

NOVEMBER 2015 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ABATACEPT 125 mg/mL injection, 4 x 1 mL autoinjector</p> <p>Orencia®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Rheumatoid arthritis</p>	<p>To request an Authority Required listing for an autoinjector presentation.</p>	<p>The PBAC recommended a Section 85 Authority Required listing of abatacept 125 mg/mL injection, 4 x 1 mL autoinjector for the treatment of severe rheumatoid arthritis. The PBAC also recommended that abatacept 125mg/mL injection, 4 x 1mL autoinjector and abatacept 125mg/mL injection, 4 x 1mL pre-filled syringe should be considered equivalent for the purposes of substitution at the point of dispensing.</p>
<p>AFLIBERCEPT 40 mg/mL solution for intravitreal injection. The injection volume is 50µL (equivalent to 2mg aflibercept) / Single-use vial or pre-filled syringe / 1 single-use vial in a carton or pre-filled syringe in a blister pack.</p> <p>Eylea®</p> <p>Bayer Australia Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Branch retinal vein occlusion (BRVO)</p>	<p>To request an Authority Required listing for the treatment of branched retinal vein occlusion.</p>	<p>The PBAC recommended extending the listing of aflibercept as Section 85 Authority required benefit to include treatment of a patient with macular oedema secondary to branched retinal vein occlusion (BRVO). The PBAC considered that authority applications through the PBS and Specialised Drugs Branch of the Department of Human Services would be appropriate for aflibercept, similar to existing administrative arrangements for ranibizumab in BRVO.</p> <p>The PBAC recommended the listing of aflibercept on a cost-minimisation basis with ranibizumab. The PBAC determined that the equi-effective doses are aflibercept 2 mg injection and 0.5 mg ranibizumab injection.</p> <p>On the basis of the indirect evidence using laser photocoagulation as the common reference, there appears to be no difference in benefits and harms between aflibercept and ranibizumab.</p>

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<p>AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and LOW IN TRYPTOPHAN oral liquid: powder for, 30 x 18 g sachets</p> <p>GA1 Anamix Junior®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Proven glutaric aciduria type 1</p>	<p>To request a Restricted Benefit listing for glutaric aciduria type 1.</p>	<p>The PBAC recommended the listing of GA1 Anamix Junior® as a Restricted Benefit for glutaric aciduria type 1 on a cost-minimisation basis against GA Gel® and XLYS LOW TRY Maxamaid® at an equivalent price per gram of protein.</p>
<p>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE oral liquid: powder for, 30 x 36 g sachets</p> <p>HCU Anamix Junior®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for pyridoxine non-responsive homocystinuria.</p>	<p>The PBAC recommended the listing of HCU Anamix Junior® as a Restricted Benefit for pyridoxine non-responsive homocystinuria on a cost-minimisation basis against HCU Gel® and XMET Maxamaid® at an equivalent price per gram of protein.</p>

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<p>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 130 mL x 30 cans</p> <p>PKU Easy Liquid[®]</p> <p>Orpharma Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU Easy Liquid[®] as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis to the existing PKU Cooler 15[®] listing at the same price per gram of protein.</p>
<p>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid: powder for, 34 g x 30 bottles</p> <p>PKU Easy Shake & Go[®]</p> <p>Orpharma Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU Easy Shake & Go[®] as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis against PKU Express-15[®] listing at the same price per gram of protein.</p>
<p>AMINO ACID FORMULA without PHENYLALANINE tablets, 110 g x 4 bottles</p> <p>PKU Easy Microtabs[®]</p> <p>Orpharma Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU Easy Microtab[®] as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis to the existing Phlexy-10[®] listing at the same price per gram of protein.</p>

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<p>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and LOW IN ISOLEUCINE oral liquid: powder for, 30 x 18 g sachets</p> <p>MMA/PA Anamix Junior[®]</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for methylmalonic acidaemia and propionic acidaemia.</p>	<p>The PBAC recommended the listing of MMA/PA Anamix Junior[®] as a Restricted Benefit for methylmalonic acidaemia and propionic acidaemia on a cost-minimisation basis against MMA/PA Gel[®] and XMTVI Maxamaid[®] at an equivalent price per gram of protein.</p>
<p>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g</p> <p>Alfamino[®] Alfamino[®] Junior</p> <p>Nestlé Health Science (Nestlé Australia Ltd)</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request an Authority Required listing for patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption.</p>	<p>The PBAC recommended the listing of Alfamino[®] as an Authority Required Benefit for patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption, with no changes to current pricing arrangements.</p> <p>The PBAC recommended the listing of and Alfamino[®] Junior as an Authority Required Benefit for patients with eosinophilic oesophagitis, with no changes to current pricing arrangements.</p>

