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

Evidence summary report for a limited assessment

Abiraterone film-coated tablets

Indication

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)

Company: various

Date of licence extension: 15 November 2017

All yellow underlined text in this document is confidential.

Background

In August 2021 the National Institute for Health and Care Excellence (NICE) issued a non-recommendation (TA721) for the use of abiraterone with prednisone or prednisolone for newly diagnosed high risk mHSPC in adult men in combination with ADT. Although abiraterone was subject to a Patient Access Scheme (PAS), the committee considered that the most likely Incremental Cost Effectiveness Ratio (ICER) was above the £30,000 threshold when compared with either docetaxel plus ADT or ADT alone. There were no comparisons made with enzalutamide or apalutamide as the timing of the submission to NICE meant that these treatments were not standard of care. In July 2021 NICE recommended enzalutamide (Xtandi®) as an option for treating mHSPC (TA712) and in October 2021, apalutamide was recommended; restricted for use in mHSPC where docetaxel was not suitable (TA741).

Abiraterone has been available as a generic medicine since 2022 and there has been a significant drop in the price of abiraterone compared to the original list price of Zytiga® (branded abiraterone).

NHS England has released an interim clinical commissioning policy (13 Dec 24) pending the outcome of a NICE review of TA721. In Scotland abiraterone has been available for this indication since January 2020 following appraisal by Scottish Medicines Consortium (SMC).

The European Association of Urology Guidelines for Prostate Cancer, section 6.6.8; Guidelines for the first line treatment of mHSPC include the following:

- Offer ADT combined with abiraterone acetate plus prednisone or apalutamide or enzalutamide to patients with metastatic disease who are fit for the regimen.
- Offer docetaxel only in combination with ADT plus abiraterone or darolutamide to patients with metastatic disease who are fit for docetaxel.

Criteria for a limited assessment

The Scrutiny panel reviewed the clinical request for assessment of abiraterone by AWMSG and considered that abiraterone was suitable for a limited assessment via the Licensed Medicines One Wales Medicines Assessment Group (LOWMAG). They cited the following reasons for this decision:

- This treatment is commissioned in Scotland and England.
- This treatment is deemed to be cost saving when compared to other doublet therapies.
- Abiraterone for this indication is included in the European Association of Urology (EAU) Prostate Cancer Guidelines.
- The clinical effectiveness of abiraterone is established.

The AWMSG Scrutiny Panel agreed that as the case for clinical effectiveness is established it does not warrant further review. Therefore, the limited assessment should give an overview of current use, equity of access and budget impact only. In addition, advice will be interim to NICE assessment.

Comparator(s) and place in pathway

- Enzalutamide plus ADT continued until loss of response.
- Apalutamide plus ADT continued until loss of response.

Clinical experts state that docetaxel plus ADT is no longer standard of care due to the significant risk of neutropenic sepsis, EUA guidelines do not recommend this as a treatment option.

Enzalutamide and apalutamide are potent enzyme inducers and interaction with many common medicines are to be expected. Abiraterone has fewer interactions and therefore is an option for patients on medication for co-morbidities. Abiraterone is the preferred treatment for patients at risk of neurocognitive side effects such as fatigue, falls and memory impairment. Abiraterone may be unsuitable for some patients with cardiovascular disease. Clinical efficacy of these three medicines has been shown to be comparable in a network meta-analysis conducted by Wang et al (2021).

Darolutamide with docetaxel and ADT is recommended by NICE as an option for treating hormone-sensitive metastatic prostate cancer in adults (TA903). Patients fit enough for this treatment would be offered this in preference to any of the doublet therapies included above. Clinicians therefore consider this not be a direct comparator.

Budget impact

Generic preparations of abiraterone are available, abiraterone is prescribed in secondary care and provided to patients via homecare. Table 1 provides the contract price for abiraterone plus prednisolone. Patient access scheme (PAS) prices have been provided for the comparators: enzalutamide and apalutamide which are also provided via homecare. Prices are per patient per month (28 days) and exclude VAT. There is an additional rebate for enzalutamide for this indication that we are unable to disclose.

