

March 2015 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>AFLIBERCEPT 4 mg/0.1 mL injection, 1 x 0.1 mL vial 4 mg/0.1 mL injection, 1 x 0.90 mL syringe</p> <p>Eylea®</p> <p>Bayer Australia Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular oedema.</p>	<p>To request aflibercept pre-filled syringe and vial presentations be marked as equivalent (i.e. “a” flagging) in the Schedule of Pharmaceutical Benefits.</p>	<p>The PBAC advised that aflibercept 4mg/0.1mL solution for injection and aflibercept 4mg/0.1mL pre-filled syringe for injection could be considered equivalent for the purposes of substitution at the point of dispensing.</p>
<p>ANTI-GLAUCOMA MEDICINES</p> <p>Various brands</p> <p>Optometry Australia</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Anti-glaucoma</p>	<p>The minor submission sought to amend the current PBS listings of anti-glaucoma medicines to remove the requirement for a prescribing optometrist to be working in a shared care model with an ophthalmologist, in line with recent regulatory changes made by the Optometry Board of Australia.</p>	<p>The PBAC recommended that the NOTE for anti-glaucoma preparations be amended to state <i>‘For prescribing in accordance with Optometry Board of Australia guidelines’</i>. Further, the PBAC recommend removal of the ‘PBS Guidelines for Shared Care of Glaucoma Patients’ from the Schedule of Pharmaceutical Benefits, which is the document to which the NOTE previously referred.</p> <p>The recently revised Optometry Board of Australia guidelines allow optometrists to make an initial diagnosis and initiate treatment for chronic glaucoma with Schedule 4 anti-glaucoma medications, on condition that a referral for ophthalmological assessment to confirm the diagnosis and advise on ongoing management is provided to the patient within four months.</p> <p>The PBAC re-iterated its comments from April 2011 that the competency of optometrists to prescribe is the responsibility of the Optometry Board of Australia.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE oral liquid, 30 x 130 mL & 30 x 174 mL pouch</p> <p>PKU Air[®]</p> <p>Vitaflo Australia</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>The submission sought a restricted benefit listing for phenylketonuria.</p>	<p>The PBAC noted advice from the Nutritional Products Working Party and recommended the listing of PKU Air[®] as a Restricted Benefit for the management of phenylketonuria on a cost-minimisation basis with the existing PKU Cooler listings at the same price per gram of protein.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE oral liquid: powder for, 30 x 36 g sachets</p> <p>MSUD Anamix Junior[®]</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE oral liquid: powder for, 30 x 36 g sachets</p> <p>PKU Anamix Junior[®]</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE oral liquid: powder for, 30 x 36 g sachets</p> <p>TYR Anamix Junior[®]</p> <p>Nutricia Australia Pty Ltd</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To advise of an upgrade in the nutritional formula, flavour and packaging change from 29 g sachets to 36 g sachets.</p>	<p>The PBAC recommended the listing of the new formulations in 36 g sachet sizes on a cost-minimisation basis with the existing formulations in 29 g sachet sizes at an equivalent cost per gram of protein, under the same PBS listing circumstances that apply to the current products.</p> <p>The PBAC noted advice from the Nutritional Products Working Party and had no significant concerns over the formulation upgrade for TYR Anamix Junior, MSUD Anamix Junior, PKU Anamix Junior products in terms of the appropriateness of the nutritional content of the products for their intended uses.</p> <p>Whilst the PBAC recommended the listing of the new formulations in 36 g sachet sizes on a cost-minimisation basis with the existing formulations in 29 g sachets at an equivalent cost per gram of protein, the PBAC suggested the Department monitor use and financial expenditure on these products.</p>

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<p>AMINO ACID SYNTHETIC FORMULA oral liquid: powder for, 400 g</p> <p>Alfamino[®] Junior</p> <p>Nestle Australia Ltd</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>The submission sought to list a new formulation suitable for children aged 1 year and older for the same indications as the existing Alfamino product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome.</p>	<p>The PBAC noted advice from the Nutritional Products Working Party and recommended listing Alfamino Junior as an Authority Required benefit for the same indications as Neocate Advance with the exception of eosinophilic oesophagitis on a cost-minimisation basis against Neocate Advance at an equivalent price per gram of protein.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN oral liquid: powder for, 500 g</p> <p>XLYS LOW TRY Maxamum[®]</p> <p>Nutricia Australia Pty Ltd</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>The submission sought a Restricted benefit listing for patients over 8 years of age with glutaric aciduria.</p>	<p>The PBAC noted advice from the Nutritional Products Working Party and recommended the listing of XLYS LOW TRY Maxamum as a Restricted Benefit for patients with glutaric aciduria type 1 on a cost-minimisation basis against GA Express 15 at an equivalent price per gram of protein.</p>
<p>APIXABAN 2.5 mg and 5 mg, tablets</p> <p>Eliquis[®]</p> <p>Bristol-Myers Squibb</p> <p>Change to listing</p> <p>(Major submission)</p>	<p>Deep vein thrombosis and pulmonary embolism</p>	<p>The submission sought an Authority Required listing for apixaban for the treatment of deep vein thrombosis and pulmonary embolism, collectively referred to as venous thromboembolism.</p>	<p>The PBAC recommended the listing of apixaban for the treatment of deep vein thrombosis and pulmonary embolism on a cost-minimisation basis with rivaroxaban. The equi-effective doses are apixaban 2.5 mg and 5 mg twice daily to rivaroxaban 20 mg daily.</p>