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<p>ARSENIC 10 mg/10 mL injection, 10 x 10 mL vials</p> <p>Phenasen®</p> <p>Phebra</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Acute promyelocytic leukaemia</p>	<p>To request an extension to the current Section 100 PBS listing of arsenic trioxide injection to include first-line treatment of acute promyelocytic leukaemia (APL).</p>	<p>The PBAC recommended the extension of the current listing of arsenic trioxide to include the first line treatment of patients with acute promyelocytic leukaemia (APL). The recommendation was made on the basis the cost-effectiveness of arsenic trioxide in combination with ATRA+/-chemotherapy over ATRA+chemotherapy alone.</p>
<p>ATAZANAVIR + COBICISTAT atazanavir 300 mg + cobicistat 150 mg tablet, 30</p> <p>Evotaz®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>HIV infection</p>	<p>To request Section 100 HSD Authority Required (STREAMLINED) listing for the treatment of HIV-1 infection.</p>	<p>The PBAC recommended Section 100 Highly Specialised Drugs Program (HSD) listing of atazanavir/cobicistat fixed dose combination for the treatment of HIV. The PBAC recommended the special arrangements under the HSD Community Access Program, Authority Required (STREAMLINED).</p> <p>The PBAC recommended the listing of atazanavir/cobicistat on a cost-minimisation basis with atazanavir plus ritonavir provided concomitantly. The equi-effective doses are atazanavir 300 mg (one capsule) plus cobicistat 150 mg (one tablet) once daily over 48 weeks is equal to atazanavir 300 mg (one capsule) plus ritonavir 100 mg (one tablet) once daily over 48 weeks.</p> <p>The PBAC acknowledged that the TGA has accepted the bioequivalence of atazanavir/cobicistat to atazanavir and cobicistat taken concomitantly (Study 511). The PBAC also noted that additional two efficacy and safety trials (Study 114 and Study 105) comparing atazanavir plus cobicistat to atazanavir plus ritonavir also demonstrated non-inferior efficacy and safety. Based on the evidence presented, the PBAC agreed there appears to be no difference in benefits and harms between atazanavir/cobicistat and atazanavir plus cobicistat or ritonavir.</p>

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<p>BENZTROPINE MESYLATE Solution for injection 2 mg/2 mL vial</p> <p>Benztropine Omega[®]</p> <p>A Menarini Australia Pty Ltd</p> <p>(Minor Submission)</p>	<p>Acute dystonic reactions</p>	<p>To request an unrestricted benefit listing of an alternative brand (Benzotropine Omega[®]) on the PBS in the General Schedule and Prescriber Bag.</p>	<p>The PBAC recommended listing of the proposed alternative brand of benztropine injection with the greater maximum quantity of 1 pack of 10 ampoules. The PBAC advised that a clinical need exists for benztropine injection, and that it was desirable that it remain available on the PBS for the treatment of acute dystonic reactions.</p>
<p>BUPRENORPHINE 15 microgram/hour patch, 2 25 microgram/hour patch, 2 30 microgram/hour patch, 2 40 microgram/hour patch, 2</p> <p>Norspan[®]</p> <p>Mundipharma Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Pain</p>	<p>To list additional strengths for the same indications currently applying to the existing patches.</p>	<p>The PBAC recommended the listing of four additional strengths of buprenorphine patches (15 microgram/hour, 25 microgram/hour, 30 microgram/hour, and 40 microgram/hour) on the general schedule as a Restricted Benefit listing for chronic severe disabling pain.</p>
<p>CALCIPOTRIOL + BETAMETHASONE calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g & 60 g</p> <p>Daivobet[®]</p> <p>LEO Pharma Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Chronic stable plaque psoriasis</p>	<p>To request amendments to the current PBS listing of calcipotriol + betamethasone gel for the treatment of chronic stable psoriasis vulgaris of the scalp to include treatment of the body and amend the current PBS listing of the 60 g presentation from Authority Required listing to Restricted benefit.</p>	<p>The PBAC recommended the Restricted Benefit listing of calcipotriol + betamethasone gel (for the 30 g strength), and the Authority Required (Streamlined) listing of calcipotriol + betamethasone gel (for the 60 g strength) both for the treatment of chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either a vitamin D analogue or potent topical corticosteroid monotherapy on a cost-minimisation basis against calcipotriol + betamethasone ointment. This recommendation extends the current listing for the treatment of the scalp to a listing for the treatment of the whole body.</p>

