

AUGUST 2017 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>DENOSUMAB</p> <p>60 mg/mL injection, 1 mL syringe</p> <p>Prolia®</p> <p>Amgen Australia Pty Limited</p> <p>Matters outstanding</p>	<p>Osteoporosis</p>	<p>At the November 2016 meeting, the PBAC considered a DUSC analysis on the use of medicines for osteoporosis, including an assessment of the predicted and actual use of denosumab. The PBAC requested additional information on denosumab, including updated efficacy and safety data since it was listed for osteoporosis.</p>	<p>The PBAC considered that the new evidence presented by the sponsor did not raise any additional concerns about the long-term safety of treatment with denosumab. However the PBAC noted that ceasing denosumab therapy can lead to an early onset of loss of clinical benefit compared to other osteoporosis medicines. The PBAC did not consider that a more extensive review of denosumab was required at this time.</p> <p>The PBAC noted that the overall budget impact for the listing of denosumab had been substantially higher than anticipated. The PBAC recalled that as part of its July 2010 recommendation, denosumab was expected to mainly replace zoledronic acid as the alternative injectable therapy. The PBAC noted that in practice, denosumab had mostly substituted for oral instead of injectable therapies. The PBAC further noted that the alternative medicines to denosumab were allocated to the F2 formulary whereas denosumab was allocated to the F1 formulary. As such, denosumab had a higher price relative to other osteoporosis medicines. The PBAC requested that the Department approach the sponsor to consider options to address the budget impact of denosumab.</p>

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<p>ETANERCEPT</p> <p>50 mg in 1 mL single use pre-filled syringes, 4, 1 pack Injection 50 mg in 1 mL single use auto-injector, 4, 1 pack</p> <p>Brenzys®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Severe active rheumatoid arthritis, ankylosing spondylitis, severe psoriatic arthritis and severe chronic plaque psoriasis</p>	<p>To request changes to the initial 2 and continuing treatment restrictions for etanercept to Authority Required (STREAMLINED).</p> <p>To request a change to prescribing software to give preference to Brenzys for patients naïve to treatment with etanercept.</p>	<p>The PBAC recommended that all initial treatment restrictions for etanercept, including those for new patients, patients changing treatment and recommencing treatment, remain as Authority Required (in writing) listings. The PBAC affirmed this in relation to the listings for etanercept for the treatment of severe active rheumatoid arthritis, ankylosing spondylitis, severe psoriatic arthritis and severe chronic plaque psoriasis.</p> <p>The PBAC recommended that the continuing restrictions for etanercept for the above noted conditions could be split into first continuing and subsequent continuing restrictions. The PBAC recommended that the first continuing restrictions be Authority Required (in writing) restrictions retaining the response to treatment criteria that currently exists in the continuing restrictions. The PBAC recommended that the subsequent continuing restrictions be Authority Required (STREAMLINED) restrictions.</p> <p>The PBAC recommended that subsequent continuing restrictions for etanercept retain the requirement for patients to be responding to treatment.</p> <p>The PBAC noted the request for a change to the PBS Schedule and prescribing software to give preference to the biosimilar brand of etanercept for patients naïve to treatment with etanercept. The PBAC noted that this is a matter for Government, however it did not have any concerns about encouraging prescribing of a biosimilar brand rather than the reference biological agent brand for treatment of naïve patients, including through notes in the Schedule and prescribing software changes.</p>