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<p>CANAKINUMAB 150 mg vial, subcutaneous injection</p> <p>Ilaris®</p> <p>Novartis Pharmaceuticals Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Systemic juvenile idiopathic arthritis</p>	<p>The submission sought an Authority Required (Written only) listing for canakinumab for the treatment of systemic juvenile idiopathic arthritis in patients meeting certain criteria.</p>	<p>The PBAC recommended canakinumab as a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of systemic juvenile idiopathic arthritis in patients meeting certain criteria on a cost-minimisation basis with tocilizumab. The equi-effective doses were determined to be canakinumab dosed at 4 mg/kg every 4 weeks is equivalent to tocilizumab dosed at either 8 mg/kg (for patients weighing greater than 30 kg) or 12 mg/kg (for patients weighing less than 30 kg) every 2 weeks. The PBAC recommended that the canakinumab restriction target the same patient population (as well as the same prescriber types) as tocilizumab's restriction.</p>
<p>DACLATASVIR 60 mg or 30 mg, tablets</p> <p>Daklinza®,</p> <p>Bristol-Myers Squibb</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Hepatitis C virus (HCV) infection</p>	<p>The submission sought a Section 85 Authority Required (Streamlined) listing for daclatasvir for treatment of chronic hepatitis C virus (HCV) infection, in combination with sofosbuvir.</p>	<p>The PBAC recommended the Authority Required listing of ledipasvir/sofosbuvir, and sofosbuvir and daclatasvir for the treatment of chronic Hepatitis C (CHC).</p> <p>The PBAC considered that it was reasonable to assume that one treatment course of daclatasvir (in combination with sofosbuvir) was as effective as one course of ledipasvir/sofosbuvir for genotype 1 patients and sofosbuvir (in combination with ribavirin) in genotype 3 patients.</p> <p>The PBAC reiterated that new treatments for HCV were very effective and listing of these products would offer options for treatment of Genotype 1-6 CHC.</p> <p>The PBAC considered that it was appropriate for the new all oral treatment to be listed in the General Schedule, rather than Section 100 Highly Specialised Drug Program, to facilitate the longer term objectives for access to treatment, increase treatment rates and better outcomes with a view to treat all patients with CHC over time.</p> <p>The PBAC did not accept that the treatments are cost-effective at the price proposed by the sponsor.</p> <p>The PBAC noted that there was a prevalent population of approximately 230,000 patients with CHC in Australia. The estimates of the number of patients treated with the availability of an all oral interferon free treatment, presented by the DUSC, indicated that approximately 62,000 patients could</p>

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			<p>be treated in the next years. Treating this range of patients, the PBAC noted that at the price submitted by the sponsor, the proposed budget impact was exceeding \$3 billion over 5 years.</p> <p>The PBAC advised the Minister:</p> <ul style="list-style-type: none"> • that there is the high clinical need for all oral interferon-free treatments of CHC to be made available on the PBS, • that these treatments would be cost-effective at \$15,000/QALY range and that there was no basis on which to recommend that any one treatment be more expensive than another, • there is a large opportunity cost to health care system. Given this large opportunity cost, the cost of a course of treatment should be set irrespective of the duration, and that other pricing policies be considered, • that the current treatments for CHC, such as peginterferon and ribavirin alone and in combination with telaprevir, boceprevir or simeprevir, are no longer cost-effective at the prices currently listed on the PBS.
<p>DAPAGLIFLOZIN 10 mg tablet, 28</p> <p>Forxiga®</p> <p>AstraZeneca Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>The submission sought an Authority Required (Streamlined) listing for dapagliflozin 10mg tablets for the treatment of patients with type 2 diabetes mellitus in combination with metformin and a sulfonylurea.</p>	<p>The PBAC recommended the listing of dapagliflozin for the treatment of type 2 diabetes mellitus in combination with metformin and a sulfonylurea. The recommendation was based on a cost analysis compared with insulin that included drug acquisition costs and the costs of healthcare resource consumption. The equi-effective doses are dapagliflozin 10mg (oral) and insulin glargine 24 IU/day (subcutaneous).</p>
<p>DTPa-hepB-IPV-Hib VACCINE 0.5 mL pre-filled syringe</p> <p>Hexaxim®</p> <p>Sanofi Pasteur</p> <p>New listing</p> <p>(Major submission)</p>	<p>Diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b</p>	<p>The submission sought National Immunisation Program listing for Hexaxim (antigens against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b, DTPa-hepB-IPV-Hib) as a primary vaccine course.</p>	<p>The PBAC recommended the listing of Hexaxim on the National Immunisation Program for the primary vaccination series against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b at 2, 4 and 6 months of age, on a cost-minimisation basis. The equi-effective doses are Hexaxim 3 x 0.5mL and Infanrix Hexa 3 x 0.5mL, when an 18-month DTPa-containing booster is available on the NIP.</p>