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<p>CEFUROXIME cefuroxime axetil powder for oral suspension 125 mg (base) per 5 mL, 100 mL cefuroxime 250 mg tablets, 20</p> <p>Zinnat®</p> <p>Aspen Pharmacare Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Bacterial infection</p>	<p>To request Unrestricted benefit for two new pack sizes, 125 mg/5 mL in 100 mL oral suspension and 250 mg tablets in a pack size of 20.</p>	<p>The PBAC recommended the General Schedule listing of:</p> <ol style="list-style-type: none"> 1. A new pack size of 20 for the currently listed cefuroxime, tablet 250 mg (as axetil). 2. A new pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL.
<p>CITRULLINE 1 g tablet, 300</p> <p>Citrulline Easy Tablets®</p> <p>Orpharma Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for urea cycle disorders.</p>	<p>The PBAC recommended the listing of Citrulline Easy Tablets® as a Restricted Benefit for the treatment of urea cycle disorders on a cost-minimisation basis to the existing Citrulline 1000® listing at an equivalent price per gram of citrulline.</p>

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<p>DABRAFENIB and TRAMETINIB dabrafenib 50 mg capsule, 120 dabrafenib 75 mg capsule, 120 trametinib 2 mg tablet, 30 trametinib 500 microgram tablet, 30</p> <p>Tafinlar[®] Mekinist[®]</p> <p>Novartis Oncology</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Melanoma</p>	<p>To request a change from an Authority Required listing to a Streamlined Authority listing.</p>	<p>The PBAC recommended that the restriction levels of dabrafenib and trametinib be amended from Authority Required (telephone) to STREAMLINED Authority, noting that there were no changes to the content of the restriction wording.</p>
<p>DACLATASVIR 30 mg tablet, 28 60 mg tablet, 28</p> <p>Daklinza[®]</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Change to recommended listing</p> <p>(Major Submission)</p>	<p>Combination with sofosbuvir for chronic hepatitis C</p>	<p>Re-submission to request Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis C virus infection and to provide an update of the clinical trial and early access programme data.</p>	<p>The PBAC recommended expanding the Authority Required listing of daclatasvir in combination with sofosbuvir for the treatment of all patients with Genotype 1 and Genotype 3 chronic hepatitis C (CHC). Based on the clinical evidence provided in the submission, the PBAC considered that the clinical efficacy of treatment with daclatasvir in combination with sofosbuvir was not supported in the following groups: Genotype 2 CHC patients, Genotype 4 CHC patients, Genotype 5 CHC patients and Genotype 6 CHC patients.</p>

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<p>ELVITEGRAVIR, COBICISTAT, EMTRICITABINE and TENOFOVIR ALAFENAMIDE tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30</p> <p>TBC</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>HIV infection</p>	<p>To request Section 100 HSD Authority Required (STREAMLINED) for the treatment of HIV infection.</p>	<p>The PBAC recommended Section 100 Highly Specialised Drugs Program (HSD) listing of elvitegravir with cobicistat, emtricitabine and tenofovir alafenamide (EVG/c/FTC/tenofovir alafenamide) fixed dose combination for the treatment of HIV. The PBAC recommended the special arrangements under the HSD Community Access, Authority Required (STREAMLINED).</p> <p>The PBAC recommended the listing of EVG/c/FTC/tenofovir alafenamide on a cost-minimisation basis with elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (Stribild®). The equi-effective doses are elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg in a FDC product, once daily is equal to elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (EVG/c/FTC/tenofovir DF) in a FDC product, once daily.</p> <p>The PBAC noted that the primary trials (Study 104 and Study 111) and supplementary trial (Study 109) reported the proportion of patients with HIV ribonucleic acid (RNA) < 50 copies/mL as the clinically relevant outcome. The PBAC also noted that in terms of safety, there were similar rates of adverse events and serious adverse events in treatment-naïve patients (Studies 104 and 111). The PBAC agreed that EVG/c/FTC/tenofovir alafenamide was non-inferior to EVG/c/FTC/tenofovir DF in comparative efficacy and safety.</p>
<p>EMPAGLIFLOZIN 10 mg tablet, 30 25 mg tablet, 30</p> <p>Jardiance®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Type 2 diabetes (in combination with insulin)</p>	<p>To request an Authority Required (STREAMLINED) listing of empagliflozin as add-on to insulin for the treatment of patients with type 2 diabetes.</p>	<p>The PBAC recommended the PBS listing of empagliflozin in combination with insulin on a cost minimisation basis with dapagliflozin.</p>