Table 1. Medicine acquisition costs for abiraterone and comparators

Medicine	Dose	28 days (excluding VAT)	Comment
Abiraterone	1000 mg od (2 x 500 mg)	¶¶	All Wales contract price
Prednisolone	5mg od	£0.73	Drug Tariff price
Net cost		¶¶	
Comparators			
Apalutamide	240 mg od (1 x 240 mg)	¶¶	PAS price
Enzalutamide	160 mg od (4 x 40 mg)	¶¶	PAS price
od: once daily; PAS: Patient Access Scheme ¶¶ Commercial in confidence data removed			

Table 2 provides the costs associated with the use of abiraterone for mHSPC in Wales. The median treatment duration with abiraterone in the STAMPEDE clinical trial was 33 months. Median treatment duration for apalutamide and enzalutamide was reported to be 39 and 40 months respectively (TITAN and ARCHES clinical trials). For the purposes of the budget impact we have assumed 3 years of treatment for abiraterone and comparator treatments.

Clinical experts indicate that for Velindre Cancer Centre, just over 100 patients commenced treatment with an androgen-receptor targeted treatment in the last year. Of these they anticipate 5–10% would be eligible for abiraterone. VCC covers cancer care for around 50% of the population in Wales. Extrapolating estimated patient numbers to all of Wales result in 10–20 new patients eligible per year. Clinical experts estimate this will rise by 10% per year.

Based on prescribing data for VCC, it is estimated that in the absence of abiraterone 40% of patients would receive apalutamide and 60% would receive enzalutamide, these figures have been used to calculate the medicine acquisition costs in a market without abiraterone for this indication.

Table 2 Cost of abiraterone for the treatment of newly diagnosed high risk mHSPC

	Year 1	Year 2	Year 3	Year 4	Year 5
Sub-population of new eligible patients each year	10–20	11–22	12–24	13–27	15–29
Uptake of medicine (%)	100%	100%	100%	100%	100%
Cumulative number of patients receiving medicine*	10–20	21–42	33–66	36–73	40–80
Comparator acquisition costs†	¶¶	¶¶	¶¶	¶¶	¶¶
Abiraterone acquisition costs	¶¶	¶¶	¶¶	¶¶	¶¶
Net medicine acquisition savings	¶¶	¶¶	¶¶	¶¶	¶¶

*Estimated treatment duration of 3 years
†A market without abiraterone assumes 40% of patients receive apalutamide and 60% receive enzalutamide; rounded to whole numbers.
¶¶ Commercial in confidence data removed

Using abiraterone plus prednisolone instead of apalutamide is estimated to save [commercial in confidence text removed] per patient per year. For enzalutamide the saving increases to [commercial in confidence text removed] per patient per year (excluding the additional rebate). For an estimated 10–20 patients in year 1 increasing by 10% year on year results in a cost saving of between [commercial in confidence text removed] in year 1 rising to between [commercial in confidence text removed] in year 5. Actual cost savings will be lower than quoted when the rebate for enzalutamide is applied. [commercial in confidence text removed].

Monitoring costs and adverse event costs have not been included, abiraterone requires serum transaminase monitoring every 2 weeks for the first 3 months of treatment and once a month thereafter. In practice at VCC patients are monitored 3–4 weeks after starting treatment, the monitoring interval is then increased for those with stable levels. This may be on an outpatient basis or in primary care and is not expected to significantly affect the budget impact. The proportions of patients receiving the comparator medicines apalutamide and enzalutamide have been based on VCC prescribing data and may not be representative for the remaining areas of Wales. Homecare costs have not been included, all three medicines are expected to

be provided via homecare arrangements. VAT is not incurred on medicines provided via homecare.

Impact on health and social care services

Minimal impact.

Patient factors

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

Equality and health impact assessment

AWTTC have completed an Equality and Health Impact Assessment in parallel with each development stage of the project. This follows 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.

It is not expected that abiraterone will have a potential negative impact on people based on the protected characteristics of the Equality Act 2010. Prostate cancer is more common in older people, it is expected that abiraterone will have a positive impact on older people with prostate cancer who meet criteria for treatment. The adverse effect profile and lower drug interaction potential of abiraterone may have a positive impact for people with co-morbidities or those at risk of neurocognitive side effects. Prostate cancer is more common in black people than white people. It can affect any person who has a prostate gland, including biological sex men and trans females. Abiraterone is expected to have a positive effect on the overall outcomes of all eligible patients regardless of gender reassignment.

Additional information

This report should be cited as: All Wales Therapeutics and Toxicology Centre. Evidence status report for a limited assessment. Abiraterone film-coated tablets. Metastatic hormone sensitive prostate cancer. Reference number: 6441. March 2025.