</p>	<p>negative HTA) if a patient cohort indicates that there is an unmet need for the medicine.</p>	
<p>6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities</p>	<p>A One Wales decision ensures equity of access to a medicine independent of the health board in which the patient resides.</p> <p>For negative recommendations requests may be pursued through the IPFR panels locally. Where several requests are made for the same medicine and indication the IPFR process, with emphasis on the individual patient, may result in variation in access across Wales.</p> <p>Some of the medicines considered are available as oral treatments and are therefore easier to access for those people living remotely. Some are available through schemes some as Homecare.</p>	<p>Negative One Wales advice is reviewed annually and if new evidence becomes available the medicines may be re-considered and potentially recommended.</p>	<p>The Chief Executive Management Team are responsible for endorsing a One Wales decision following the reconsideration of a medicine.</p> <p>As part of the decision-making process, patient impact is considered.</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
<p>6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service</p>	<p>The One Wales process applies to all people registered with the NHS in Wales. Groups such as refugees, asylum seekers and some homeless people may fall outside of NHS services and as such would not have access to One Wales medicines.</p>	<p>There are organisations who are involved with people who cannot or are unable to access NHS services. These organisations work to identify such individuals and encourage NHS engagement.</p>	<p>Clinical Boards have a duty to reduce health inequalities in access to services and outcomes. Boards work with government and third sector organisations to address the unmet needs of these patients.</p>

7. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>7.1 People being able to access the service offered: Consider access for those living in areas of deprivation and/or those experiencing health inequalities</p> <p>Well-being Goal - A more equal Wales</p>	<p>Patients have the same access to medicines recommended through One Wales regardless of where they reside in Wales. Patient organisations and representatives are encouraged to input into the decision-making process and can attend OWMAG meetings in person or via TEAMS and previously tele- or video conferencing. If attendance is not possible then a patient statement can be submitted which is presented to the group. This process improves access to treatment where there is an unmet need in a timely manner.</p>	<p>AWTTC will be continuing to work on outreach projects for patient groups and healthcare professionals to encourage engagement with the One Wales process. A short, animated information video is available on the AWTTC website to provide information to both healthcare professionals and members of the public. The video is available in English and Welsh, is subtitled and uses plain language for accessibility.</p>	<p>There is no action necessary at this time.</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc</p> <p>Well-being Goal – A healthier Wales</p>	<p>There does not appear to be any impact on healthy lifestyles at this time.</p>	<p>There are no mitigation or recommendations necessary at this time</p>	<p>There is no action necessary at this time.</p>
<p>7.3 People in terms of their income and employment status: Consider the impact on the availability and accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions</p>	<p>The process allows the impact of the disease on employment status to be considered as part of the discussions by OWAG. Patient organisations, lay members and clinicians have opportunity to inform the group as to how the disease affects the employment of patients and how the medicine may affect this.</p>	<p>In order to provide transparency, the One Wales decision and rationale, evidence status reports, patient organisation summaries and minutes of the OWMAG meeting are available on the AWTTTC website. Patient organisation summaries will only be available where patient confidentiality is ensured.</p>	<p>There is no action necessary at this time.</p>

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
Well-being Goal – A prosperous Wales			
<p>7.4 People in terms of their use of the physical environment: Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces</p> <p>Well-being Goal – A resilient Wales</p>	There does not appear to be any impact on the use of the physical environment at this time.	There are no mitigation or recommendations necessary at this time	There is no action necessary at this time.
<p>7.5 People in terms of social and community influences on their health: Consider the impact on family</p>	There does not appear to be any impact on social and community influences at this time.	There are no mitigation or recommendations necessary at this time	There is no action necessary at this time.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos</p> <p>Well-being Goal – A Wales of cohesive communities</p>			
<p>7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate</p> <p>Well-being Goal – A globally responsible Wales</p>	<p>This is an innovative process, which allows for evidence to be gathered for medicine effectiveness and tolerance in the ‘real world’. Outcome data can be used to evaluate the medicine in the patients in Wales and in some cases can provide additional information for future Health Technology Assessment.</p>	<p>Improve data collection with more detailed patient outcome reporting. Investigate the potential for patient-reported outcomes.</p>	<p>AWTTC in collaboration with clinicians will be responsible for gathering and analysing outcome data. AWTTC is investigating the use of BlueTeq to support data collection.</p>

