

**November 2007 PBAC Outcomes – Positive Recommendations**

<b>Drug Name and Sponsor</b>	<b>Drug Use and Type</b>	<b>Listing requested by Sponsor</b>	<b>PBAC Recommendation</b>
Abatacept, powder for infusion, 250mg, Orencia® Bristol-Myers Squibb Pharmaceuticals  Major submission	Rheumatoid arthritis	Sect. 100 Private Hospital Authority Required – in combination with methotrexate in adults with severe active rheumatoid arthritis who have failed to achieve a response with prior Disease Modifying Anti-Rheumatic Drug (DMARD) therapy.	The PBAC recommended the listing on a cost-minimisation basis compared with infliximab. The PBAC recommended that the equi-effective doses were abatacept 10mg/kg administered on days 1, 15, 29 and then every 28 days, and infliximab 3mg/kg administered on days 1, 15, 43 and then every 56 days.
Adalimumab, pre-filled syringe, pre-filled pen, 40 mg in 0.8mL, Humira® Abbott Australasia Pty Ltd  Major submission	Crohn disease	Authority Required – treatment of certain adult patients with moderate to severe Crohn disease.	The PBAC recommended listing on a cost-minimisation basis compared with infliximab. The PBAC considered the equi-effective doses to be adalimumab 160/80mg (week 0, 2), then 40mg every two weeks thereafter and infliximab 5mg/kg (weeks 0, 2 6 and every 8 weeks thereafter).
Adalimumab, pre-filled syringe, pre-filled pen, 40 mg in 0.8mL, Humira® Abbott Australasia Pty Ltd  Minor submission	Biological disease modifying anti-rheumatic drug	Amend restriction for psoriatic arthritis to allow prior treatment with leflunomide.	The PBAC had no objection to the inclusion of leflunomide as an alternative DMARD to sulfasalazine in the psoriatic arthritis initial criteria.
Adefovir dipivoxil, tablet 10 mg, Hepsera® Gilead Sciences Pty Ltd  Minor submission	Hepatitis B	To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.	The PBAC agreed to the proposed amendment and agreed that it should apply to all hepatitis B treatments.
Adefovir dipivoxil, tablet 10 mg, Hepsera® Gilead Sciences Pty Ltd and the Australian Liver Association  Minor submission	Hepatitis B	To allow continued use of lamivudine in combination with adefovir in patients with chronic hepatitis B in patients who have failed lamivudine.	The PBAC agreed to the proposed change in listing.

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<p>Amino acids – synthetic formula, Elecare<sup>®</sup>, Abbott Australasia Pty Ltd, Neocate<sup>®</sup>, Neocate Advance<sup>®</sup>, Nutricia Australia Pty Limited</p> <p>Minor submission</p>	<p>Cows' milk protein allergy (CMPA)</p>	<p>Request from Wyeth Australia Pty Ltd to re-instate requirement to trial soy formula</p>	<p>The PBAC recommended that the restrictions be amended for protein hydrolysate formula and medium chain triglycerides, and amino acid formula to reinstate soy formula as the first line treatment for CMPA, but include exemption criteria for infants and children with a severe form assessed by a paediatric gastroenterologist or specialist allergist.</p>
<p>Amino acid synthetic formula, Neocate LCP<sup>®</sup>, Nutricia Australia Pty Limited</p> <p>Minor submission</p>	<p>Cows' milk protein allergy (CMPA)</p>	<p>Request from Wyeth Australia Pty Ltd to re-instate requirement to trial soy formula</p>	<p>The PBAC recommended that the restrictions be amended for protein hydrolysate formula and medium chain triglycerides, and amino acid formula to reinstate soy formula as the first line treatment for CMPA, but include exemption criteria for infants and children with a severe form assessed by a paediatric gastroenterologist or specialist allergist.</p>
<p>Amino Acid Formula with Vitamins and Minerals without Methionine, liquid, 130 mL, HCU Cooler<sup>®</sup>, Vitaflo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Inherited metabolic disorders</p>	<p>New restricted benefit listing for homocystinuria - a rare inborn error of protein metabolism which is due to a deficiency of the enzyme cystathionine beta synthase (CBS)</p>	<p>The PBAC recommended listing on a cost minimisation basis compared with HCU Express powder at an equivalent cost per gram of protein and at the new price agreed for products to treat homocystinuria.</p>
<p>Benzathine penicillin, injection 900 mg in 2 mL, Bicillin L-A<sup>®</sup>, Aspen Pharmacare Australia Pty Ltd</p> <p>Minor submission</p>	<p>Antibiotic</p>	<p>Unrestricted listing</p>	<p>The PBAC had no objection to the Secretariat proposal to list this product, which includes an injector with the syringe in a self-contained unit ready to use under the same conditions as, and to replace, the current PBS-listed product Bicillin L-A Tubex<sup>®</sup> sold in a separate Tubex<sup>®</sup> injector which has been discontinued for over 1 year.</p>

