

5.15 ABIRATERONE

500 mg tablet, ZYTIGA[®], Janssen-Cilag Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to request the listing of an additional strength, 500 mg abiraterone tablet for use in combination with a corticosteroid for the treatment of metastatic castration resistant carcinoma of the prostate.

2 Requested listing

- 2.1 The submission sought to list the 500 mg tablets on the PBS under Section 85 General Schedule as per the current listing for abiraterone 250mg.
- 2.2 No changes to the wording of the current abiraterone restriction were proposed.

3 Background

- 3.1 Abiraterone is TGA registered for the treatment of patients with metastatic advanced prostate cancer in combination with prednisone or prednisolone.
- 3.2 Abiraterone 500 mg tablet was TGA registered on 17 February 2017.
- 3.3 At its March 2017 meeting, the PBAC recommended amending the PBS Authority Required listing for abiraterone to enable treatment in combination with steroids other than prednisone or prednisolone.

4 Current situation

- 4.1 The submission claimed that the listing of the 500 mg tablet with a 2 x 500mg tablet once-daily dosing regimen is intended to replace the current listing of abiraterone 250 mg tablets with a 4 x 250 mg tablet once-daily dosing regimen. The sponsor claimed that the 500 mg tablets would reduce the patient pill burden and may improve compliance for a group of patients with multiple comorbidities who receive multiple treatments. The sponsor claimed that the improved film-coated formulation of the 500 mg tablets may aid swallowing for patients who are older and may have difficulty swallowing, while masking the undesirable taste of the tablet.
- 4.2 The sponsor stated that the 250mg tablet listings would be maintained for a period of time to ensure continuity of supply while patients transition to the new 500 mg form.

For more detail on PBAC's view, see section 6 "PBAC outcome."

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Clinical trials

5.3 As a minor submission, no new clinical trials were presented in the submission.

Economic analysis

5.4 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

5.5 No change to the published or effective price or to the current deed of agreement for abiraterone was proposed by the sponsor. The proposed (published and effective) price for the 60 tablet pack of abiraterone 500mg is equivalent to the 120 tablet pack of abiraterone 250mg tablets.

5.6 The sponsor claimed that there would be no impact to commonwealth expenditure with the listing of the 500 mg tablet.

Quality use of medicines

5.7 The sponsor claimed that it was developing a quality of use medicines programme to be rolled out one month prior to listing to aid in patients transitioning to the 500 mg tablet.

6 PBAC Outcome

6.1 The PBAC recommended the Authority Required (STREAMLINED) listing of abiraterone acetate 500 mg tablets for use in combination with prednisone or prednisolone for the treatment of metastatic castration-resistant carcinoma of the prostate.

6.2 The PBAC noted that the proposed maximum quantity and number of repeats provides an equivalent amount of abiraterone acetate as the current PBS listed 250 mg strength.

6.3 The PBAC noted that the 500 mg strength tablet was considered bioequivalent to 2 x 250 mg strength tablets by the TGA.

6.4 The PBAC noted that the listing of the 500 mg strength would reduce the pill burden and may improve compliance for some patients.

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- 6.5 The PBAC noted that the listing of the 500 mg strength would be cost neutral to the PBS as the proposed AEMP is the same as the price of the current listed 250 mg strength.
- 6.6 The PBAC recalled its previous advice that abiraterone acetate is not suitable for prescribing by nurse practitioners.
- 6.7 The PBAC advised that the Early Supply Rule should apply as it currently applies to the current listed 250 mg strength.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
ABIRATERONE ACETATE abiraterone acetate 500 mg tablet, 120	1	2	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:	<p>The treatment must be in combination with a corticosteroid,</p> <p>AND</p> <p>The treatment must not be used in combination with chemotherapy,</p> <p>AND</p> <p>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,</p> <p>AND</p> <p>Patient must have a WHO performance status of 2 or less,</p> <p>AND</p> <p>Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone,</p> <p>AND</p> <p>Patient must not have received prior treatment with enzalutamide, OR Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.</p>
Administrative Advice:	Special Pricing Arrangements apply.

8 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.

9 Sponsor's Comment

The sponsor had no comment.