

**12.01 ABIRATERONE ACETATE,
Tablet 250 mg,
Zytiga[®], Janssen-Cilag Pty Ltd.**

1 Purpose of Application

- 1.1 The Medical Oncology Group of Australia (MOGA) sought an amendment to the current Authority Required PBS listing for abiraterone acetate, used for the treatment of metastatic castration resistant prostate cancer (mCRPC) to enable treatment in combination with steroids other than prednisone or prednisolone.

2 Requested listing

- 2.1 The submission requested the following changes to the existing restriction:
- 2.2 The proposed change to the existing listing is shown in italics and deletions are shown in strikethrough:

Public Summary Document – March 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
ABIRATERONE ACETATE abiraterone acetate 250 mg tablet, 120	1	2	\$3601.42	Zytiga [®]	Janssen-Cilag Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Prostate cancer
PBS Indication:	Castration resistant metastatic carcinoma of the prostate
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	The treatment must be in combination with a steroid such as prednisone or prednisolone a corticosteroid, AND The treatment must not be used in combination with chemotherapy, AND Patient must have failed treatment with docetaxel due to resistance or intolerance; OR Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND Patient must have a WHO performance status of 2 or less, AND Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, AND Patient must not have received prior treatment with enzalutamide; OR Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 Abiraterone acetate is TGA registered for use with prednisone or prednisolone, for the treatment of patients with mCRPC, who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) or who have received prior chemotherapy containing a taxane.
- 3.2 Abiraterone acetate was listed on the PBS for the treatment of patients with mCRPC on 1 August 2013.
- 3.3 The applicant indicated that recent studies comparing abiraterone used in combination with prednisone or dexamethasone resulted in similar toxicity, but with a higher proportion of patients in the dexamethasone arm achieving prostate serum antigen reductions of greater than 50%. The applicant therefore argued that allowing abiraterone to be used in combination with other steroids, such as dexamethasone, would improve the benefit gained from abiraterone, without impairing toxicity or tolerability.
- 3.4 The applicant proposed no new restrictions.

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

5 PBAC Outcome

- 5.1 The PBAC recommended the proposed amendment of the current Authority Required PBS listing for abiraterone acetate when used for the treatment of mCRPC, on the basis that it was reasonable for the choice of corticosteroids used in combination with abiraterone acetate to be a clinical decision.
- 5.2 The PBAC noted published data presented by the applicant indicated that abiraterone with dexamethasone was at least as effective as prednisone with abiraterone for the treatment of prostate cancer.
- 5.3 The PBAC considered it most likely that the oral form of dexamethasone would be used in combination with abiraterone, and therefore there should be no additional costs associated with increased IV infusions.

- 5.4 The PBAC recalled its previous advice that abiraterone acetate is not suitable for prescribing by nurse practitioners.
- 5.5 The PBAC noted that this submission is not eligible for an Independent review, as it received a positive recommendation.

Outcome:
Recommended.

6 Recommended listing:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
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Clinical criteria:	The treatment must be in combination with a corticosteroid, AND The treatment must not be used in combination with chemotherapy, AND Patient must have failed treatment with docetaxel due to resistance or intolerance; OR Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND Patient must have a WHO performance status of 2 or less, AND Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, AND Patient must not have received prior treatment with enzalutamide; OR Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to

recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.