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<p>EMPAGLIFLOZIN with METFORMIN empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 empagliflozin 5 mg + metformin hydrochloride 850 mg tablet, 60 empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 850 mg tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60</p> <p>TBC</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Type 2 diabetes</p>	<p>To request an Authority Required (STREAMLINED) listing of empagliflozin with metformin fixed dose combination (FDC) for the treatment of patients with type 2 diabetes.</p>	<p>The PBAC recommended empagliflozin/metformin FDC on a cost-minimisation basis with empagliflozin and metformin taken concomitantly.</p>
<p>EMPAGLIFLOZIN 10 mg tablet, 30 25 mg tablet, 30</p> <p>Jardiance®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Type 2 diabetes (triple oral therapy)</p>	<p>To request an Authority Required (STREAMLINED) listing of empagliflozin for use in combination with metformin and a sulfonyl urea (triple therapy) for the treatment of patients with type 2 diabetes.</p>	<p>The PBAC recommended the PBS listing of empagliflozin in triple oral combination with metformin and a sulfonylurea on a cost minimisation basis with dapagliflozin.</p>

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<p>FENTANYL CITRATE (BUCCAL) 100 microgram tablet: buccal, 4 100 microgram tablet: buccal, 28 200 microgram tablet: buccal, 4 200 microgram tablet: buccal, 28 400 microgram tablet: buccal, 4 400 microgram tablet: buccal, 28 600 microgram tablet: buccal, 4 600 microgram tablet: buccal, 28 800 microgram tablet: buccal, 4 800 microgram tablet: buccal, 28</p> <p>Fentora[®]</p> <p>Teva Pharma Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Breakthrough pain</p>	<p>Re-submission to request an Authority Required (Palliative Care Schedule) listing for the treatment of breakthrough cancer pain.</p>	<p>The PBAC recommended listing fentanyl citrate buccal tablets as an Authority Required benefit on the Palliative Care Schedule for the treatment of breakthrough pain in patients undergoing palliative care for cancer. The recommendation was made on a cost-minimisation basis with fentanyl citrate sublingual tablets. The equi-effective doses were not estimated. However, an assumption of one dose per episode of breakthrough pain was considered reasonable, and it was noted that the resubmission proposed flat pricing across dose strengths, addressing the issue of variability during titration.</p>
<p>FLUCLOXACILLIN 1 g injection, 10 vials</p> <p>Flucoxacillin Hospira brand</p> <p>Hospira Pty Ltd</p> <p>(Minor Submission)</p>	<p>Beta-lactam antibacterials</p>	<p>To request listing of a 10 vial pack of flucloxacillin 1 g injection on the PBS.</p>	<p>The PBAC recommended listing of the proposed alternative pack size of flucloxacillin 1 g injection to maintain supply on the PBS in light of an ongoing shortage of the 5 vial pack size in the Australian market.</p>

