March 2008 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
BIOLOGICAL DISEASE MODIFYIING ANTIINFLAMMATORY DRUGS ADALIMUMAB, injection, 40 mg in 0.8 mL pre-filled syringe and injection 40 mg in 0.8 mL pre-filled pen, Humira®, Abbott Australasia Pty Ltd 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®, Wyeth Pharmaceuticals INFLIXIMAB, powder for I.V. infusion, 100 mg, Remicade®, Schering-Plough Pty Ltd. Minor Submission	Psoriatic arthritis	Request to remove the requirement of rheumatoid factor negative status in the listings for psoriatic arthritis.	The PBAC recommended removing the requirement for a record of rheumatoid factor negative status from the initial and continuing criteria in order to qualify for PBS-subsidised bDMARDs for psoriatic arthritis following advice from the Australian Rheumatology Association (ARA).
BOSENTAN, tablets, 62.5 mg and 125 mg, Tracleer® Actelion Pharmaceuticals Australia Pty Ltd Major submission	Pulmonary Arterial Hypertension (PAH)	Extend the Section 100 listing to include pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts including Eisenmenger's physiology.	The PBAC recommended the extension to listing as requested on the basis of acceptable cost-effectiveness compared with standard care.
CALCIPOTRIOL, scalp solution, 50 micrograms per g (0.005%), 30mL Daivonex® CSL Limited Minor submission	Topical non-steroidal antipsoriatic agent	Restricted benefit listing for chronic stable type psoriasis vulgaris.	The PBAC recommended listing on a cost-minimisation basis compared with the calcipotriol cream with the equi-effective doses considered to be 1 mL of 0.005% scalp lotion equivalent to 1 g of 0.005% cream.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
CARMELLOSE SODIUM with GLYCERIN, eye drops 5 mg-9 mg per mL (0.5%-0.9%), Optive® Allergan Australia Pty Ltd Minor submission	Dry eyes	Restricted benefit listing for the treatment of severe dry eye syndrome.	The PBAC recommended a restricted benefit listing for severe dry eye syndrome, including Sjorgren's syndrome, on a cost-minimisation basis compared other PBS listed multiple dose lubricant eye drops. The PBAC further recommended inclusion in the list of pharmaceutical benefits for optometrical use. The Committee acknowledged that the 6 month shelf life after opening has been accepted by the TGA.
CETUXIMAB, solutions for I.V. infusion, Erbitux® Merck Serono Australia Pty Ltd Minor submission	Cancer	Request to replace the word "suspended" with "interrupted" in the NOTE associated with the restriction for continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx.	The PBAC had no objection to the requested amendment.
CETUXIMAB, solution for I.V. infusion, 100 mg in 20 mL, 500 mg in 100 mL, Erbitux® Merck Serono Australia Pty Ltd Minor submission	Cancer	Request to list new presentations.	The PBAC recommended the listing of the additional presentations.
CLARITHROMYCIN, powder for oral liquid, 250 mg per 5 mL, 50 mL, Klacid® Abbott Australasia Pty Ltd Minor submission	Antibiotic	Unrestricted listing	The PBAC recommended a restricted benefit listing for the treatment of pertussis and atypical mycobacterial infections only.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
CLONAZEPAM, oral liquid 2.5 mg per mL, 10 mL, Rivotril® Roche Pty Ltd Minor submission	Anti-epileptic	Request from the Palliative Care Medicines Working Group (PCMWG) for inclusion in Emergency Drug (Doctor's Bag) supply.	The PBAC recommended the addition to the Emergency Drug (Doctor's Bag) Supplies list.
CLOPIDOGREL, tablet, 75 mg (base), Plavix® and Iscover® sanofi-aventis and Bristol-Myers Squibb Major submission	Anticoagulant	Authority Required (Streamlined) for the treatment of Acute Coronary Syndromes (ACS)	The PBAC recommended listing as requested for the treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin to prevent early and long-term atherothrombotic events, on the basis of acceptable cost-effectiveness compared to aspirin alone.