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<p>EMPAGLIFLOZIN 25 mg tablet</p> <p>Jardiance®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>This Secretariat listing sought to amend the PBS restriction for empagliflozin to be identical to that of dapagliflozin's following the sponsor's offer of a lower price that matches that of dapagliflozin's.</p>	<p>The PBAC recommended out-of-session the amendment of empagliflozin's restriction to match that of dapagliflozin's.</p>
<p>EXENATIDE injection, 5 microgram/0.02 mL injection: solution, 60 unit doses, 10 microgram/0.04 mL injection: solution, 60 unit doses</p> <p>Byetta®</p> <p>AstraZeneca Australia Pty Ltd</p> <p>Change to Listing</p> <p>(Major Submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>The submission sought Authority Required (Streamlined) listing for exenatide twice daily for treatment of Type 2 diabetes mellitus in combination with insulin.</p>	<p>The PBAC recommended the listing of exenatide twice daily for treatment of Type 2 diabetes mellitus in combination with insulin on a cost-analysis basis. The equi-effective doses are exenatide 18.6 mcg per day (9.3 mcg twice daily) and rapid- and short-acting insulin, 36.8 international unit (IU) per day.</p> <p>The PBAC accepted that exenatide used in combination with insulin is at least as effective as insulin intensification and has some clinical advantages including weight loss and a small reduction in minor hypoglycaemic episodes.</p>
<p>FEBUXOSTAT, 80 mg tablet, 28,</p> <p>Adenuric®</p> <p>A.Menarini Australia Pty Ltd</p> <p>New listing</p> <p>(Major re-submission)</p>	<p>Second-line treatment of chronic symptomatic gout</p>	<p>The re-submission sought an Authority required (STREAMLINED) listing for the second-line treatment of chronic symptomatic gout.</p>	<p>The PBAC recommended the listing of febuxostat as an Authority Required benefit. The recommended listing was for patients who are contraindicated to, or intolerant of, allopurinol. The recommendation was made on the basis of a clinical need for an alternative to probenecid in this patient population, and on the basis that febuxostat is likely to represent a cost-effective treatment compared to probenecid in a targeted, second line-treatment patient population. To reduce the risk of unexpected Commonwealth expenditure on febuxostat if used beyond the recommended listing, the PBAC recommended that a risk share agreement be implemented whereby financial expenditure beyond an agreed level would be rebated to the Commonwealth.</p> <p>The PBAC did not recommend the listing of febuxostat for the patient population described by the submission as 'allopurinol insufficient'. This was</p>

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			because inadequate clinical evidence had been presented to establish the cost-effectiveness of febuxostat in this patient population.

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<p>FOLLITROPIN ALFA and LUTROPIN ALFA injection, 150 IU and 75 IU, Powder for injection Vial of solvent, 1mL water for injection</p> <p>Pergoveris®</p> <p>Merck Serono Australia Pty Ltd</p> <p>New Listing</p> <p>(Minor Submission)</p>	<p>Stimulation of follicular development</p>	<p>The re-submission sought a Section 100 (IVF/GIFT) Program, listing for follitropin alfa and lutropin alfa (Pergoveris®), a fixed dose combination product of recombinant follicle-stimulating hormone (rFSH) and recombinant luteinising hormone (rLH).</p>	<p>The PBAC recommended the listing of the fixed dose combination product follitropin alfa and lutropin alfa, on the basis that it should be available only under special arrangements under Section 100 (IVF/GIFT program) listing.</p> <p>The PBAC recommended the listing on a cost-minimisation basis to the individual components.</p> <p>The PBAC accepted the proposed price for the FDC product as being equal to the sum of the prices of its individual components, Luveris (recombinant luteinising hormone) and Gonal-f (recombinant follicle-stimulating hormone).</p>
<p>GLATIRAMER ACETATE 40 mg/mL injection</p> <p>Copaxone®</p> <p>bioCSL</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Multiple sclerosis</p>	<p>The submission sought the same Authority Required restriction as for the existing 20mg/mL listing for treatment of multiple sclerosis.</p>	<p>The PBAC recommended the listing of glatiramer acetate 40 mg/mL injection for the treatment of multiple sclerosis. The PBAC noted that the TGA was satisfied that the three-times-weekly regimen (providing 480 mg per month) would deliver a similar treatment benefit compared with the daily regimen (providing 560 mg per month), and therefore concluded that the sponsor's claim of non-inferiority in terms of efficacy and safety was reasonable.</p>
<p>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid, 28 x 250 mL cartons,</p> <p>PKU Glytactin® RTD 10, PKU Glytactin® RTD 15</p> <p>Cortex Health Pty Ltd</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>The submission sought a restricted benefit listing for phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU Glytactin RTD as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis with Camino Pro Bettermilk at the same price per gram of energy unit.</p>

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<p>GLUCOSE INDICATOR BLOOD</p> <p>glucose indicator blood strip: diagnostic</p> <p>100 Betachek C50[®]</p> <p>National Diagnostic Products Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Blood glucose monitoring</p>	<p>The submission sought to list a new brand of blood glucose test strip.</p>	<p>The PBAC recommend the listing of Betachek C50[®] under the same conditions as currently PBS-listed blood glucose test strips.</p>
<p>INSULIN GLARGINE</p> <p>3 mL cartridges, 100 IU/mL</p> <p>Basaglar[®]</p> <p>Eli Lilly</p>	<p>Diabetes mellitus</p>	<p>The PBAC was requested by the sponsor to consider the unrestricted benefit listing of insulin glargine (Basaglar[®]), a biosimilar of the PBS-listed insulin glargine, Lantus[®].</p>	<p>The PBAC recommended the listing of insulin glargine Basaglar[®] for the treatment of type 1 and 2 diabetes mellitus on cost-minimisation basis with Lantus. The equi-effective doses are 100 IU/mL Basaglar and 100 IU/mL Lantus.</p> <p>The Minister requested the advice of the PBAC on the marking as equivalent (i.e. “a” flagging) in the Schedule of Pharmaceutical Benefits of the insulin glargine products, Basalgar and Lantus. The advice is not being published at this stage.</p>