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<p>FLUTICASONE FUROATE 100 microgram/actuation inhalation: powder for, 30 actuations 200 microgram/actuation inhalation: powder for, 30 actuations</p> <p>Arnuity® Ellipta®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Asthma</p>	<p>To request Unrestricted listing for the treatment of asthma.</p>	<p>The PBAC recommended the listing of fluticasone, in the form fluticasone furoate (FF), as an unrestricted benefit on a cost-minimisation basis to fluticasone, in the form fluticasone propionate (FP). The equi-effective doses were considered to be FF 100 microgram once daily and FP 250 microgram twice daily, and FF 200 microgram once daily and FP 500 microgram twice daily.</p>
<p>GLUCOSE INDICATOR BLOOD diagnostic, 100 diagnostic strips</p> <p>2in1 Smart Blood Glucose measuring test strips (BGTS)</p> <p>Merchantshub Networks (AustPacific) Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Diabetes</p>	<p>To request an Unrestricted Benefit listing and Restricted Benefit listing for blood glucose monitoring.</p>	<p>The PBAC recommended listing under the same conditions as currently PBS-listed blood glucose test strips.</p>

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<p>GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALS oral liquid: powder for, 30 x 49 g sachets</p> <p>Camino Pro Bettermilk®</p> <p>Cortex Health Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request an increase in pack size, from 28 sachets to 30 sachets per pack.</p>	<p>The PBAC recommended the change in listing of Camino Pro Bettermilk® to an increased pack size of 30 sachets per pack at the same price per gram of protein.</p>
<p>HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</p> <p>KetoCal®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To advise the PBAC and Nutritional Products Working Party of an upgrade to the formulation.</p>	<p>The PBAC had no objection to the formulation change to KetoCal® and accepted the changes as requested, noting that there was no change to the current PBS listing for this product.</p>

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<p>HPV types 16 and 18 injection, 0.5 mL syringe</p> <p>Cervarix®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Human papillomavirus</p>	<p>To request inclusion in the National Immunisation Program for the prevention of persistent infection, premalignant cervical lesions and cervical cancer caused by human papillomavirus types 16 and 18.</p>	<p>The PBAC recommended the current listing on the National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1) for Human papillomavirus (HPV) Vaccine (Cervarix) for the vaccination of a female who is at least 12 years old but less than 14 years of age to be changed from three doses to two doses.</p>
<p>INSULIN GLARGINE 100 international units/mL injection, 5 x 3 mL cartridges</p> <p>Basaglar®, Basaglar KwikPen®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Diabetes</p>	<p>To request further advice from the PBAC regarding its previous recommendation for the PBS listing of Basaglar.</p>	<p>The PBAC advised the Minister that the Basaglar and Lantus brands of insulin glargine cartridges, and the Basaglar KwikPen and Lantus Solostar brands of insulin glargine pre-filled disposable pens respectively, could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution by the pharmacist at the point of dispensing.</p>
<p>ITRACONAZOLE 50 mg capsule, 60</p> <p>Lozanoc®</p> <p>Mayne Pharma International Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Systemic fungal infections</p>	<p>Re-submission to request an Authority Required (STREAMLINED) listing for the treatment of systemic mycoses.</p>	<p>The PBAC recommended the Authority Required (Streamlined) listing of itraconazole 50mg capsule for the same indications (systemic aspergillosis, systemic sporotrichosis, systemic histoplasmosis, disseminated pulmonary histoplasmosis infection, chronic pulmonary histoplasmosis infection, oropharyngeal candidiasis, and oesophageal candidiasis) and with same restriction rules as they currently apply to the PBS-listed itraconazole 100mg capsule.</p> <p>In making this recommendation, the PBAC noted the sponsor's offer of 16% price reduction of itraconazole 50mg capsule compared to the existing PBS-listed itraconazole 100mg capsule. The PBAC was of the view that an equivalent cost per treatment course should apply to both products, as both are expected to deliver the same clinical outcomes.</p>