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<p>Bupropion hydrochloride, tablet, 150 mg (sustained release), Zyban<sup>®</sup>, GlaxoSmithKline Australia Pty Ltd</p> <p>Minor submission</p>	<p>Smoking cessation</p>	<p>Request that a patient be allowed to try both bupropion and varenicline in any given year if necessary.</p>	<p>The PBAC recommended that the current restriction for bupropion be changed to allow a 6 month timeframe between commencing a course of bupropion and varenicline, which would allow both bupropion and varenicline to be prescribed per 12 month period.</p>
<p>Calcium tablet 250 mg (as citrate) Citracal<sup>®</sup>, Key Pharmaceuticals Pty Ltd</p> <p>Calcium tablet (chewable) 500 mg (as carbonate), Cal-Supp<sup>®</sup>, iNova Pharmaceuticals (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>Chronic kidney disease</p>	<p>Requests a review of the maximum quantity and repeats available under a Streamlined Authority listing in patients with chronically high levels of phosphate.</p>	<p>The PBAC recommended an increase in the maximum quantity of calcium tablets available for use in the treatment of hyperphosphataemia associated with chronic renal failure to provide an average of one month's supply.</p>
<p>Cinacalcet, tablet, 30, 60, 90 mg, Sensipar<sup>®</sup> Amgen Australia Pty Ltd</p> <p>Major submission</p>	<p>Chronic kidney disease</p>	<p>Sect. 100 Private Hospital Authority Required – Initial and continuing treatment of secondary hyperparathyroidism in patients with chronic kidney disease receiving dialysis</p>	<p>The PBAC recommended the listing of cinacalcet on the PBS on the basis of acceptable cost-effectiveness compared with placebo. Maintenance therapy will also be permitted through Section 85.</p>
<p>Clostridium botulinum toxin Type A, powder for injection, 500 units, Dysport<sup>®</sup> Ipsen Pty Ltd</p> <p>Major submission</p>	<p>Treatment of spasticity</p>	<p>Sect. 100 listing – moderate-severe spasticity of the upper limb in adults following a stroke as an adjunct to physical therapy</p>	<p>The PBAC recommended an extension to the Section 100 botulinum toxin program to include the treatment of moderate to severe spasticity of the upper limb in adults following a stroke, as second line therapy when standard management has failed or as an adjunct to physical therapy, on the basis of an acceptable cost-effectiveness ratio compared with standard management (placebo).</p>
<p>Clozapine, suspension, 50 mg/mL, Clopine<sup>®</sup>, Hospira Australia Pty Ltd</p> <p>Minor submission</p>	<p>Schizophrenia</p>	<p>To list another form – clozapine is currently available only in tablet form.</p>	<p>The PBAC approved the listing.</p>

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Efavirenz, tablet, 200 mg, Stocrin <sup>®</sup> , Merck Sharp & Dohme (Australia) Pty Ltd  Minor submission	HIV infection	To list another form (tablet) – 200 mg capsules currently exist	The PBAC approved the listing.
Epoetin alfa, pre-filled syringe, all strengths Eprex <sup>®</sup> , Janssen-Cilag Pty Ltd  Minor submission	Anaemia (low levels of red blood cells)	To notify the PBAC of a minor product change (the fitting of a needle guard to prevent needle stick injuries).	The PBAC approved the change.
Essential Amino Acids Formula with Minerals and Vitamin C, Powder, 400 g, Dialamine <sup>®</sup> , Nutricia Australia Pty Limited  Minor submission	Urea cycle disorders	To consolidate pack sizes – a larger container size (400 g) will replace the existing 200 g container size but the number of repeats will be reduced.	The PBAC approved the change.
Etanercept, injection set containing 4 vials powder for injection 25 mg and 50 mg and 4 pre-filled syringes solvent 1mL, injection 50 mg in 1 mL single use pre-filled syringes, 4, Enbrel <sup>®</sup> , Wyeth Pharmaceuticals  Minor submission	Biological disease modifying anti-rheumatic drug	Amend restriction for psoriatic arthritis to allow prior treatment with leflunomide	The PBAC had no objection to the inclusion of leflunomide as an alternative DMARD to sulfasalazine in the psoriatic arthritis initial criteria.
Entecavir monohydrate, tablets 500 microgram and 1 mg, Baraclude <sup>®</sup> , Bristol-Myers Squibb Pharmaceuticals  Minor submission	Hepatitis B	To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.	The PBAC agreed to the proposed amendment for consistency with the recommendation for adefovir

