Abiraterone

Section: 8. Immunomodulators and antineoplastics > 8.2. Antineoplastics and supportive medicines > 8.2.4. Hormones and antihormones

ATC codes: L02BX03

Indication	Malignant neoplasms of prostate ICD11 code: 2C82.Z
INN	Abiraterone
Medicine type	Chemical agent
List type	Complementary
Formulations	**Oral > Solid:** 250 mg ; 500 mg
EML status history	First added in 2019 (TRS 1021) Changed in 2021 (TRS 1035)
Sex	Male
Age	Adolescents and adults
Therapeutic alternatives	enzalutamide (ATC codes: L02BB04)
Patent information	Patents have expired in most jurisdictions Read more about patents.
Tags	Cancer
Wikipedia	Abiraterone
DrugBank	Abiraterone

Summary of evidence and Expert Committee recommendations

The Expert Committee noted that prostate cancer is the second most common cancer in men worldwide and the fourth most common cancer overall, and that treatment options for metastatic, castration-resistant prostate cancer are limited. The Committee acknowledged that enzalutamide and abiraterone, as oral treatments, offer several advantages over other treatment options as they do not require intravenous administration, leukapheresis, or the use of radiopharmaceutical compounds. The Committee recalled its previous recommendations not to include enzalutamide on the EML, recommending instead listing abiraterone based on advantages offered by dosing strategies, lower pill burden, better adherence and availability of generics which would allow potential cost savings. The Committee noted that the current cost of enzalutamide is very high for both patients and health systems. The Committee noted that enzalutamide for metastatic, castration-resistant prostate cancer largely meets the EML criteria for survival benefit (i.e. at least 4 to 6 months survival gain) and the European Society of Medical Oncology's magnitude of clinical benefit scale (ESMO-MCBS) v1.1 score, and appears to demonstrate comparable efficacy and safety to abiraterone. However, no direct trial data are available, leaving some uncertainty about which medicine is the best therapeutic option. Enzalutamide has a different mechanism of action and a different toxicity profile, making it a first-choice medicine in patients not eligible to be treated with or unable to tolerate abiraterone. Unlike abiraterone, enzalutamide does not require concomitant use of prednisolone. The Committee considered that having multiple treatment options included on the EML may provide opportunities for countries to negotiate better prices as part of their national procurement processes. In some countries, competition and price reduction will be facilitated by the fact both abiraterone and enzalutamide

have generic versions available. Therefore, the Committee recommended that enzalutamide be included on the complementary list of the EML as a therapeutic alternative to abiraterone. The listing of abiraterone should be qualified with a square box indicating enzalutamide as an alternative for national selection. The Committee considered that this could provide opportunities for cost savings at the country level and increase access to medicines associated with favourable outcomes. As currently the prices of abiraterone and enzalutamide are a major obstacle for health care systems, the Committee recommends that countries address this problem through multiple actions, including price negotiations, competitive tendering and expanded use of generics. The Committee recommended that the Medicines Patent Pool explore with manufacturers how to facilitate affordable access to enzalutamide through public health-oriented licences. The Committee also requested that WHO prioritize abiraterone and enzalutamide as potential candidates for prequalification to facilitate access to affordable and quality-assured products. Refer to the 2021 summary for enzalutamide for full details of the Committee's consideration and recommendation.