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<p>PEMBROLIZUMAB</p> <p>Powder for injection 50 mg Solution for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck, Sharp and Dohme (Australia) Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Classical Hodgkin's lymphoma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with refractory classical Hodgkin's lymphoma, or those who have relapsed after 3 or more prior lines of therapy.</p>	<p>The PBAC recommended the Authority Required listing of pembrolizumab for the treatment of relapsed or refractory classical Hodgkin's Lymphoma (rrcHL), on a cost-minimisation basis against brentuximab vedotin (BV).</p> <p>In making this recommendation, the PBAC considered that pembrolizumab treatment showed promising overall response rates in a heavily pre-treated, refractory patient population, and that the clinical claim of non-inferiority compared with BV was supported by the evidence provided.</p> <p>The PBAC advised that under subsection 101(3BA) of the <i>National Health Act 1953</i> that pembrolizumab should not be treated as interchangeable on an individual patient basis with any other drugs.</p>
<p>VEDOLIZUMAB</p> <p>300 mg injection, 1 vial</p> <p>Entyvio®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing</p> <p>Matters outstanding</p>	<p>Severe ulcerative colitis and Crohn disease</p>	<p>To request the grandfathering restrictions for ulcerative colitis and Crohn disease be extended beyond 12 months so that the sponsor's clinical trial patients are able to transition to PBS-subsidised vedolizumab, and also to request the grandfathering restrictions to be extended to enable paediatric patients who are currently receiving vedolizumab under the Therapeutic Goods Administration Special Access Scheme for ulcerative colitis or Crohn disease to transition to PBS-subsidised vedolizumab on reaching their 18th birthday.</p>	<p>The PBAC recommended that the grandfather restriction for vedolizumab for the treatment of ulcerative colitis (UC) be reinstated and the grandfather restriction for the treatment of Crohn disease (CD) be retained on the PBS each for six months after the completion of trial C13800. As the sponsor advised that trial C13800 is due for completion at the end of 2017 at the latest, the grandfather restrictions for each of UC and CD should be removed in July 2018.</p> <p>The PBAC recommended that separate restrictions for vedolizumab for the treatment of UC and CD for paediatric patients turning 18 be listed, noting that it is not appropriate for grandfather restrictions to be retained on the PBS on an ongoing basis. The PBAC recommended that these restrictions be removed from the PBS after two years, noting the sponsor's intention to submit for listing in paediatric patients should Australian registration be obtained in this population.</p> <p>The PBAC recommended that the restrictions for vedolizumab for the treatment of UC and CD for paediatric patients turning 18 should have the same initiation requirements (at the time the patient started non-PBS subsidised treatment) as the initial treatment restrictions on the PBS.</p>

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<p>TIOTROPIUM Solution for inhalation, 2.5 microgram/actuation, Powder for inhalation, 18 microgram Spiriva Respimat® Spiriva®</p> <p>TIOTROPIUM + OLODATEROL (FDC) Solution for inhalation, tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation Spiolto Respimat®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>ACLIDINIUM Powder for inhalation, 322 microgram/actuation Bretaris Genuair®</p> <p>ACLIDINIUM + EFORMOTEROL (FDC) Powder for inhalation, acclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation Brimica Genuair®</p> <p>A. Menarini Australia Pty Limited</p>	<p>Chronic Obstructive Pulmonary Disease (COPD)</p>	<p>To consider the findings of the final report for the Post-market review of COPD medicines.</p>	<p>The PBAC considered the report on the Post-market Review of Chronic Obstructive Pulmonary Disease (COPD) medicines including stakeholder submissions, the sponsors' pre-PBAC responses and the DUSC and ESC advices. Overall, the PBAC accepted the key findings presented in the Review Report.</p> <p>The PBAC noted that there appears to be a high rate of initiation to inhaled corticosteroids (ICS)/long-acting beta agonists (LABAs) in COPD which is inconsistent with clinical guidelines. The PBAC recommended in its advice to the Minister to increase the PBS restriction level to Authority Required (STREAMLINED) for ICS/LABAs inhalers that have dual listings on the PBS for the treatment of COPD and asthma.</p> <p>The PBAC recommended removing the current PBS requirement in the LAMA/LABA PBS restrictions to stabilise patients on both individual monotherapy inhalers before commencing a fixed-dose combination (FDC) long-acting muscarinic antagonist (LAMA)/LABA. The PBAC also recommended adding PBS restriction notes to check inhaler device technique and to confirm a diagnosis of COPD with spirometry. The PBAC encouraged healthcare professionals and consumers to access helpful educational resources available through the Lung Foundation Australia and NPS MedicineWise to improve management of individuals with COPD. Improving use of inhaled medicines in accordance with current clinical guidelines would also improve the cost-effective use of therapies for COPD.</p> <p>The PBAC noted that the Review had not identified any new evidence on the effectiveness of COPD medicines that would change previous PBAC decisions regarding their costs-effectiveness. Accordingly, no cost-effectiveness review was recommended at this stage.</p>

