

Equality and Health Impact Assessment

Abiraterone, with prednisone or prednisolone, for treatment of newly diagnosed, high-risk, metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT)

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: 05/02/2025

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| 1. | AWTTC contact details | Tel: 02921 826900 Email: awttc@wales.nhs.uk |
| 2. | State the objectives of the project. | <p>AWTTC will prepare an evidence status report (ESR) for a limited AWSMG assessment for the use in NHS Wales of abiraterone, with prednisone or prednisolone, for the treatment of newly diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).</p> <p>The ESR will summarise current use of abiraterone in NHS Wales, budget impact, and equity of access across Wales and the rest of the UK. AWTTC will request the views of patient organisations relevant to the condition, and will send the evidence summary report to the company (marketing authorisation holder) and to clinicians for comment. Clinicians, company representatives and patient organisation representatives will be invited to attend the Licensed One Wales Medicines Assessment Group (LOWMAG) meeting. The LOWMAG constitution is available online.</p> |
| 3. | Evidence and background information considered. For example: | In August 2021 the National Institute for Health and Care Excellence (NICE) issued a non-recommendation (TA721) for the use of abiraterone with prednisone/prednisolone for newly diagnosed high risk metastatic hormone |



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| <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>sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).</p> <p>Since the availability of generics in 2022 there has been a significant drop in the price of abiraterone compared to the original list price of Zytiga® (branded abiraterone). Velindre Cancer Centre have been recruiting patients in to the STAMPEDE trial to receive treatment with abiraterone. This trial has now closed. In December 2024 NHSE released an interim clinical commissioning policy pending the outcome of a NICE evaluation of the use of generic abiraterone acetate in this high-risk mHSPC population. In Scotland abiraterone has been available for this indication since January 2020 following appraisal by Scottish Medicines Consortium (SMC).</p> <p>The European Association of Urology Guidelines for Prostate Cancer, section 6.6.8; Guidelines for the first line treatment of mHSPC include the following:</p> <ul style="list-style-type: none">• Offer ADT combined with abiraterone acetate plus prednisone or apalutamide or enzalutamide to patients with M1 disease who are fit for the regimen.• Offer docetaxel only in combination with ADT plus abiraterone or darolutamide to patients with M1 disease who are fit for docetaxel. <p>Results from the LATITUDE study in 1,199 people with newly diagnosed high-risk hormone-sensitive metastatic prostate cancer showed median progression-free survival was 14.8 months with ADT alone and 33.0 months with abiraterone in combination (hazard ratio [HR] 0.47, 95% confidence interval [CI] 0.39 to 0.55). Based on the planned final analysis of overall survival, the median overall survival with ADT alone was 36.5 months compared with 53.3 months with abiraterone in combination (HR 0.66, 95% CI 0.56 to 0.78).</p> <p>Results of the STAMPEDE UK multi-arm non-blinded adaptive study showed that, at a median follow up of 3.3 years, the hazard ratio for progression-free survival for abiraterone plus ADT compared with ADT alone in the high-risk</p> |
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metastatic subgroup was 0.46 (95% CI 0.36 to 0.59), and for overall survival was 0.54 (95% CI 0.41 to 0.70). The HR for overall survival was maintained after 8 years of follow up (HR 0.54, 95% CI 0.43 to 0.69).

A systematic review and network meta-analysis conducted by [Wang et al. 2021](#) showed improved overall survival when added to ADT included abiraterone acetate (hazard ratio [HR], 0.61; 95% credible interval [CI], 0.54-0.70), apalutamide (HR, 0.67; 95% CI, 0.51-0.89), and docetaxel (HR, 0.79; 95% CI, 0.71- 0.89); improved radiographic progression-free survival when added to ADT included enzalutamide (HR, 0.39; 95% CI, 0.30-0.50), apalutamide (HR, 0.48; 95% CI, 0.39- 0.60), abiraterone acetate (HR, 0.51; 95% CI, 0.45-0.58), and docetaxel (HR, 0.67; 95% CI 0.60-0.74).