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<p>IVABRADINE tablets, 5 mg and 7.5 mg (as hydrochloride)</p> <p>Coralan®</p> <p>Servier Laboratories Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Chronic heart failure</p>	<p>The submission sought both a:</p> <p>(i) Change to the listing from Authority Required to Authority Required (Streamlined); and</p> <p>(ii) Change to the wording of the restriction to include echocardiography as an appropriate test for measuring resting heart rate.</p>	<p>The PBAC recommended that the listing of ivabradine for the treatment of heart failure be amended as follows:</p> <p>(i) Change the listing from Authority Required to Authority Required (Streamlined); and</p> <p>(ii) Change the wording of the restriction (prescriber instructions) to include echocardiography as an appropriate test for measuring resting heart rate.</p>
<p>LACOSAMIDE tablet, 50 mg</p> <p>Vimpat®</p> <p>UCB Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Intractable partial epileptic seizures</p>	<p>The submission sought the listing of a 50 mg strength of lacosamide for the maintenance treatment of intractable partial epileptic seizures.</p>	<p>The PBAC recommended the listing of lacosamide, 50mg strength for continuation treatment for 56 tablets (ie 4 x 14 packs), with the five repeats, consistent with the other strengths. The PBAC agreed with the submission that it would be appropriate for patients to be maintained on the lowest dose that effectively controls their condition. The PBAC recommended listing based on a proportional price, at the ex-manufacturer level, to the currently listed 50mg tablets (which are 14 tablets per pack).</p>

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<p>LEDIPASVIR 90 mg / SOFOSBUVIR 400 mg, fixed dose combination tablet</p> <p>Harvoni[®],</p> <p>Gilead Sciences PTY LTD.</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Hepatitis C virus (HCV) infection</p>	<p>The submission sought Section 100 (Highly Specialised Drug Program) Authority Required (Streamlined) listing for the fixed dose combination of ledipasvir/sofosbuvir for treatment of patients with genotype 1 chronic hepatitis C (CHC), irrespective of previous treatment history. The drugs included in this fixed dose combination product are not currently PBS listed as monotherapies.</p>	<p>The PBAC recommended the Authority Required listing of ledipasvir/sofosbuvir, and sofosbuvir and daclatasvir for the treatment of chronic Hepatitis C (CHC).</p> <p>The PBAC reiterated that new treatments for HCV were very effective and listing of these products would offer options for the treatment of Genotype 1-6 CHC.</p> <p>The PBAC considered that it was appropriate for the new all oral treatment to be listed in the General Schedule, rather than Section 100 Highly Specialised Drug Program, to facilitate the longer term objectives for access to treatment, increase treatment rates and better outcomes with a view to treat all patients with CHC over time.</p> <p>The PBAC did not accept that the treatments are cost-effective at the price proposed by the sponsor.</p> <p>The PBAC noted that there was a prevalent population of approximately 230,000 patients with CHC in Australia. The estimates of the number of patients treated with the availability of an all oral interferon free treatment, presented by the DUSC, indicated that approximately 62,000 patients could be treated in the next years. Treating this range of patients, the PBAC noted that at the price submitted by the sponsor, the proposed budget impact was exceeding \$3 billion over 5 years.</p> <p>The PBAC advised the Minister:</p> <ul style="list-style-type: none"> • that there is the high clinical need for all oral interferon-free treatments of CHC to be made available on the PBS, • that these treatments would be cost-effective at \$15,000/QALY range and that there was no basis on which to recommend that any one treatment be more expensive than another, • there is a large opportunity cost to health care system. Given this large opportunity cost, the cost of a course of treatment should be set irrespective of the duration, and that other pricing policies be considered, • that the current treatments for CHC, such as peginterferon and ribavirin alone and in combination with telaprevir, boceprevir or simeprevir, are no longer cost-effective at the prices currently listed on the PBS.

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<p>LURASIDONE 40 mg and 80 mg, tablets</p> <p>Latuda®</p> <p>Commercial Eyes P/L for Dainippon Sumitomo Pharma Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Schizophrenia</p>	<p>The re-submission sought Authority Required (Streamlined) listing for lurasidone 40 mg and 80mg tablets for the treatment of schizophrenia.</p>	<p>The PBAC recommended the listing of lurasidone tablets as an Authority Required (Streamlined) listing for the treatment of schizophrenia. The recommendation was formed on the basis of a cost-minimisation analysis to ziprasidone. The PBAC considered that the equi-effective doses are lurasidone 80 mg and ziprasidone 114.15 mg.</p>

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<p>LUTROPIN ALFA 75 IU, Powder for injection</p> <p>Luveris®</p> <p>Merck Serono Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Stimulation of follicular development</p>	<p>The submission sought Section 100 (IVF/GIFT program) listing for lutropin alfa for the treatment of severe luteinising hormone deficiency.</p>	<p>The PBAC recommended the listing of lutropin alfa for the treatment of severe luteinising hormone deficiency, on the basis that it should be available only under special arrangements under Section 100 (IVF/GIFT program).</p> <p>The PBAC was satisfied that lutropin alfa provides, for a small group of women who have inadequate levels of luteinising hormone, a significant improvement in clinical pregnancies and potential live births in comparison with recombinant follicle stimulating hormone alone.</p> <p>On the basis of meta-analysis evidence of poor responders (the relevant PBS population) presented in the submission, for every 100 patients treated with lutropin alfa + recombinant follicle stimulating hormone in comparison with recombinant follicle stimulating hormone alone;</p> <ul style="list-style-type: none"> • Approximately 6 additional patients would achieve clinical pregnancy over a duration of exposure of one treatment cycle. • There was no significant difference in the number of live births. • There was no significant difference in the frequency of ovarian hyperstimulation syndrome over a duration of exposure of one treatment cycle (adverse event data were for 'normal responders' only).