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<p>IVACAFTOR 150 mg tablet, 56</p> <p>Kalydeco®</p> <p>Vertex Pharmaceuticals (Australia) Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Cystic fibrosis</p>	<p>To present additional efficacy and safety data in patients aged 6 years and older who have a G551D or other gating (class III) mutation in the CFTR gene who have severe cystic fibrosis.</p>	<p>The PBAC noted the additional efficacy and safety data on the use of ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 6 years and older with a G551D or other gating (class III) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene who have severe CF disease (forced expiratory volume in one second (FEV1) <40% predicted).</p> <p>The PBAC considered that the clinical evidence presented in the submission showed some benefit in severe CF group however, the PBAC noted that the absolute increase in FEV1 was lower in patients under the compassionate access program across different countries than observed among patients in the PERSIST trial. The PBAC considered that it remains uncertain whether this will translate into significant patient relevant improvements in health.</p> <p>Notwithstanding the concerns stated above, the PBAC considered it reasonable to continue providing access to ivacaftor for CF patients aged 6 years and older with a G551D or other (gating class III) mutation who have severe CF disease FEV1 <40% (predicted).</p>
<p>LAPATINIB 250 mg tablet</p> <p>Tykerb®</p> <p>Novartis Oncology</p> <p>(Non major/minor Submission)</p>	<p>Metastatic (Stage IV) HER2 positive breast cancer</p>	<p>To changed the restriction for lapatinib for the treatment of metastatic (Stage IV) HER2 positive breast cancer</p>	<p>The PBAC recommended a change to the listing of lapatinib for metastatic (Stage IV) HER2 positive breast cancer, removing the restriction that ‘Patient must not have received prior treatment with trastuzumab emtansine’, noting that lapatinib may be a preferred treatment choice in patients with brain metastases.</p> <p>The PBAC recommended that the restriction for trastuzumab emtansine should also be amended as a flow-on consequence to allow patients to access trastuzumab emtansine following treatment with lapatinib.</p> <p>The PBAC requested the Department to correspond with the sponsors about these matters.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>MESALAZINE 1.2 g tablet: modified release, 60</p> <p>Mezavant®</p> <p>Shire Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Ulcerative colitis</p>	<p>To request an increase in the maximum PBS listed quantity, from 60 tablets to 120 tablets.</p>	<p>The PBAC recommended an increase in maximum quantity to 2 packs of 60 tablets for mesalazine 1.2 g modified released tablets (Mezavant) for the treatment of ulcerative colitis (UC), at the same price per mg (ex-man) as the currently PBS-listed 1x 60 tablets.</p>
<p>NETUPITANT and PALONOSETRON netupitant 300 mg + palonosetron 500 microgram capsule, 1</p> <p>Akynzeo®</p> <p>Specialised Therapeutics Australia</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Nausea and vomiting</p>	<p>Re-submission to request Authority Required (STREAMLINED) and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) listing for the prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.</p>	<p>The PBAC recommended listing netupitant + palonosetron fixed dose combination (NEPA FDC) as an Authority Required STREAMLINED benefit on the General Schedule and under the Section 100 program Efficient Funding of Chemotherapy Related Benefits, for the prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy, and anthracycline plus cyclophosphamide based regimens in patients with breast cancer.</p> <p>The PBAC recommended listing at the price proposed in the submission, with the PBAC noting the lower DPMQ offered for NEPA compared with aprepitant. The PBAC noted that the economic analysis presented in the original submission was a cost comparison and the equi-effective doses were difficult to establish, however considered that an assumption that each chemotherapy course would be treated with one capsule of NEPA FDC or one capsule of aprepitant 165 mg plus a 5 HT3 receptor antagonist to be reasonable.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>NIVOLUMAB concentrate solution for infusion, 40 mg/4 mL, 4ml vial concentrate solution for infusion, 100 mg/10 mL, 10ml vial</p> <p>Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Melanoma</p>	<p>Re-submission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable stage III or stage IV malignant melanoma.</p>	<p>The PBAC recommended listing nivolumab as monotherapy treatment for patients with unresectable stage III or stage IV malignant melanoma, noting the revised main comparator in the re-submission, pembrolizumab, and a pricing proposal that provided the Commonwealth greater certainty with respect to nivolumab pricing.</p> <p>The recommendation was made on a cost-minimisation basis with pembrolizumab, where the price of nivolumab is derived to ensure the same cost per patient to the PBS as has been agreed for pembrolizumab, minus the additional infusion costs associated with nivolumab treatment.</p>
<p>OMALIZUMAB 150 mg/mL injection, 1 x 1 mL syringe</p> <p>Xolair®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Severe chronic idiopathic urticaria</p>	<p>To request Section 100 Authority Required PBS listing for the treatment of patients with severe uncontrolled chronic idiopathic urticaria.</p>	<p>The PBAC recommended the listing of omalizumab for the treatment of chronic idiopathic urticaria, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program). The recommendation was formed on the basis of a cost-minimisation analysis compared with cyclosporin.</p> <p>The PBAC accepted that omalizumab was non-inferior to cyclosporin and superior to placebo in terms of clinical effectiveness.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>OMALIZUMAB 75 mg/0.5 mL injection, 1 x 0.5 mL syringe 150 mg/mL injection, 1 x 1 mL syringe</p> <p>Xolair®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Severe allergic asthma</p>	<p>To propose a revision of PBS restrictions for omalizumab for the treatment of severe allergic asthma.</p>	<p>The PBAC recommended expanding the listing of omalizumab for the treatment of severe allergic asthma in patients with a baseline IgE of 30-75 IU/mL on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program).</p>
<p>OXYCODONE + NALOXONE oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg tablet: modified release, 28 tablets oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg tablet: modified release, 28 tablets oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg tablet: modified release, 28 tablets</p> <p>Targin®</p> <p>Mundipharma Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Pain</p>	<p>To list additional strengths for the same indications currently applying to the existing tablets.</p>	<p>The PBAC recommended the listing of three additional strengths of oxycodone + naloxone (oxycodone 2.5mg + naloxone 1.25mg, oxycodone 15mg + naloxone 7.5mg, and oxycodone 30mg + naloxone 15mg) on the General Schedule as a Restricted Benefit listing for chronic severe disabling pain.</p>

