

MARCH 2017 PBAC OUTCOMES - DEFERRALS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ENZALUTAMIDE</p> <p>Capsule 40 mg</p> <p>Xtandi®</p> <p>Astellas Pharma Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Prostate cancer</p>	<p>Resubmission to request an Authority Required listing for the treatment of asymptomatic metastatic castration resistant prostate cancer in chemotherapy-naïve patients.</p>	<p>The PBAC deferred recommending an extended PBS listing for enzalutamide for the treatment of metastatic castrate-resistant prostate cancer (mCRPC) prior to docetaxel, on the basis of requiring: a further price reduction to maintain an acceptable ICER, after including in the economic model a more appropriate assumption of the duration of post-docetaxel treatments in the active surveillance arm of the model; a broadening of the proposed restriction to include symptomatic patients, given that restriction to asymptomatic patients was unworkable and inappropriate; and a review of the financial estimates to provide a basis for a meaningful risk share arrangement to manage uncertainties regarding utilisation in the pre- and post-docetaxel settings.</p> <p>The clinical trial evidence presented in the submission does not specifically provide a comparison of the current treatment (i.e., enzalutamide after docetaxel) versus proposed treatment (enzalutamide before docetaxel) for the management of patients, which was of interest to the PBAC. However, on the basis of direct evidence presented by the resubmission the comparison of enzalutamide and active surveillance, (or 'placebo' in the trial), in the PREVAIL trial in asymptomatic or mildly symptomatic, chemotherapy naïve mCRPC patients over a maximum treatment duration of 31 months resulted in significant increases in the time:</p> <ul style="list-style-type: none"> • before a patient was given cytotoxic chemotherapy (median of approximately 17.2 months) • before onset of cancer pain (median of approximately 5.5 months) • on treatment (either enzalutamide or placebo), which may be related to time to 'disease progression' (median of approximately 13.1 months). <p>The PBAC considered that a claim of superior comparative efficacy with respect to quality of life outcomes compared to watchful waiting was reasonable, but that the effect size was modest. The PBAC accepted the claim that enzalutamide has a manageable safety profile.</p>
		<p>Sponsor Comment:</p>	<p>Astellas will continue to work with the PBAC to address the points raised to improve access to enzalutamide for metastatic castration resistant prostate cancer, chemotherapy-naïve patients.</p>

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<p>GOSERELIN</p> <p>3.6 mg implant, 1</p> <p>Zoladex Implant®</p> <p>Medical Oncology Group of Australia</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Breast cancer</p>	<p>To request a Restricted Benefit listing for the prevention of chemotherapy induced menopause in breast cancer.</p>	<p>At the November 2016 meeting, the PBAC deferred making a recommendation regarding a change in the listing of goserelin.</p> <p>The PBAC again deferred the request to change the current PBS restriction for goserelin 3.6 mg implant to enable women with hormone receptor negative breast cancer to access this treatment to reduce chemotherapy-induced premature menopause.</p> <p>The PBAC noted that the clinical evidence indicated that goserelin was effective in reducing the risk of premature menopause in women receiving cyclophosphamide for breast cancer. By extrapolation, it was biologically plausible that goserelin would also be effective in other conditions (not just breast cancer) being treated with alkylating agents, such as cyclophosphamide.</p> <p>This deferral was to allow for the Department and the sponsor to explore appropriate listing conditions that would enable all patients undergoing therapy with alkylating agents to potentially benefit from the use of goserelin.</p> <p>The manufacturer/supplier of goserelin is AstraZeneca Pty Ltd.</p>
		<p align="center">Sponsor Comment:</p>	<p>MOGA is disappointed with the outcome but is looking forward to working with the PBAC and AstraZeneca to ensure that breast cancer patients have access to subsidized Goserelin to reduce the risk of premature ovarian failure secondary to chemotherapy.</p>
<p>MIGALASTAT</p> <p>Capsule 150 mg</p> <p>Galafold®</p> <p>Amicus Therapeutics</p>	<p>Fabry disease</p>	<p>To request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of Fabry disease.</p>	<p>The PBAC deferred making a recommendation on the listing of migalastat for Fabry Disease pending the outcome of the TGA evaluation.</p> <p>Agalsidase alfa and agalsidase beta are available for patients for Fabry Disease via the Life Saving Drugs Program. The PBAC recognised that these enzyme replacement therapies (ERT) are not listed on the PBS and have not been considered to be cost-effective for listing on the PBS but agreed that these two treatments were the appropriate comparators.</p> <p>The clinical evidence in the submission was one head-to-head trial (ATTRACT) comparing migalastat to ERT in treatment-experienced patients, and one head-to-head trial (FACETS) comparing migalastat to placebo in treatment-naïve patients. Based on this available clinical data,</p>

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			<p>the PBAC did not accept the clinical claim that migalastat would provide patients a similar treatment effect as ERT in treatment naïve patients and in treatment experienced or switch patients.</p> <p>In addition to knowing the outcome of the TGA evaluation, the PBAC considered further information from the sponsor would be required to address the PBAC's concerns for this deferred submission.</p>
		Sponsor Comment:	Amicus accepts the decision to defer the decision until the TGA outcome is known. Amicus is concerned that the PBAC did not accept the clinical claim and plans on submitting further information to address the PBAC's concerns.
<p>VENETOCLAX</p> <p>Tablet 10 mg Tablet 50 mg Tablet 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	Relapsed/refractory chronic lymphoid leukaemia (CLL)	To request an Authority Required listing for the treatment of relapsed/refractory CLL.	<p>The PBAC deferred making a decision regarding venetoclax for the treatment of certain patients with chronic lymphocytic leukaemia (CLL). The PBAC was unable to compare the potential benefit, cost and cost-effectiveness of venetoclax against currently funded therapy, as it considered that the comparator of ofatumumab nominated in the submission was not relevant because there is no overlap in the listed PBS population for ofatumumab and the requested PBS population for venetoclax. The PBAC instead considered the nominated secondary comparators of ibrutinib and idelalisib to be more relevant comparators, given the PBAC's recent considerations of these medicines in similar CLL populations. The PBAC was also particularly uncertain about the relative clinical place, comparative effectiveness and safety, and duration of therapy of venetoclax against these two alternatives, and considered that these uncertainties flowed on to the economic evaluations and financial analyses. The PBAC deferred making a decision pending further information clarifying these issues.</p>
		Sponsor Comment:	AbbVie is committed to working with the PBAC to clarify the issues raised in order to ensure Australian patients receive timely access to VENETOCLAX as a funded treatment option for certain patients with Chronic Lymphocytic Leukaemia (CLL).