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<p>OBINUTUZUMAB 1000 mg/40 mL solution for infusion, 1 x 40 mL vial</p> <p>Gazyva®</p> <p>Roche Products Pty Ltd.</p> <p>New Listing</p> <p>(Major submission)</p>	<p>Previously untreated CD20 positive chronic lymphocytic leukaemia</p>	<p>The re-submission sought Section 100 (Efficient Funding of Chemotherapy) listing for obinutuzumab in combination with chlorambucil for the treatment of chronic lymphocytic leukaemia in unfit elderly patients with comorbidities. The first submission was considered by the PBAC in July 2014.</p>	<p>The PBAC recommended the listing of obinutuzumab for the treatment of chronic lymphocytic leukaemia in patients with comorbidities on the basis that it should be available only under special arrangements under Section 100. The PBAC considered that a written authority listing would be appropriate to help prevent usage beyond the population in whom the comparative effectiveness and cost-effectiveness of the drug have been demonstrated, particularly given the restriction's use of a potentially subjective rating scale (the Cumulative Illness Rating Scale) that has not been used in a PBS restriction before.</p> <p>On the basis of direct evidence presented by the re-submission, the comparison of obinutuzumab plus chlorambucil and rituximab plus chlorambucil over a median follow-up of 27.3 months, resulted in:</p> <ul style="list-style-type: none"> • An improvement in median progression-free survival of approximately 13.8 months, • Approximately 29 fewer patients per 100 having progressed, • Approximately 13 fewer patients per 100 patients requiring a re-treatment, • No differences in overall survival. <p>On the basis of direct evidence presented by the re-submission, for every 100 patients treated with obinutuzumab plus chlorambucil, in comparison to rituximab plus chlorambucil, over a median duration of follow-up of 27.3 months</p> <ul style="list-style-type: none"> • Approximately 16 additional patients would have Grade 3-5 infusion-related reactions, • Approximately 7 additional episodes of grade 4 neutropenia but no additional episodes of infection (all-Grade infection) • Approximately 7 additional patients would have Grade 3-4 thrombocytopenia. <p>The PBAC considered that the submission's revised economic analysis was a suitable basis for determining the cost-effectiveness of obinutuzumab, and considered that the resulting incremental cost effectiveness ratios for the comparisons against rituximab plus chlorambucil, and chlorambucil monotherapy respectively were reliable.</p> <p>Given that it was difficult to reliably estimate patient numbers, the PBAC considered that a Risk Sharing Arrangement between the sponsor and the Government would be required.</p>

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<p>PANITUMUMAB, 100 mg/5 mL injection, 1 x 5 mL vial 400 mg/20 mL injection, 1 x 20 mL vial</p> <p>Vectibix®</p> <p>Amgen Australia</p> <p>Change to Listing</p> <p>(Minor Submission)</p>	<p>Metastatic colorectal cancer</p>	<p>The submission sought first-line listing of panitumumab for RAS wild-type metastatic colorectal cancer</p>	<p>The PBAC recommended the first-line listing of panitumumab, for the treatment of RAS wild-type metastatic colorectal cancer, on a cost-minimisation basis with cetuximab. The equi-effective doses are panitumumab 6 mg/kg every two weeks and cetuximab 250 mg/m² weekly, following an initial loading dose of 400 mg/m².</p> <p>The PBAC recalled that it had previously accepted the two anti-EGFR inhibitors as being clinically equivalent. This minor submission was an anticipated flow-on from the PBAC's positive recommendation in November 2014, when the PBAC had recommended the listing of cetuximab for the first-line treatment of metastatic colorectal cancer, on a cost-minimisation basis compared with bevacizumab.</p>
<p>PEMBROLIZUMAB 50 mg injection: powder for, 1 vial 100 mg injection: powder for, 1 vial</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>(Major Submission)</p>	<p>Melanoma</p>	<p>To submission sought Section 100 (Highly Specialised Drugs) listing of pembrolizumab for the treatment of unresectable Stage III or Stage IV malignant melanoma.</p>	<p>The PBAC recommended an Authority Required listing of pembrolizumab as monotherapy in unresectable stage III or metastatic (stage IV) malignant melanoma in the context of a managed entry framework with an initial risk share arrangement to achieve the same cost per patient as ipilimumab. Based on the evidence provided by the sponsor, the PBAC recommended that treatment be limited to patients who have not been exposed to ipilimumab, noting that the sponsor would subsidise ongoing access to pembrolizumab for patients who are refractory to ipilimumab.</p> <p>In making its recommendation, the PBAC considered that the most rigorous comparative data for the relevant patient population came from the early results of the randomised KN-006 trial directly comparing pembrolizumab with ipilimumab. The PBAC noted from these results that the overall response rate was 33% for pembrolizumab compared to 12% for ipilimumab, and the increase in median progression free survival was 4.1 months for pembrolizumab compared to 2.8 months for ipilimumab, considering that these differences were likely to be clinically meaningful for patients. The PBAC also noted the overall response rate reported for the different ipilimumab-naïve subgroups of KN-001 ranged between 33% and 37%.</p> <p>At the consumer hearing, patient groups indicated that they believed the response rate with pembrolizumab was 90% rather than 33% to 37% as reflected in the data presented by the sponsor, with consumers also considering that the response to pembrolizumab is durable and sustained.</p>