The [Summary of Product Characteristics](#) (SmPC) warns that abiraterone may cause hypertension, hypokalaemia and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Blood pressure, serum potassium and fluid retention should be monitored monthly. Increased liver enzymes are a very common adverse event and serum transaminases should be monitored every two weeks for the first three months of starting treatment with abiraterone and monthly after that. Due to the risk of hypoglycaemia and hyperglycaemia with prednisolone, caution is recommended when treating patients with diabetes. Myopathy and rhabdomyolysis are uncommon adverse events most likely to develop in the first 6 months of starting treatment.

Abiraterone, enzalutamide and apalutamide are all given orally. Abiraterone may be unsuitable for some patients with cardiovascular disease.

Clinical experts estimated that they expected 10–20 new patients would be eligible for abiraterone treatment per year across Wales, and that this would rise by 10% per year.

Generic abiraterone is deemed to be cost saving when compared to apalutamide and enzalutamide. Abiraterone also has fewer interactions (than



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| | | enzalutamide and apalutamide) (e.g. those on DOACS) and is also the optimal choice for patients at risk of neurocognitive side effects (fatigue, falls, memory impairment etc). |
| 4. | Who will this project affect? | People in Wales with newly diagnosed, high-risk, metastatic hormone-sensitive prostate cancer (mHSPC), 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). |
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| <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>Prostate cancer is more common in older people; we might expect a positive impact on older people with prostate cancer if the criteria for treatment with abiraterone are met.</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</p> | <p>N/A</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). |
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| | 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 . | | |
| 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. Abiraterone is an oral treatment that can be given in outpatient and in community setting. This could have a positive impact by helping compliance for people who find it difficult to travel to a hospital for treatment. Abiraterone may be preferential for patients with co-morbidities due to lesser interactions with other medicines for the same indication. The adverse effect profile also makes abiraterone the best choice for patients at | 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 |



| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| | risk of neurocognitive side effects such as falls, fatigue, memory impairment. Patients with diabetes will require additional blood sugar monitoring. | | |
| 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. Prostate cancer can affect anyone with a prostate gland; we might expect a potential positive impact on people with prostate cancer if the criteria for treatment are met. | 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). |
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| | 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. | Abiraterone is not recommended for use during pregnancy or in people who may be pregnant. Please refer to the SmPC . The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment. | N/A | N/A |
| 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. Prostate cancer is more common in black people than white people . We might expect | Note in the project document that people of different race and ethnicities can have varying responses to medicines. | N/A |



| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| | a potential positive impact on people with prostate cancer if the criteria for treatment are met, including for black people. | | |
| 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 or 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: <ul style="list-style-type: none">• 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). |
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| 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. | Abiraterone is an oral treatment and can be given in outpatient and in community setting. 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). |
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| | people based on where they live. | | |
| 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 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. Abiraterone might benefit carers by reducing a patient's need for help with work, family and personal tasks. As an oral treatment it might have a positive impact on carers by reducing the need for hospital visits. | 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). |
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| 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) |
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| 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. Abiraterone is an oral treatment and can be given in outpatient and in community setting.. | 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 | 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) |
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| | 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. | N/A | N/A |

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

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| <p>7.1 Please summarize the potential positive and/or negative impacts of the project.</p> | <p>No potential negative impacts identified. We might expect a potential positive impact on people with this type of prostate cancer, and their families and carers. Prostate cancer is more common in black men than white men, abiraterone offers an additional treatment option regardless of race or ethnicity.</p> |
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Action plan for mitigation or improvement and implementation

| | Action | Lead(s) | Timescale | Actions taken |
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| <p>7.2 What are the key actions identified as a result of completing the EqHIA?</p> | <ul style="list-style-type: none"> • consult with clinical experts in Wales, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website • AWTTC to prepare an Evidence Summary Report (ESR) • ESR to clinicians and company for comment • Licensed One Wales Medicines Assessment Group (LOWMAG) meet to consider and make a recommendation to AWMSG. • AWMSG meet to consider and make a recommendation to Welsh Government about this use of abiraterone in Wales. | <p>AWTTC</p> | <p>Feb-May 2025</p> <p>Mar 2025</p> <p>Mar 2025</p> <p>Apr 2025</p> <p>May 2025</p> | |

| | Action | Lead(s) | Timescale | Actions taken |
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| 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). | AWTTC | Mar 2025 | |
| 7.5 Review of project and EqHIA | This will be reviewed in accordance with the policy. | AWTTC | [TBC] | |

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