CYSTINE with CARBOHYDRATE, sachets 4 g containing 500 mg cystine, 30, Cystine Amino Acid Supplement® Vitaflo Australia Pty Ltd Minor submission	Food	Restricted benefit listing for homocystinuria.	The PBAC recommended a restricted benefit listing for pyridoxine non-responsive homocystinuria at the price requested.
DULOXETINE HYDROCHLORIDE, capsules, 30 mg and 60 mg Cymbalta® Eli Lilly Australia Pty Ltd Major submission	Antidepressant	Restricted benefit for major depressive disorders (MDD)	The PBAC recommended the listing of duloxetine on the PBS for major depressive disorders on a cost-minimisation basis compared with venlafaxine and that the equi-effective doses are duloxetine 60 mg and venlafaxine 150 mg.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
EPOETIN ALFA, injection containing 30,000 units in 0.75 mL, prefilled syringe, Eprex 30,000® Janssen-Cilag Pty Ltd Minor submission	Anaemia (low levels of red blood cells)	Addition of an intermediate strength to the current listings.	The PBAC recommended listing as requested.
ERLOTINIB, tablets, 25 mg, 100 mg and 150 mg, Tarceva® Roche Products Pty Limited Minor submission	Lung Cancer	Authority Required listing for: Treatment as monotherapy for patients with stage IIIB or IV non-small cell lung cancer with a WHO performance status of 3 or less, after prior platinum-based chemotherapy, where: (1) disease progression has occurred following treatment with docetaxel or pemetrexed; or (2) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated.	The PBAC recommended the listing of erlotinib tablet on the PBS for the treatment of a patient with non-small cell lung cancer who meets certain criteria on the basis of acceptable cost-effectiveness compared with best supportive care at the new price proposed. Continuation of treatment was recommended for patients who have not developed progressive disease.
ESCITALOPRAM OXALATE, tablets,10 mg and 20 mg, Lexapro® Lundbeck Australia Pty Ltd Major submission	Antidepressant	Restricted benefit for moderate to severe generalised anxiety disorder (GAD).	The PBAC recommended listing for moderate to severe generalised anxiety disorder (GAD) in a patient who has not responded to non-pharmacological therapy and for whom: (a) a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or (b) who has been assessed by a psychiatrist. Listing was recommended on the basis of acceptable cost-effectiveness compared to placebo.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ESCITALOPRAM OXALATE, tablets,10 mg and 20 mg, Lexapro® Lundbeck Australia Pty Ltd Major submission	Antidepressant	Restricted benefit for moderate to severe social anxiety disorder (SAD/Social Phobia).	The PBAC recommended listing for moderate to severe social anxiety disorder (social phobia; SAD), in a patient who has not responded to non-pharmacological therapy and for whom: (a) a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or (b) who has been assessed by a psychiatrist. Listing was recommended on the basis of acceptable cost-effectiveness compared to placebo.
FILGRASTIM, injection, 300 micrograms and 480 micrograms, 300 micrograms in 0.5 mL single use pre-filled syringe, 480 micrograms in 0.5 mL single use pre-filled syringe, Neupogen®,. PEGFILGRASTIM, injection, 6 mg in 0.6 mL single use pre-filled syringe, Neulasta® Amgen Australia Pty Ltd Minor submission	Prevention of neutropenia	Request to replace the entries for Ewing's sarcoma, osteosarcoma and rhabdomyosarcoma in the current restrictions with "sarcoma".	The PBAC agreed to the request.
FLUDARABINE, 10 mg tablet and 50 mg injection, Fludara® Bayer Health Care Bayer Schering Pharma Major submission	Chronic Lymphocytic Leukaemia (CLL).	Authority required listing for the treatment of advanced or progressive B-cell chronic lymphocytic leukaemia (CLL).	The PBAC recommended the listing on fludarabine on the PBS for the treatment of B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease on a cost-effectiveness basis against the main comparator, chlorambucil, at the price proposed.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
GEFITINIB, tablet, 250 mg, Iressa® AstraZeneca Pty Ltd Minor submission	Lung cancer	Request by the PBAC Secretariat to remove the clause relating to the 'grandfather' arrangements for patients commencing treatment prior to July 2004, or between July 2004 and December 2004.	The PBAC recommended that the grandfather clause be removed from the current gefitinib restriction noting that patients who required this clause would have received treatment by now.