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			<p>The PBAC were highly concerned at this mismatch between the sponsor's data and public expectations of the drug.</p> <p>The PBAC considered that based on the early data provided, pembrolizumab appears to be more effective than ipilimumab, but the magnitude of this benefit is uncertain, particularly for overall survival. The PBAC also concluded that pembrolizumab is no worse than ipilimumab in terms of safety, and possibly less toxic. The PBAC considered that the modelled economic evaluation could not be relied upon to estimate the incremental cost-effectiveness of pembrolizumab with sufficient confidence to determine the basis for any price advantage over ipilimumab.</p> <p>The PBAC recalled that, in November 2014, it had noted the clinical need and importance of early access to new medicines for melanoma patients and so recommended listing via a managed entry scheme (MES) to be made transparent to affected patients, prescribers and competing companies. The sponsor has provided reassurances that more robust evidence will be forthcoming in the foreseeable future to better inform its modelling, and the PBAC has proposed a plan to review this evidence in the near future. Should the modelled extent of benefits not be realised, the Committee has recommended measures to minimise risk of unjustified health care expenditure.</p> <p>In the event that the subsequent model at the end of the MES results in revising the price of pembrolizumab, the PBAC considered that the risk sharing arrangement be retained with caps reflecting the duration of pembrolizumab therapy as determined by the trial-based duration of progression-free survival as it was considered that pembrolizumab may be continued in the setting of disease progression regardless of the wording in the PBS restriction.</p>

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<p>POSACONAZOLE 100 mg modified release tablet</p> <p>Noxafil®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>(Minor submission)</p>	<p>Fungal infections</p>	<p>The submission sought Authority Required listing of a new presentation of posaconazole for the same indications as those that apply to the oral liquid presentation.</p>	<p>The PBAC recommended listing posaconazole tablets on the PBS as an Authority Required item for prophylaxis and treatment of invasive fungal infections.</p> <p>The PBAC noted that due to the differing treatment regimens between the tablet and liquid preparations, it was not possible to calculate equi-effective doses or a simple comparative price per milligram. The PBAC considered that the price per treatment course should be equivalent for the two formulations of posaconazole.</p>
<p>PROPRANOLOL 3.75 mg/mL oral liquid, 2 x 120 mL</p> <p>Hemangiol®</p> <p>Pierre Fabre Australia Pty Ltd</p> <p>(Minor Submission)</p>	<p>Infantile hemangioma</p>	<p>The submission sought Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy.</p>	<p>The PBAC recommended the listing of propranolol oral liquid on the PBS for the treatment of severe proliferating infantile haemangiomas in patients who require systemic therapy. The PBAC considered the treatment to be equivalent to currently available propranolol solutions.</p>
<p>Quadrivalent influenza vaccine 0.5 mL pre-filled syringe,</p> <p>Fluarix Tetra®</p> <p>GlaxoSmithKline Australia Pty Ltd.</p> <p>New Listing</p> <p>(Major Submission)</p>	<p>Influenza</p>	<p>The submission sought listing on the National Immunisation Program – Designated Vaccines List, for the prevention of seasonal influenza.</p>	<p>The PBAC recommended the listing of quadrivalent influenza vaccine on the National Immunisation Program – Designated Vaccines List for the prevention of seasonal influenza. The recommendation was made on a cost-minimisation basis with trivalent influenza vaccine. The equi-effective doses are Fluarix Tetra 60 µg for once off vaccination annually and Fluarix 45 µg, Fluvax 45 µg, or Vaxigrip 45 µg for once off vaccination annually.</p> <p>The PBAC considered that the clinical evidence presented was appropriate to conclude non-inferior efficacy and toxicity compared to trivalent influenza vaccine. The PBAC recommended that the quadrivalent influenza vaccine should be made available to the same patient population as the trivalent influenza vaccine that is currently included on the National Immunisation Program.</p>

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<p>RUXOLITINIB tablets, 5 mg, 15 mg and 20 mg, Jakavi[®], Novartis. New listing (Major Submission)</p>	<p>Myelofibrosis</p>	<p>The re-submission sought an Authority Required listing for ruxolitinib for first-line or second-line management of myelofibrosis in patients satisfying certain clinical criteria. The first submission was considered in July 2013, with a subsequent re-submission considered in July 2014</p>	<p>The PBAC recommended listing of ruxolitinib for the treatment of myelofibrosis. The PBAC was satisfied that ruxolitinib provides a major advance in care for patients with poor prognosis and/or with symptoms refractory to current care.</p> <p>However, the PBAC considered that ruxolitinib was not acceptably cost-effective at the price proposed. The PBAC concluded that ruxolitinib would be cost-effective at a reduced price that produces an ICER, derived from the base case, that is lower than what was presented in the re-submission.</p> <p>On the basis of direct evidence presented by the re-submission, for every 100 intermediate-2 and high risk patients (risk level identified according to the International Working Group criteria 2009) treated with ruxolitinib in comparison to placebo:</p> <ul style="list-style-type: none"> • Approximately 8 fewer patients will have died over a median duration of follow-up of 144 weeks. • Approximately 41 additional patients who are intolerant or irresponsive to best available therapy would have a spleen response over a maximum duration of follow-up of 24 weeks. • Approximately 27 additional patients would have at least one anaemic episode over a median duration of follow-up of 144 weeks compared with placebo. • Approximately 39 additional patients would have at least one thrombocytopenia episode over a median duration of follow-up of 144 weeks compared with placebo. <p>The PBAC also noted that for both the COMFORT-1 and COMFORT-II studies presented in the submission, the crossover of patients from placebo or best available therapy to ruxolitinib means that the degree of improvement in overall survival is uncertain, and may be greater than the observed estimates, which are based on the intention-to-treat analyses.</p>