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<p>Famciclovir, tablet, 250 mg, Famvir<sup>®</sup> Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Minor submission</p>	<p>Genital herpes</p>	<p>To propose a new, shorter dosing regimen that will be equally as effective as the current dosing regimen.</p>	<p>The PBAC approved of the new dosing regimen.</p>
<p>Fentanyl citrate, lozenges, 200, 400, 600, 800, 1200, and 1600 micrograms, Actiq<sup>®</sup> Orphan Australia Pty Ltd</p> <p>Major submission</p>	<p>Severe pain</p>	<p>Sect. 85 Authority Required listing – breakthrough pain in palliative care patients receiving opioids for cancer pain</p>	<p>The PBAC recommended listing in the Palliative Care Section of the PBS on the basis of a high but acceptable cost-effectiveness ratio.</p>
<p>Filgrastim, injection, 300 micrograms in 1 mL and 480 micrograms in 1.6ml, and single use pre-filled syringe, 300 micrograms in 0.5 mL and 480 micrograms in 0.5 mL Neupogen<sup>®</sup>, Amgen Australia Pty Ltd</p> <p>Minor submission</p>	<p>Neutropenia</p>	<p>Amend the restriction to allow use in patients with breast cancer receiving docetaxel in combination with an anthracycline, and patients with non-Hodgkin lymphoma - aggressive grades or low grade receiving an anthracycline-containing regimen</p>	<p>The PBAC recommended the change for consistency with the recommendations for pegfilgrastim.</p>
<p>Human Papilloma Virus vaccine Cervarix<sup>®</sup> GlaxoSmithKline Australia Pty Ltd</p> <p>Minor submission</p>	<p>Cervical cancer</p>	<p>This re-submission seeks to address the concerns of the PBAC arising from the July 2007 PBAC meeting and listing on the National Immunisation Program.</p>	<p>The PBAC was prepared to accept that Cervarix is acceptably cost-effective and thus recommended the inclusion of Cervarix in the National Immunisation Program.</p> <p>The PBAC also recommended that GSK provide the same contribution towards the national cervical screening program as had the sponsor of Gardasil. Further, in any risk-sharing agreement, the same conditions concerning the possibility of a requirement for re-vaccination if the efficacy of the vaccine should wane, should apply.</p>

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Imiquimod, cream, 5% Aldara <sup>®</sup> , iNovo Pharmaceuticals (Australia) Pty Ltd  Minor submission	Skin cancer	To make minor amendments to the restriction wording.	The PBAC had no objection to the changes to the wording of the restriction requested by the sponsor to clarify the clinical place and current listing for imiquimod.
Infliximab, powder for I.V. infusion, 100 mg, Remicade <sup>®</sup> , Schering- Plough Pty Ltd  Minor submission	Biological disease modifying anti- rheumatic drug	Amend restriction for psoriatic arthritis to allow prior treatment with leflunomide.	The PBAC had no objection to the inclusion of leflunomide as an alternative DMARD to sulfasalazine in the psoriatic arthritis initial criteria.
Insulin detemir rys, injections, 100units/mL Levemir <sup>®</sup> , Novo Nordisk Pharmaceuticals Pty Ltd  Major submission	Diabetes	Extension to listing - unrestricted listing	The PBAC recommended changing the current restricted benefit listing of insulin detemir for type 1 diabetes to an unrestricted listing on a cost- minimisation basis compared with insulin glargine. The analysis of the trials suggested a daily per unit ratio of 1.10 of detemir to glargine.
Interferon alfa-2A, injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe and injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe, Roferon-A <sup>®</sup> , Roche Products Pty Ltd  Minor submission	Immunomodulating drug	To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.	The PBAC agreed to the proposed amendment for consistency with the recommendation for adefovir