GLUCOSE INDICATOR**,** blood electrode strips, Freestyle Lite® 100 Abbott Australasia Pty Ltd Minor submission	Testing strips for use by diabetics	Unrestricted benefit.	The PBAC had no objection to listing an additional brand of blood glucose test strips.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
HEPATITIS B DRUGS ADEFOVIR DIPIVOXIL, tablet, 10 mg, Hepsera® Gilead Sciences Pty Ltd. ENTECAVIR MONOHYDRATE, tablets, 0.5 mg and 1 mg, Baraclude®, Bristol-Myers Squibb. 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®, Roche Products Pty Ltd INTERFERON ALFA-2B, solution for injection 10,000,000 i.u. in 1 mL single dose vial, Intron A®, solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen®, solution for injection 18,000,000 i.u. in 3 mL single dose vial, Intron A®, solution for injection 25,000,000 i.u. in 2.5 mL single dose vial, Intron A®, solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen® and solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen®, Schering- Plough Pty Ltd. LAMIVUDINE, tablet 100 mg and oral solution 5 mg per mL, 240 mL, Zeffix®, GlaxoSmithKline Pty Ltd	Hepatitis B	To amend the definition of antihepadnaviral failure in the current PBS restriction.	The PBAC recommended replacing criteria 2(a) and 2(b) in the Hepatitis B restrictions for patients who are antihepadnaviral naïve (entecavir 0.5 mg, interferon alfa-2a, interferon-2b, lamivudine and peginterferon alfa 2) with the following: "(2) (a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;". In the listings for patients who have had prior treatment for hepatitis B (adefovir and entecavir 1 mg), the PBAC recommended replacing ctiterion 1(a) with the following: (1) (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or". The PBAC agreed that these changes would clearly indicate that ALT is being used as a surrogate for HBV DNA.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
HEPATITIS B DRUGS (Continued) 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® Roche Products Pty Ltd Minor submission			
HYOSCINE BUTYLBROMIDE, injection 20 mg in 1 mL, Buscopan® Boehringer Ingelheim Pty Limited Minor submission	Antispasmodic	Request from the Palliative Care Medicines Working Group (PCMWG) for inclusion in Emergency Drug (Doctor's Bag) supply.	The PBAC recommended the addition to the Emergency Drug (Doctor's Bag) Supplies list.
ILOPROST TROMETAMOL, solution for inhalation, 20 micrograms (base) in 2 mL, Ventavis® Schering Pty Ltd Minor submission	Pulmonary arterial hypertension (PAH)	Request to remove the word 'adult' from the current restriction.	The PBAC recommended the removal of the word "adult" and amendment to the iloprost listing as appropriate to allow use in paediatric patients following advice from clinical experts.
IMATINIB MESYLATE, tablets, 100 mg and 400 mg, Glivec® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Imatinib-sensitive rare diseases	Authority required – for the treatment of four rare diseases: dermatofibrosarcoma protuberans (DFSP), hypereosinophilic syndrome or chronic eosinophilic leukaemia (HES/CEL), myelodysplastic syndromes or myeloproliferative disorders (MDS/MPD), aggressive systemic mastocytosis (ASM).	The PBAC recommended the listing of imatinib on the PBS these rare diseases on the basis of acceptable clinical benefit and acceptable but high cost-effectiveness compared with standard medical management.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
LERCANIDIPINE WITH ENALAPRIL, tablets, 10 mg-10 mg, 10 mg-20 mg, Zan-Extra® Solvay Pharmaceuticals Major submission	High blood pressure	Restricted benefit for hypertension in patients who are not adequately controlled with either lercanidipine or enalapril monotherapy.	The PBAC recommended the requested listing on a cost-minimisation basis compared with the individual components.