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<p>SECUKINUMAB powder for injection, 150 mg, pre-filled syringe, 150 mg/mL, and pre-filled pen, 150 mg/mL</p> <p>Cosentyx®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>(Major submission)</p>	<p>Plaque psoriasis</p>	<p>The submission sought a General Schedule Authority Required listing for the treatment of severe chronic plaque psoriasis that is refractory to treatment with non-biological disease modifying anti rheumatic drugs (DMARDs) in patients meeting certain criteria.</p>	<p>The PBAC recommended listing secukinumab as a General Schedule Authority Required benefit for the treatment of severe chronic plaque psoriasis that is refractory to treatment with non-biological disease modifying anti rheumatic drugs (DMARDs) in patients meeting certain criteria, on a cost-minimisation basis with adalimumab. The equi-effective doses are estimated as secukinumab 300 mg every 4 weeks (based on the clinical trials) is equivalent to adalimumab 40 mg fortnightly (based on the Product Information).</p> <p>The PBAC noted that the submission’s cost-minimisation analysis of secukinumab versus ustekinumab and evaluation’s cost-minimisation analysis of secukinumab versus adalimumab were both relevant considerations. The PBAC observed the proposed price for secukinumab to be substantially more costly than the alternative therapy of adalimumab. For secukinumab to be PBS-listed at a substantially more costly price than adalimumab, the PBAC needed to be satisfied that secukinumab for some patients, provides a significant improvement in efficacy or reduction of toxicity over adalimumab. Based on the evidence presented in the submission and the material before the Committee, the PBAC was not satisfied that secukinumab provides a significant improvement in efficacy or reduction of toxicity over adalimumab. Therefore, there was no basis for secukinumab to have a price advantage over adalimumab.</p> <p>The PBAC noted that etanercept was the comparator of the current PBS bDMARD psoriasis listings, including ustekinumab. The PBAC recommended to the Minister that a cost-effectiveness review of the PBS bDMARDs for psoriasis be undertaken because there is emerging evidence of variations in response to TNF-alfa inhibitors in psoriasis, with etanercept appearing to be less efficacious than other agents.</p>

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<p>SOFOSBUVIR 400 mg, tablet</p> <p>Sovaldi[®],</p> <p>Gilead Sciences Pty Ltd.</p> <p>New Listing</p> <p>(Major Submission)</p>	<p>Hepatitis C virus (HCV) infection</p>	<p>The re-submission sought a Section 100 (Highly Specialised Drug Program), Authority Required (Streamlined) listing for sofosbuvir for the treatment of chronic hepatitis C (CHC) in the treatment-naïve genotype 1-6 and treatment-experienced genotype 2-3 patients. The first submission was considered by the PBAC in July 2014.</p>	<p>The PBAC recommended the Authority Required listing of ledipasvir/sofosbuvir, and sofosbuvir and daclatasvir for the treatment of chronic Hepatitis C (CHC).</p> <p>The PBAC reiterated that new treatments for HCV were very effective and listing of these products would offer options for treatment of Genotype 1-6 CHC.</p> <p>The PBAC considered that it was appropriate for the new all oral treatment to be listed in the General Schedule, rather than Section 100 Highly Specialised Drug Program, to facilitated the longer term objectives for access to treatment, increase treatment rates and better outcomes with a view to treat all patients with CHC over time.</p> <p>The PBAC did not accept that the treatments are cost-effective at the price proposed by the sponsor.</p> <p>The PBAC noted that there was a prevalent population of approximately 230,000 patients with CHC in Australia. The estimates of the number of patients treated with the availability of an all oral interferon free treatment, presented by the DUSC, indicated that approximately 62,000 patients could be treated in the next years. Treating this range of patients, the PBAC noted that at the price submitted by the sponsor, the proposed budget impact was exceeding \$3 billion over 5 years.</p> <p>The PBAC advised the Minister:</p> <ul style="list-style-type: none"> • that there is the high clinical need for all oral interferon-free treatments of CHC to be made available on the PBS, • that these treatments would be cost-effective at \$15,000/QALY range and that there was no basis on which to recommend that any one treatment be more expensive than another, • there is a large opportunity cost to health care system. Given this large opportunity cost, the cost of a course of treatment should be set irrespective of the duration, and that other pricing policies be considered, • that the current treatment for CHC, such as peginterferon and ribavirin alone and in combination with telaprevir, boceprevir or simeprevir, are no longer cost-effective at the prices currently listed on the PBS.