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<p>PASIREOTIDE 20 mg IM injection 40 mg IM injection 60 mg IM injection</p> <p>Signifor®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Inadequately controlled acromegaly</p>	<p>To request Section 100 HSD Authority Required listing for the treatment of acromegaly in patients failing therapy on existing somatostatin analogues</p>	<p>The PBAC recommended the listing of pasireotide as second-line therapy for the treatment of patients with acromegaly, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program). The PBAC agreed that pasireotide, for some patients, provided superior efficacy and inferior safety compared to octreotide and lanreotide. The PBAC considered that the price of pasireotide should be reduced to offset the cost of treating hyperglycaemia and diabetes attributable to treatment with this drug.</p>
<p>RIBAVIRIN 400 mg tablet, 28 600 mg tablet, 28</p> <p>lbavir®</p> <p>Clinect Py Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Hepatitis C</p>	<p>Section 85 Authority Required (STREAMLINED) listing for the treatment of hepatitis C viral infection in patients 18 years or older who have compensated liver disease.</p>	<p>The PBAC recommended the Authority Required listing of ribavirin in combination with direct acting antivirals (DAAs) for the treatment of chronic hepatitis C (CHC). While the submission requested treatment of patients infected with Genotype 2 and 3 HCV, the PBAC noted that in clinical practice, some other patient groups may derive benefit from the additional of ribavirin to a course of an interferon-free regimen. The PBAC considered that access to ribavirin should not be restricted to patients infected with specific genotypes of the virus.</p>
<p>RISPERIDONE various forms and strengths</p> <p>Risperdal®</p> <p>Janssen Cilag Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Behavioural disturbances in patients with dementia</p>	<p>To request a change in the PBS restriction to specify moderate to severe dementia of the Alzheimer type and with a limited duration of 12 weeks treatment, to align with the safety related updated TGA indication.</p>	<p>The PBAC recommended an amendment to be made to the current risperidone restriction for the treatment of dementia to align with the revised TGA indication, restricting use to moderate to severe dementia of the Alzheimer's type and limiting duration of treatment to 12 weeks.</p>