MEMANTINE HYDROCHLORIDE, tablet, 10 mg & oral drops, 10 mg/mL, Ebixa® Lundbeck Australia Pty Ltd Major submission	Alzheimer's disease	Authority required for moderately severe Alzheimer's disease with similar wording to the listed acetylcholinesterase inhibitors.	The PBAC recommended listing as the sole PBS subsidised therapy for the treatment of moderately severe Alzheimer's disease in patients with a Mini Mental State Examination Score (MMSE) of 10-14. The PBAC was not convinced that it was no worse than the comparators but agreed it was acceptably cost effective at the reduced price offered.
MESALAZINE, tablet (enteric coated), 500 mg and sachet containing granules, 500 mg per sachet, Salofalk® Orphan Australia Pty Ltd Minor submission	Intestinal anti-inflammatory	Request to increase the maximum quantities from 100 to 200.	The PBAC agreed to the request.
METHOTREXATE, tablet 10 mg, Methoblastin®. Pfizer Australia Pty Ltd. Minor submission	Anti-metabolite	Unrestricted listing of a 15 tablet pack size.	The PBAC recommended the unrestricted listing of the smaller pack size. As a consequence, the PBAC recommended a restricted benefit listing for the currently listed 50 tablet pack size, restricting use to patients requiring more than 20 mg per week.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
NICOTINE, transdermal patch, releasing 15 mg per 16hrs, Nicorette® Johnson & Johnson Pacific Pty Limited Minor submission	Smoking cessation aid	Authority required listing for use by Aboriginal and Torres Strait Islander people for the treatment of tobacco dependence.	The PBAC recommended an Authority required listing as the sole PBS-subsidised therapy. for nicotine dependence in an Aboriginal or Torres Strait Islander person The PBAC recommended only 2 courses of PBS-subsidised nicotine replacement therapy be authorised per year, noting that this population eschews oral aids for smoking cessation.
NILOTINIB, capsule, 200 mg, Tasigna® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Chronic Myeloid Leukaemia (CML)	Authority Required (Section 85) for the treatment of the chronic and accelerated phases of Chronic Myeloid Leukaemia (CML) in patients who are imatinib intolerant or imatinib resistant.	The PBAC recommended the listing of nilotinib for the treatment of chronic and accelerated phase Philadelphia positive chronic myeloid leukaemia in patients who have failed imatinib and meet certain criteria on a cost-minimisation basis compared with dasatinib. The PBAC deferred a final decision for nilotinib as a third line treatment.
PEMETREXED DISODIUM, powder for I.V. infusion, 100 mg and 500 mg (base), Alimta® Eli Lilly Australia Pty Limited Minor submission	Cancer	Amendments to listings which would reduce wastage associated with use of the 500 mg powder.	The PBAC had no objection to the addition of the following wording and Note to the existing Authority required restrictions for pemetrexed for mesothelioma and non-small cell lung cancer: “Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient’s BSA should be provided at the time of the authority approval. NOTE: No applications for increased maximum quantities for the 500 mg vial will be authorised.”

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
PHENOXYMETHYLPENICILLIN, paediatric oral suspension 150 mg per 5 mL, 100 mL, Abbocillin V® and Cilicaine V® Sigma Pharmaceuticals (Australia) Pty Ltd Minor submission	Antibiotic	Unrestricted listing	The PBAC recommended the listing of a new strength of phenoxymethylpenicillin suspension as the two current strengths of 125 mg and 250 mg per 5 mL will be deleted from the PBS schedule due to supply problems.
POSACONAZOLE, oral suspension, 40 mg per mL, 105 mL, Noxafil® Schering-Plough Pty Limited Major submission	Anti Fungal	Section 100 (Highly Specialised Drug) listing for the prophylaxis of invasive fungal infections in patients thirteen years of age and older, and who are at high risk.	The PBAC recommended an extension to its previous Authority required recommendation to include prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of infection as defined by anticipated neutropenia or graft versus host disease. Listing was on the basis of acceptable cost-effectiveness compared with fluconazole and itraconazole.