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<p>SUNITINIB (AS MALATE) 37.5 mg capsule, 28</p> <p>Sutent®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to Listing</p> <p>(Minor submission)</p>	<p>Pancreatic neuroendocrine tumours</p> <p>Stage IV clear cell renal cell carcinoma</p> <p>Gastrointestinal stromal tumours</p>	<p>The submission sought to list a 37.5 mg capsule sunitinib (as malate) for the treatment of pancreatic neuroendocrine tumours, stage IV clear cell renal cell carcinoma and gastrointestinal stromal tumours, under the same conditions as current PBS-listed strengths.</p>	<p>The PBAC recommended the listing of 37.5 mg capsule sunitinib (as malate) for the treatment of pancreatic neuroendocrine tumours, stage IV clear cell renal cell carcinoma and gastrointestinal stromal tumours, under the same conditions as current PBS-listed strengths.</p>
<p>TESTOSTERONE 12.5 mg/1.25 g (1%) gel, 88g pump bottle x 2</p> <p>Testogel®</p> <p>Besins Healthcare Australia Pty Ltd</p> <p>New Listing</p> <p>(Minor Submission)</p>	<p>Androgen deficiency</p>	<p>The submission sought Authority Required listing of a new presentation of 1% testosterone gel, Testogel®, which is a pump bottle rather than the currently listed sachets.</p>	<p>The PBAC recommended the listing of testosterone gel 1% pump bottles under the same conditions as the existing listing for the testosterone 1% gel sachets, but with four repeats rather than five to account for the increased number of doses provided with each prescription.</p>
<p>TESTOSTERONE 50 mg/mL(5%W/V), cream, 50 mL</p> <p>AndroForte 5®</p> <p>Lawley Pharmaceuticals Pty Ltd.</p> <p>New Listing</p> <p>(Major Submission)</p>	<p>Androgen deficiency</p>	<p>The submission sought Authority Required listing of testosterone 5% (w/v) cream, AndroForte 5®, for the treatment of androgen deficiency.</p>	<p>The PBAC recommended the listing of testosterone cream on a cost-minimisation basis with testosterone 1% gel. The equi-effective doses are testosterone 5% cream 100 mg daily and testosterone 1% gel 50 mg daily. The PBAC recommended listing of testosterone 5% cream under the same conditions as the currently listed testosterone products.</p>

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<p>TOFACITINIB 5 mg tablet</p> <p>Xeljanz®</p> <p>Pfizer Australia Pty Ltd</p> <p>(Major submission)</p>	<p>Severe active rheumatoid arthritis</p>	<p>The submission sought Authority Required listing for the treatment of severe active rheumatoid arthritis in patients meeting certain criteria.</p>	<p>The PBAC recommended listing tofacitinib as an Authority Required listing for the treatment of severe active rheumatoid arthritis in patients meeting certain criteria on a cost-minimisation basis with adalimumab. The equi-effective doses are tofacitinib 5 mg twice daily and adalimumab 40 mg subcutaneously every fortnight.</p> <p>Given the evidence of statistically significantly greater changes in lipid parameters resulting from tofacitinib treatment, the PBAC considered that the inclusion of hypercholesterolemia management costs for a proportion of patients would be appropriate as a cost-offset.</p>
<p>TRIGLYCERIDES MEDIUM CHAIN FORMULA oral liquid, 8 x 500 mL cartons</p> <p>Nutrini Peptisorb®</p> <p>Nutricia Australia Pty Ltd</p> <p>(Minor submission)</p>	<p>Medicinal food</p>	<p>The submission sought a Restricted benefit listing for the dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis, gastrointestinal disorders, radioenteritis, chemotherapy or bone marrow transplant.</p>	<p>The PBAC recommended listing Nutrini Peptisorb as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides involving fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders on a cost-minimisation basis against Peptamen Junior with the same price per gram of energy equivalence between Nutrini Peptisorb and Peptamen Junior.</p>
<p>VEDOLIZUMAB 300 mg vial</p> <p>Entyvio®</p> <p>Takeda Pharmaceuticals Australia.</p> <p>New listing</p> <p>(Major submission)</p>	<p>Crohn's disease</p>	<p>The submission requested a Section 100, Authority Required listing for vedolizumab for the treatment of moderate to severe Crohn's disease.</p>	<p>The PBAC recommended the listing of vedolizumab for the treatment of severe Crohn's disease in adult patients, on the basis that it should be available only under special arrangements under Section 100.</p> <p>The PBAC recommended the listing of vedolizumab on a cost-minimisation basis with infliximab and adalimumab. The PBAC considered that the equi-effective doses are:</p> <ul style="list-style-type: none"> • vedolizumab – 300mg administered at week 0, week 2, week 6 and then every 8 weeks thereafter; • Infliximab – 5mg/kg administered at week 0, week 2, week 6 and then every 8 weeks thereafter; and • adalimumab 160mg at week 0, 80mg at week 2, 40mg at week 6 and then every 2 weeks thereafter.

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<p>VEDOLIZUMAB 300 mg vial</p> <p>Entyvio®</p> <p>Takeda Pharmaceutical Australia.</p> <p>New listing</p> <p>(Major submission)</p>	<p>Ulcerative colitis</p>	<p>The re-submission sought a Section 100, Authority Required, listing for vedolizumab for the treatment of moderate to severe ulcerative colitis. The first submission was March 2014.</p>	<p>The PBAC recommended listing of vedolizumab for the treatment of moderate to severe ulcerative colitis in adult patients, on the basis that it should be available only as Authority required under the Section 100 Highly Specialised Drugs Program.</p> <p>The PBAC recommended the listing of vedolizumab on a cost-minimisation basis with infliximab. The PBAC considered that the equi-effective doses are:</p> <ul style="list-style-type: none"> • vedolizumab – 300mg administered at week 0, week 2, week 6 and then every 8 weeks thereafter; and • Infliximab – 5mg/kg administered at week 0, week 2, week 6 and then every 8 weeks thereafter.