[GUIDANCE IS OUTDATED AND HAS BEEN WITHDRAWN ON 19 DECEMBER 2022.]

Abiraterone

for treating metastatic prostate cancer

Technology Guidance from the MOH Drug Advisory Committee

Guidance recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Generic abiraterone acetate 250 mg tablet (Abiranat) in line with its registered indications for treating:
  - newly diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT);
  - metastatic castration-resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy is not yet clinically indicated; and
  - metastatic castration-resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

Subsidy status

Generic abiraterone acetate 250 mg tablet (Abiranat) is recommended for inclusion on the MOH Standard Drug List (SDL) for the abovementioned indications.

SDL subsidy **does not** apply to proprietary abiraterone acetate 250 mg and 500 mg tablets (Zytiga).

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Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of abiraterone for treating metastatic prostate cancer. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for abiraterone was considered in line with its registered indications.

1.2 The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.3 Additional factors, including social and value judgments, may also inform the Committee's subsidy considerations.

Clinical need

2.1 The Committee noted that most prostate cancers are diagnosed during early stages of the disease, however, about 20% of patients have stage IV (metastatic) disease at diagnosis. Metastatic disease is managed by suppression of the male hormone testosterone, also termed androgen deprivation therapy (ADT), either surgically or chemically. Most prostate cancers are initially sensitive to hormonal manipulation (metastatic hormone-sensitive prostate cancer (mHSPC)), but the disease usually progresses and becomes resistant to ADT (metastatic castration-resistant prostate cancer (mCRPC)). Men with mCRPC who are asymptomatic or minimally symptomatic may receive second-line hormonal therapies or be actively monitored for disease progression until chemotherapy (e.g. docetaxel) is indicated. In local practice, chemotherapy is only used in up to 20% of patients and is delayed for as long as possible due to its myelosuppressive toxicity.

2.2 Abiraterone is the most commonly used hormone therapy in Singapore for prostate cancer. Both proprietary and generic formulations of abiraterone have HSA approval for treating mHSPC and mCRPC. The Committee noted that hormone therapies constitute routine clinical care for metastatic disease and agreed that there was a high clinical need to consider abiraterone for subsidy in view of the therapeutic gap in the MOH List of Subsidised Drugs.

Clinical effectiveness and safety

3.1 The Committee acknowledged that three randomised controlled trials showed that abiraterone statistically significantly improved overall survival and progression-free survival compared to placebo in patients with newly diagnosed high-risk mHSPC, chemotherapy-naïve mCRPC, and mCRPC whose disease had progressed on or after docetaxel therapy. No head-to-head trials comparing abiraterone with docetaxel were identified.

3.2 The Committee noted that abiraterone was well tolerated and had a comparable safety profile to placebo. Adherence to abiraterone in the trials was generally high.

Cost effectiveness

4.1 No published local cost-effectiveness studies of abiraterone were identified. An evaluation reported by NICE (UK) indicated that the base case ICER for proprietary abiraterone compared with best supportive care was likely to be between £28,600 and £32,800 per QALY gained for the treatment of prostate cancer after failure of ADT, prior to chemotherapy. The most plausible ICER was considered to be less than £50,000 per QALY gained for men whose disease had progressed on or after docetaxel.

4.2 The Committee heard that with the availability of generic abiraterone, which is considerably less expensive than the proprietary product, the ICERs will be lower; therefore, the cost effectiveness of generic abiraterone was likely to be favourable in the local context.

Estimated annual technology cost

5.1 The Committee noted that the annual cost impact was estimated to be SG$500,000 to less than SG$1 million in the first year of listing generic abiraterone (Abiranat) on the SDL. The annual cost impact was estimated to increase in subsequent years once most patients have switched from the proprietary product.

Additional considerations

6.1 The Committee indicated that a brand-specific listing (for Abiranat) may be removed over time once the generic adoption rate is high and multiple generic brands are available.

Recommendation

7.1 Based on available evidence, the Committee recommended generic abiraterone 250 mg tablet (Abiranat) be listed on the SDL for treating metastatic prostate cancer in line with its registered indications, in view of the current therapeutic gap in the MOH List of Subsidised Drugs, acceptable clinical effectiveness, and the substantial cost savings that are likely to be generated by generic substitution.

About the Agency

The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore residing within the Ministry of Health. It conducts evaluations to inform the subsidy of treatments, and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. The guidance is based on the evidence available to the Committee as at 9 April 2020. This guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

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