RALTEGRAVIR, tablet, 400 mg, Isentress® Merck Sharp & Dohme (Australia) Pty Limited Major submission	Human Immunodeficiency Virus (HIV)	Section 100 (Highly Specialised Drug) for the treatment in combination with other antiretroviral agents, of HIV infection in antiretroviral experienced patients.	The PBAC recommended listing for the treatment of HIV infection in antiretroviral experienced patients in combination with other antiretroviral agents on the basis of high and acceptable incremental cost-effectiveness compared to placebo.
RISEDRONATE SODIUM, tablet, 75 mg, Actonel® 75 mg Sanofi Aventis Australia Pty Ltd Minor submission	Osteoporosis	Authority required (streamlined) listing similar to current listings for risedronate.	The PBAC recommended listing as requested on a cost-minimisation basis compared with risedronate 5 mg tablet.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
RIVASTIGMINE HYDROGEN TARTRATE, transdermal patches, 9 mg rivastigmine (releasing approximately 4.6 mg per 24 hour), Exelon® Patch 5, 18 mg rivastigmine (releasing approximately 9.5 mg per 24 hour), Exelon® Patch 10, Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Alzheimer's disease	Authority required restriction for mild to moderately severe Alzheimer's disease.	The PBAC recommended the listing of rivastigmine transdermal patches on a cost-minimisation basis compared with rivastigmine capsules. The equi-effective doses for the purposes of cost- minimisation are one 18 mg rivastigmine patch (releasing approximately 9.5 mg per 24 hour, Exelon® Patch 10) is equivalent to rivastigmine capsules at a dose of between 9 mg and 12 mg.
SEVELAMER HYDROCHLORIDE, tablet, 800 mg, Renagel® Genzyme Australasia Pty Ltd Minor submission	Chronic kidney disease	Request to broaden restriction to allow for use in children.	The PBAC recommended removing the word "adult" from the current restriction for sevelamer after receiving expert advice that there is no pharmacological or other reason why a child receiving dialysis and who complies with the biochemical parameters of the restriction should be denied access to PBS-subsidised treatment with sevelamer.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
SITAGLIPTIN PHOSPHATE, tablets, 25 mg, 50 mg and 100 mg, Januvia® Merck Sharp & Dohme (Australia) Pty Limited Major submission	Type 2 diabetes	Authority Required (Streamlined) – dual oral combination therapy with metformin or a sulfonylurea where glycosylated haemoglobin (HbA1c) is > than 7%.	The PBAC recommended the listing of sitagliptin for the treatment, as part of dual oral combination therapy with metformin or a sulfonylurea, of a patient with Type 2 diabetes whose HbA1c is greater than 7% prior to initiation of sitagliptin despite treatment with metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. Listing was recommended on a cost-minimisation basis against rosiglitazone with the equi-effective doses being sitagliptin 100 mg daily and rosiglitazone 8 mg daily. The PBAC rejected the application to list sitagliptin for use in Type 2 diabetes in combination with metformin where metformin treatment alone provides inadequate control, and in the absence of a sulfonylurea contraindication or intolerance on the basis of highly uncertain cost-effectiveness.
SOMATROPIN injection, 0.8 mg, 1 mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2 mg, 5 mg, 12mg, Genotropin® and Genotropin MiniQuick® Pfizer Australia Pty Ltd Major submission	Prader-Willi Syndrome	Section 100 Growth Hormone Program for improvement of body composition and treatment of short stature associated with Prader-Willi Syndrome in paediatric patients.	The PBAC recommended the listing of somatropin on the PBS under the Section 100 Human Growth Hormone Program to include improvement of body composition and short stature associated with Prader-Willi Syndrome (PWS) in patients up to 18 years of age on the basis of high but acceptable cost-effectiveness compared with placebo.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
SOMATROPIN, injection, 0.6 mg (1.8 I.U.), with diluent in a single use syringe (without preservative), Genotropin MiniQuick®, Pfizer Australia Pty Ltd Minor submission	Growth Hormone	Section 100 Growth Hormone Program	The PBAC recommended the listing of a new formulation for use under the Growth Hormone program.