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<p>RITUXIMAB Injection for infusion 100 mg/10 mL, 2 x 10 mL vials</p> <p>Mabthera®</p> <p>Roche Products Pty Ltd</p> <p>(Minor Submission)</p>	<p>Severe, active granulomatosis with polyangiitis and microscopic polyangiitis</p>	<p>To seek a PBAC recommendation to add the 100 mg/10 mL injection presentation of rituximab to the July 2015 recommendation to list the 500 mg/50 mL injection for severe active granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The 100mg vial was omitted from the sponsor's submission.</p>	<p>The PBAC recommended the inclusion of the 100 mg vial of rituximab in the July 2015 recommendation to list rituximab 500 mg/50mL, 1 x 50mL vial for remission induction in patients with severe, active granulomatosis with polyangiitis and microscopic polyangiitis on the basis that it should be available only under special arrangements under the Section 100 Highly Specialised Drugs Program.</p>
<p>SIMEPREVIR 150mg capsule, 7</p> <p>Olysio®</p> <p>Janssen Cilag Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Hepatitis C</p>	<p>Section 85 Authority Required listing for the treatment of patients with genotype 1 chronic hepatitis C.</p>	<p>The PBAC recommended the Authority Required listing of simeprevir in combination with sofosbuvir (SMV+SOF) for the treatment of patients with genotype 1 chronic hepatitis C (CHC) infection on the basis of non-inferior efficacy and safety with ledipasvir/sofosbuvir (LDV/SOF) or daclatasvir in combination with sofosbuvir (DCV+SOF) or paritaprevir/ritonavir/ombitasvir + dasabuvir ± ribavirin (Viekira PAK/Viekira PAK-RBV).</p> <p>The PBAC recalled that on the basis of the available evidence, it had previously considered it reasonable to accept that a course of SMV+SOF was non-inferior in terms of comparative efficacy with a course of LDV/SOF or DCV+SOF or Viekira PAK/Viekira PAK-RBV for treatment of Genotype 1 CHC; and that it was reasonable to consider that a course of SMV+SOF had a similar safety profile as the ribavirin-free courses of LDV/SOF, DCV+SOF and Viekira PAK.</p>
<p>STRONTIUM RANELATE 2 g granules for oral suspension, 28 x 2g sachets</p> <p>Protos®</p> <p>Servier Laboratories</p> <p>(Non major/minor Submission)</p>	<p>Osteoporosis</p>	<p>To seek advice for delisting</p>	<p>The PBAC reaffirmed its previous advice of July 2015 that at its current price strontium is not cost-effective. The PBAC reaffirmed that the continued listing of strontium on the PBS be based on the condition that the price is reduced such that the ICER would around \$15,000 to \$45,000 per QALY.</p>

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<p>THYROXINE SODIUM 25 microgram tablet, 200 50 microgram tablet, 200 75 microgram tablet, 200 100 microgram tablet, 200 125 microgram tablet, 200 200 microgram tablet, 200</p> <p>Eltroxin[®]</p> <p>Aspen Pharmacare Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Thyroid hormone deficiency thyroid stimulating hormone-responsive tumours of the thyroid</p>	<p>To request Unrestricted benefit listing of a new brand and additional strengths of thyroxine sodium.</p>	<p>The PBAC noted this medicine is clinically essential and the Eltroxin brand has the benefit of not requiring refrigeration, in ambient temperatures up to 25 degrees Celsius. The PBAC agreed that the 125 mcg strength may offer additional dosing benefits, but did not agree that the 25 mcg strength was a clinically necessary dose, noting that 50 mcg of thyroxine sodium is the usual therapeutic dose for neonates.</p> <p>The PBAC therefore recommended the listing of five strengths (50, 75, 100, 125 and 200 mcg) of Eltroxin as an unrestricted benefit. The PBAC did not recommend the listing of the 25 mcg strength.</p> <p>The PBAC noted the ACPM and TGA Delegate advice that Eltroxin is not bioequivalent to or interchangeable with the Eutroxsig and Oroxine brands on a dose by dose basis and that dose titration may be required for Eltroxin. It recommended that a note be included in the administrative advice of the listing to advise that the brands are not substitutable.</p> <p>The PBAC recommended that Eltroxin is suitable for prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicines for, a patient has been initiated by a medical practitioner</p>
<p>TRIGLYCERIDES MEDIUM CHAIN oral liquid: powder for, 400 g</p> <p>Monogen[®]</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To advise the PBAC and Nutritional Products Working Party of an upgrade to the formulation.</p>	<p>The PBAC had no objection to the formulation change to Monogen[®] and accepted the changes as requested, noting that there was no change to the current PBS listing for this product.</p>

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<p>USTEKINUMAB 45 mg/0.5 mL injection vial, 1</p> <p>Stelara®</p> <p>Janssen Cilag Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Psoriatic arthritis</p>	<p>Authority Required listing for the treatment of severe active psoriatic arthritis.</p>	<p>The PBAC recommended an Authority Required listing of ustekinumab for the treatment of psoriatic arthritis. The equi-effective doses are ustekinumab 45 mg administered at weeks 0, 4 and then every 12 weeks thereafter equals certolizumab 400 mg at weeks 0, 2 and 4 followed by 200 mg every 2 weeks or 400 mg every 4 weeks.</p>