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<p>Interferon alfa-2B, solution for injection 10,000,000 i.u. in 1 mL single dose vial, Intron A<sup>®</sup>, solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen<sup>®</sup>, solution for injection 18,000,000 i.u. in 3 mL single dose vial, Intron A<sup>®</sup>, solution for injection 25,000,000 i.u. in 2.5 mL single dose vial, Intron A<sup>®</sup>, solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen<sup>®</sup> and solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen<sup>®</sup>, Schering- Plough Pty Ltd</p> <p>Minor submission</p>	<p>Immunomodulating drug</p>	<p>To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.</p>	<p>The PBAC agreed to the proposed amendment for consistency with the recommendation for adefovir.</p>
<p>Isoleucine Amino Acid Supplement, sachets, 4 g, Vitaflo<sup>®</sup>, Vitaflo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Maple Syrup Urine Disease (MSUD)</p>	<p>New restricted benefit listing for MSUD.</p>	<p>The PBAC recommended listing as a restricted benefit for the treatment of MSUD with a maximum quantity of 4 cartons.</p>
<p>Lamivudine, tablet 100 mg and oral solution 5 mg per mL, 240 mL, Zeffix<sup>®</sup>, GlaxoSmithKline Australia Pty Ltd</p> <p>Minor submission</p>	<p>Hepatitis B</p>	<p>To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.</p>	<p>The PBAC agreed to the proposed amendment for consistency with the recommendation for adefovir</p>
<p>Levetiracetam, oral solution, 100 mg/mL, Keppra<sup>®</sup>, UCB Pharma</p> <p>Minor submission</p>	<p>Epilepsy</p>	<p>To list a new form of levetiracetam in addition to tablets</p>	<p>The PBAC recommended listing. The PBAC considered a price premium to be justified and that this should be determined by the PBPA.</p>

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<p>Macrogol 3350; potassium chloride; sodium bicarbonate; sodium chloride, sachets containing powder for solution with electrolytes, Movicol<sup>®</sup> and Movicol Half<sup>®</sup> Norgine Pty Limited</p> <p>Minor submission</p>	<p>Constipation</p>	<p>To amend listing to unrestricted benefit and to list a half-strength product (Movicol Half)</p>	<p>The PBAC recommended the listing of Movicol Half on the PBS and an extension to the restricted benefit listing for both products for chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents.</p>
<p>Measles, mumps, rubella and varicella vaccine, powder for injection, Priorix-Tetra<sup>®</sup> GlaxoSmithKline Australia Pty Ltd</p> <p>Major submission</p>	<p>Childhood vaccine</p>	<p>Inclusion on National Immunisation Program (NIP) – vaccination against measles, mumps, rubella and varicella infection.</p> <p>Seeks addition of a second varicella injection and a change of schedule for MMR vaccine.</p>	<p>The PBAC recommended including the combination measles, mumps, rubella and varicella vaccine (MMRV) on the (NIP) as a single dose at age 12 months. PBAC agreed to the change in schedule for MMR vaccine from 4 years to 18 months.</p>
<p>Mesalazine, granules, 1 g per sachet, Salofalk<sup>®</sup>, Orphan Australia Pty Ltd</p> <p>Minor submission</p>	<p>Inflammatory bowel conditions</p>	<p>Increase in the number of repeat prescriptions available.</p>	<p>The PBAC agreed to increase the number of repeats for mesalazine granules 1 g from 2 to 5 for consistency with the number of repeats for the 1 g Pentasa<sup>®</sup> brand of mesalazine granules.</p>
<p>Methylphenidate hydrochloride, modified release capsule, 20, 30, and 40 mg, Ritalin LA<sup>®</sup>, Novartis Pharmaceuticals Pty Ltd</p> <p>Minor submission</p>	<p>Attention Deficit Hyperactivity Disorder (ADHD)</p>	<p>Treatment of ADHD in certain patients 6 to 18 years inclusive, who have demonstrated a response to immediate release methylphenidate hydrochloride.</p>	<p>The PBAC recommended listing of methylphenidate hydrochloride extended release capsules on the PBS for the treatment of attention deficit hyperactivity disorder (ADHD) in a patient aged 6 to 18 years inclusive, on a cost-minimisation basis compared with methylphenidate hydrochloride extended release tablets (Concerta<sup>®</sup>) at the same price per day as Concerta, as reflected by the equi-effective doses.</p>