SOMATROPIN, injection, 12 mg (36 I.U.), in 1 mL cartridge (with preservative), Genotropin® Pfizer Australia Pty Ltd Minor submission	Growth Hormone	A minor amendment to current listing under the Section 100 Growth Hormone Program to reflect TGA registration for use in chronic renal failure and extended shelf life.	The PBAC approved the request.
SOMATROPIN, injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative), Zomacton® Ferring Pharmaceuticals Pty Ltd Minor submission	Growth Hormone	Request to re-list under the Section 100 Growth Hormone Program a previously listed formulation.	The PBAC approved the request.
TACROLIMUS, capsules, 500 micrograms, 1 mg and 5 mg Prograf® Janssen-Cilag Pty Ltd Major submission	Prevent lung transplant rejection	Section 100 Private hospital authority required and Section 85 Authority required for management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis and treatment of lung allograft rejection. Management includes initiation, stabilisation and review of therapy as required.	The PBAC recommended extending the current listings for tacrolimus as requested to include lung transplant rejection on the basis of cost effectiveness over cyclosporin at the price proposed in the submission.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
TELBIVUDINE, tablet, 600 mg, Sebivo® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Hepatitis B	Section 100 Private hospital authority required for patients 16 years or older with chronic hepatitis B who are nucleoside analogue naïve and satisfy certain criteria.	The PBAC recommended the listing of telbivudine for the treatment of chronic hepatitis B in patients who are nucleoside analogue naïve and who are hepatitis Be antigen positive on the basis of a high and acceptable incremental cost effectiveness ratio compared to lamivudine. The PBAC rejected the listing of telbuvidine for HBeAg-negative patients on the basis of an unacceptably high and uncertain cost-effectiveness ratio compared to lamivudine at the original price proposed in the submission, and because of uncertainty in relation to the extent of any price advantage over lamivudine.
TYROSINE with CARBOHYDRATE, sachets 4 g containing 1g of tyrosine, 30, Tyrosine Amino Acid Supplement® Vitaflo Australia Pty Ltd Minor submission	Food	Restricted benefit listing for phenylketonuria.	The PBAC recommended listing as a Restricted Benefit for the management phenylketonuria at the price requested.
VALSARTAN, tablets, 40 mg, 80 mg and 160 mg, Diovan® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Hypertension	Change in maximum quantity.	The PBAC agreed with the sponsor's proposal for a new maximum quantity of 28, as the majority of use will be in patients with hypertension (once daily dosing). The PBAC noted that patients requiring twice daily dosing for heart failure will be able to obtain an authority prescription for an increased quantity.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
VARENICLINE TARTRATE, tablets, 0.5 mg, 11 and 1 mg, 14 and 1 mg 28 and tablets 1 mg 56 Champix® Pfizer Australia Pty Ltd Minor submission	Smoking cessation	Amendment to varenicline entry for consistency with bupropion entry with respect to courses of treatment during a 12 month period.	The PBAC recommended amendment to the Note to the restriction for varenicline to allow treatment with both varenicline and bupropion within a 12 month period with 6 months between commencing a course of the second product.
ZOSTER VIRUS VACCINE LIVE (Oka/Merk), injection, 0.65 mL, Zostavax®, CSL Limited Minor submission	Vaccine for shingles	Funding on the National Immunisation Program for immunocompetent persons aged 60 years and over.	The PBAC recommended listing Zoster Virus Vaccine Live on the National Immunisation Program (NIP) for the vaccination of immunocompetent persons aged 60 years and over (for an ongoing cohort of 60 year old individuals) and a catch-up cohort for all individuals aged between 61 years and less than 80 years on the basis of acceptable cost-effectiveness ratios compared to standard medical management. The PBAC considered the vaccine should not be made available to persons 80 years and over on the basis of an unacceptably high and uncertain cost effectiveness ratio.