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<p>GLYCOPYRRONIUM Powder for inhalation, 50 microgram Seebri Breezhaler®</p> <p>INDACATEROL Powder for inhalation, 150 microgram Powder for inhalation, 300 microgram Onbrez®</p> <p>INDACATEROL + GLYCOPYRRONIUM (FDC) Powder for inhalation, indacaterol 110 microgram + glycopyrronium 50 microgram Ultibro Breezhaler 110/50®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>UMECLIDIINIUM Powder for inhalation, 62.5 microgram/actuation Incruse Ellipta®</p> <p>UMECLIDIINIUM + VILANTEROL (FDC) Powder for inhalation, 62.5 microgram/actuation + vilanterol 25 microgram/actuation Anoro Ellipta 62.5/25®</p>			

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<p>FLUTICASONE + SALMETEROL (FDC) Powder for inhalation, fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation Seretide Accuhaler®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>Pressurised inhalation, fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation</p> <p>Seretide MDI 250/25® Fluticasone + Salmeterol Cipla 250/25® SalplusF Inhaler 250/25®</p> <p>GlaxoSmithKline Australia Pty Ltd Cipla Australia Pty Ltd</p>			
<p>FLUTICASONE FUROATE + VILANTEROL (FDC) Powder for inhalation, fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation Breo Ellipta 100/25®</p> <p>GlaxoSmithKline Australia Pty Ltd</p>			

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<p> BUDESONIDE + EFORMOTEROL (FDC) Pressurised inhalation, budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation Powder for inhalation, budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation Symbicort Rapihaler 200/6[®] Symbicort Turbuhaler 400/12[®] AstraZeneca Pty Ltd </p>			

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<p>Australian Rheumatology Association (ARA):</p> <p>Requests from ARA</p>	<p>Various</p>	<p>Various requests around prescribing PBS subsidised biological medicines</p>	<p>The PBAC recommended extending the restrictions for ankylosing spondylitis to allow clinical immunologists with expertise in the management of ankylosing spondylitis to prescribe the biological medicines PBS subsidised for ankylosing spondylitis.</p> <p>The PBAC also recommended removal of the requirement to re-trial disease modifying anti-rheumatic drugs (DMARDs) from the relevant biological medicines restrictions for rheumatoid arthritis and juvenile idiopathic arthritis after a treatment break of 24 months and 12 months respectively.</p> <p>The PBAC recommended the removal of the requirement to re-trial prior therapies, including DMARDs, when changing or re-commencing treatment after a break in treatment with a biological medicine from the relevant restrictions for the other indications for biological medicines listed on the PBS which have these requirements. These indications include severe chronic plaque psoriasis, severe psoriatic arthritis, active ankylosing spondylitis, moderate to severe ulcerative colitis (adult and paediatric) and severe Crohn's disease (adult and paediatric).</p> <p>The PBAC considered it would be appropriate to exclude failure to demonstrate a response to treatment with a biological medicine due to the development of a serious adverse reaction, from the treatment failure count for biological medicines. The PBAC recommended that the serious adverse reactions, each of a severity resulting in the necessity for permanent withdrawal of treatment, include serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion related to treatment with the biological medicine, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine.</p>

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<p>Authority category for imatinib, dasatinib and nilotinib listings</p>	<p>Chronic myeloid leukaemia (CML) and gastrointestinal stromal tumour (GIST)</p>	<p>To request consideration of a change in the authority level of the PBS listings of imatinib for the treatment of CML and GIST.</p>	<p>The PBAC recommended that the authority level of all current imatinib listings other than for CML in the chronic phase be changed to Authority Required (telephone) for initial treatment and Authority Required (STREAMLINED) for continuing treatment phases on the basis that it considered the risk of use outside the restrictions was now low. The PBAC considered that a decrease in the authority level of these listings would benefit patients requiring urgent treatment and ease the burden on prescribers.</p> <p>The PBAC recommended that the authority level of the imatinib listing for CML in the chronic phase be changed to Authority Required (telephone) for both initial and first continuing treatment phases, and Authority Required (streamlined) for the subsequent continuing treatment phase. The PBAC considered that an Authority required (telephone) first continuing treatment listing would help maintain restriction of use to patients in which treatment is effective.</p> <p>The PBAC did not recommend any changes to the authority level for the dasatinib and nilotinib listings for first line treatment of CML, noting that a decrease in the level of authority for these listings may result in use outside the approved CML indications and consequently a significant cost to government.</p>