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<p>Natalizumab, injection solution, 300mg in 15mL, Tysabri<sup>®</sup>, Biogen Idec Australia Pty Ltd</p> <p>Major submission</p>	<p>Multiple sclerosis</p>	<p>Sect.100 listing – initial and continuing treatment of clinically definite relapsing-remitting multiple sclerosis.</p>	<p>The PBAC recommended the listing of natilizumab on the PBS for initial and continuing treatment, by neurologists, of clinically definite relapsing-remitting multiple sclerosis (RRMS) in an ambulatory patient eighteen years of age or older on the basis of a high but acceptable cost-effectiveness ratio compared with interferon beta-1b.</p>
<p>Paliperidone, prolonged release tablet, 3, 6, 9 and 12 mg, Invega<sup>®</sup>, Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>Schizophrenia (mental illness)</p>	<p>Authority Required (Streamlined) listing for Schizophrenia – acute and maintenance treatment.</p>	<p>The PBAC recommended the listing of paliperidone on the PBS for schizophrenia on a cost-minimisation basis compared with olanzapine and that the equi-effective doses were paliperidone 9.83mg per day and olanzapine 12.91mg per day.</p>
<p>Pegfilgrastim, injection, 6 mg in 0.6 mL single use prefilled syringe, Neulasta<sup>®</sup>, Amgen Australia Pty Ltd</p> <p>Minor submission</p>	<p>Neutropenia</p>	<p>Amend the restriction for patients with non-Hodgkin lymphoma to aggressive grades or low grade receiving an anthracycline-containing regimen</p>	<p>The PBAC recommended the change to reflect current terminology.</p>
<p>Peginterferon alfa-2A, injection 135 micrograms in 0.5 mL single use pre-filled syringe, injection 180 micrograms in 0.5 mL single use pre-filled syringe, Pegasys<sup>®</sup>, Roche Products Pty Ltd</p> <p>Minor submission</p>	<p>Immunomodulating drug</p>	<p>To amend the definition of antihepadnaviral failure in the current PBS restriction to be measured by serum HBV DNA levels instead of elevated ALT (liver enzymes) levels.</p>	<p>The PBAC agreed to the proposed amendment for consistency with the recommendation for adefovir.</p>

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Pemetrexed disodium, injection, 500 mg, Alimta <sup>®</sup> Eli Lilly Australia Pty Ltd  Major submission	Cancer	Section 85 Authority Required – treatment of malignant pleural mesothelioma in combination with cisplatin	The PBAC recommended the listing of pemetrexed for malignant mesothelioma in combination with cisplatin on the basis of a high but acceptable cost-effectiveness compared with cisplatin monotherapy. The PBAC also recommended the listing of a new lower 100 mg strength for both mesothelioma and non-small cell lung cancer
Pioglitazone, tablet, 15, 30 and 45mg, Actos <sup>®</sup> Eli Lilly Australia Pty Ltd  Major submission	Diabetes	Extension of listing to include triple oral combination therapy with metformin and a sulfonylurea in type 2 diabetes	The PBAC recommended listing on a cost-minimisation basis compared with rosiglitazone and recommended that the equi-effective doses were pioglitazone 30mg daily and rosiglitazone 8mg daily.
Protein hydrolysate formula with medium chain triglycerides, Alfaré <sup>®</sup> , Nestlé Australia Ltd, Pepti-Junior, Nutricia Australia Pty Ltd  Minors submission	Cows' milk protein allergy (CMPA)	Request from Wyeth Australia Pty Ltd to re-instate requirement to trial soy formula	The PBAC recommended that the restrictions be amended for protein hydrolysate formula and medium chain triglycerides, and amino acid formula to reinstate soy formula as the first line treatment for CMPA, but include exemption criteria for infants and children with a severe form assessed by a paediatric gastroenterologist or specialist allergist.
Ramipril, capsules, 1.25 mg, 2.5 mg and 5 mg, Tryzan <sup>®</sup> , Alphapharm Pty Ltd  Minor submission	High blood pressure	Listing of a capsule form of the drug – tablets are currently available.	The PBAC recommended listing as requested.