Please answer question 8.1 following the completion of the EHIA and complete the action plan

<p>8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service</p>	<p>The One Wales process is a responsive process which allows access to medicines not usually available in NHS Wales for clearly defined cohorts of patients.</p> <p><u>For positive One Wales medicine recommendations</u></p> <p>Positive impacts</p> <ul style="list-style-type: none"> • Timely access to medicines without recourse to the Individual Patient Funding Request (IPFR) application process. • Improvement or stabilisation of clinical condition for patients receiving medication previously not routinely available. • Equity of access to these medicines across all health boards in Wales. • Reduction in workload for local health board and WHSSC IPFR panels. • Reduction in workload for clinicians who do not need to complete IPFR forms for medicines with positive One Wales advice. • For licensed medicines a One Wales recommendation allows time for clinical and cost effectiveness evidence to be gathered to inform future Health Technology Appraisal (HTA). • Collection of outcome data and annual review allows the safety and clinical effectiveness of the medicines to be monitored. <p>Negative impacts</p> <ul style="list-style-type: none"> • As with all medicines patients may experience adverse effects. <p><u>For negative One Wales medicine recommendations</u></p> <p>Positive impacts</p> <ul style="list-style-type: none"> • Decisions are reviewed annually and may be re-assessed if new evidence becomes available • If the medicine is considered by an IPFR panel the evidence status report compiled by AWTTTC is freely available and may be used as additional evidence to inform IPFR panels. <p>Negative impacts</p> <ul style="list-style-type: none"> • The medicine may be accessed via IPFR only with the associated burden on clinicians and IPFR panels and the potential for inequity of access between health boards. For negative IPFR decisions patients have the option to self-fund medicines. This may lead to inequity in access on grounds of household income.
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Action Plan for Mitigation / Improvement and Implementation

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.2 What are the key actions identified as a result of completing the EHIA?	Improve annual data collection with more detailed outcomes.	Gail Woodland and AWTTTC One Wales team	Annually	
	Investigate the practicalities of patient reported outcomes.	Gail Woodland and AWTTTC One Wales team	Ongoing	
	Improve outreach to patient groups and clinicians to raise awareness of the One Wales process.	Gail Woodland and AWTTTC One Wales team	Reviewed annually.	
	Liaise with the AWTTTC Welsh language lead to offer the option for patient organisations to communicate with the One Wales team in Welsh language.	Kelly Wood and AWTTTC One Wales team	July 2020. Reviewed for new members.	
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required? This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?	No, this equalities impact assessment has not identified any requirement for a more comprehensive assessment.	Not applicable	Not applicable	No action required

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
<p>8.4 What are the next steps?</p> <p>Some suggestions:-</p> <ul style="list-style-type: none"> • Decide whether the strategy, policy, plan, procedure and/or service proposal: <ul style="list-style-type: none"> ○ continues unchanged as there are no significant negative impacts ○ adjusts to account for the negative impacts ○ continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so) ○ stops. • Have your strategy, policy, plan, procedure and/or service proposal approved • Publish your report of this impact assessment • Monitor and review 	<p>The One Wales Policy will continue unchanged and will undergo review every three years.</p> <p>The One Wales EHIA will be published, alongside the One Wales policy, on the AWTTTC website once both documents have been endorsed by the Chief Executive Management Team.</p> <p>The EHIA will be updated as required when medicines are assessed for specific groups of people or for the treatment of diseases which affect specific groups of people.</p> <p>The EHIA will be reviewed alongside the One Wales policy every three years unless changes to legislation or best practice determine that an earlier review is required.</p>	AWTTTC	To be endorsed by the end of 2020 and reviewed every three years thereafter.	The Chief executive Management Committee are responsible for endorsement of the One Wales policy and the EHIA, and of any changes following subsequent policy reviews.