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<p>Ranibizumab, solution for intravitreal injection, 3 mg, Lucentis<sup>®</sup>, Novartis Pharmaceuticals Pty Ltd – Restrictions Working Group/Royal Australian and New Zealand College of Ophthalmologists</p> <p>Minor submission</p>	<p>Macular degeneration</p>	<p>Request to increase the number of repeats and also change the provision for fluorescein angiography to allow patients who have a contraindication to fluorescein angiography another method of diagnosis.</p>	<p>The PBAC agreed to increase the number of repeats from 1 to 2 and allow for an alternative method of diagnosis in cases where fluorescein angiography is not possible.</p>
<p>Risedronate sodium with calcium carbonate and 880 IU cholecalciferol sachets, tablet, 35 mg-2.5g, Actonel Combi D<sup>®</sup>, Sanofi-Aventis Australia Pty Ltd</p> <p>Minor submission</p>	<p>Osteoporosis</p>	<p>New combination product – addition of vitamin D to existing product (Actonel Combi).</p>	<p>The PBAC recommended listing a combination product containing risedronate sodium, calcium carbonate and cholecalciferol (vitamin D3) that treats established osteoporosis in patients who have an inadequate intake of calcium and who have low vitamin D levels on a cost-minimisation basis compared with risedronate and the combination product containing risedronate sodium and calcium carbonate.</p>
<p>Sevelamer hydrochloride, tablet 800 mg Renagel<sup>®</sup>, Genzyme Australia Pty Ltd</p> <p>Minor submission</p>	<p>Kidney disease</p>	<p>Hyperphosphataemia in adults with chronic kidney disease</p>	<p>The PBAC recommended an amended restriction to list as a highly specialised drug for management of the disease and through section 85 for maintenance purposes, following advice from the Australian and New Zealand Society of nephrologists.</p>
<p>Tacrolimus, capsule, 500 mcg, 1mg and 5mg Prograf<sup>®</sup>, Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>Heart transplant rejection</p>	<p>Extension of the current Sect.100 Private Hospital Authority Required and Sect. 85 Authority Required listings to include prevention and treatment of heart transplant rejection</p>	<p>The PBAC recommended an extension to the current Section 100 (management) and Section 85 (maintenance) listings for tacrolimus to include cardiac allograft rejection on a cost-effectiveness basis over cyclosporin at the price proposed in the submission.</p>

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Terbinafine, cream, 1%, Lamisil® Novartis Consumer Health Australasia Pty Ltd  Major submission	Fungal infections	Authority Required – treatment of fungal and yeast infection in Aboriginal and Torres Strait Islander persons	The PBAC recommended listing on a cost-minimisation basis compared with miconazole cream, under the 2004-05 Budget measure to facilitate the access to appropriate medicines for Aboriginal and/or Torres Strait Islander People.
Terbinafine, tablet, 250 mg Lamisil® Novartis Pharmaceuticals Pty Ltd  Major submission	Fungal infections	Authority Required – treatment of fungal or yeast infection in Aboriginal or Torres Strait persons not responsive to topical therapy	The PBAC recommended listing on a cost-effectiveness basis compared with griseofulvin, for treatment of dermatophyte infection (as recommended by the Expert Advisory Group on Antimicrobial Resistance).
Valine Amino Acid Supplement, sachets, 4 g, Vitaflo® Vitaflo Australia  Minor submission	Maple Syrup Urine Disease (MSUD)	New restricted benefit listing for MSUD.	The PBAC recommended listing as a restricted benefit for the treatment of MSUD with a maximum quantity of 4 cartons.
Varenicline tartrate, tablets 500 microgram and 1 mg, Champix®, Pfizer Pty Ltd  Minor submission	Smoking cessation	Request that a patient be allowed to try both bupropion and varenicline in any given 12 month period, if necessary.	The PBAC recommended that the recommended restriction for varenicline be changed to allow a 6 month timeframe between commencing a course of bupropion and varenicline, which would allow both bupropion and varenicline to be prescribed per 12 month period.
Verteporfin, powder for I.V. infusion, 15 mg, Visudyne®, Novartis – Royal Australian and New Zealand College of Ophthalmologists  Minor submission	Macular degeneration	Request to allow the period between re-treatments with verteporfin be less than 3 months.	The PBAC recommended an interval of 1 month between re-treatments.

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Zonisamide, capsules, 25, 50 and 100 mg, Zonegran <sup>®</sup> , Pharmalink Pty Limited  Major submission	Epilepsy	Authority Required – epileptic seizures not controlled by other anti-epileptic drugs.	The PBAC recommended listing on a cost-minimisation basis compared with lamotrigine.  The PBAC agreed that the equi-effective doses were zonisamide 400 mg and lamotrigine 300 mg.