JULY 2004 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	PROPOSED LISTING OR REQUEST	PBAC RECOMMENDATION
ACETYLCYSTEINE, solution for inhalation, 200 mg per mL, 5 mL, Mucomyst® Bristol-Myers Squibb Pharmaceuticals Pty Ltd	Mucolytic agent	Restricted benefit for the treatment of bronchiectasis or cystic fibrosis.	The PBAC had no objections to the Secretariat decision to list this formulation of the product.
ADALIMUMAB, injection, 40 mg in 0.8 mL pre-filled syringe, Humira® Abbott Australasia Pty Ltd	Used to treat rheumatoid arthritis.	The HIC requested an amendment to the restriction to include a minimum weekly dose for concomitant methotrexate treatment.	The PBAC recommended that concomitant methotrexate treatment be at a minimum dose of 7.5 mg weekly.
ADEFOVIR DIPIVOXIL, tablet, 10 mg Hepsera® Gilead Sciences Pty Ltd	Used for the treatment of Hepatitis B	Section 100 (Highly Specialised Drug) private hospital authority for patients with chronic hepatitis B who have failed their current antihepadnaviral therapy and who satisfy certain criteria.	The PBAC recommended for listing on the basis of acceptable cost-effectiveness compared with ongoing 'failed' lamivudine for: Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except patients with coagulation disorders considered severe enough to prevent liver biopsy); (2) Repeatedly elevated (greater than 1.2 times the upper limit of normal) 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 (HBe antigen

			positive and/or serum HBV DNA positive); (3) Female patients of childbearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. NOTE: Patients may receive treatment in combination with lamivudine for the initial three months only of PBS-subsidised adefovir therapy. Patients who are immunocompromised may receive treatment in combination with lamivudine for the initial 12 months of PBS subsidised adefovir therapy. Thereafter, PBS-subsidised adefovir must be used as monotherapy.
AMOXYCILLIN with CLAVULANIC ACID, sustained release tablet, 1000 mg-62.5 mg, Augmentin SR® and Clavamox SR® GlaxoSmithKline Australia Pty Ltd	Antibiotic	Restricted benefit listing for respiratory tract infections, where resistance to amoxycillin is suspected or proven.	The PBAC recommended listing as a restricted benefit for bacterial community-acquired pneumonia, and acute bacterial sinusitis, where resistance to amoxycillin is suspected or proven. Listing is on cost minimisation basis compared to Augmentin DUO Forte (875 mg-125 mg). The equi-effective doses were accepted as Augmentin DUO Forte one tablet twice a day and two tablets twice a day of Augmentin SR.
ANAKINRA pre-filled syringe, 100	Used to treat	Authority required listing for the	The PBAC recommended the listing of

mg in 0.67 mL, Kineret® Amgen Australia Pty Ltd	inflammatory diseases, such as rheumatoid arthritis	treatment of active rheumatoid arthritis, with eligibility criteria for initiation and continuation based on the PBAC's recommended restrictions for infliximab and etanercept, for use in patients who have failed one or more TNF-α antagonists	anakinra on the basis of acceptable cost-effectiveness compared with a subsequent TNF-alfa antagonist in patients who, within the proposed interchangeability arrangements for these biological DMARDs, are unresponsive to, or intolerant of one or more prior TNF-alfa antagonists, or in whom one or more prior TNF-alfa antagonists are contra-indicated. Link to draft restriction recommended by PBAC.
ANASTROZOLE, tablet ,1 mg, Arimidex® AstraZeneca Pty Ltd	Used for the treatment of breast cancer	Restricted benefit listing for the treatment of hormone dependent early breast cancer in post-menopausal women who have developed side effects of a severity necessitating discontinuation of tamoxifen therapy or for whom tamoxifen is inappropriate or contraindicated.	The PBAC recommended extension of the listing on the basis of acceptable cost-effectiveness compared to placebo for the second-line early breast cancer restriction requested for: Treatment of hormone-dependent early breast cancer in post-menopausal women in whom tamoxifen therapy is contraindicated; Treatment of hormone-dependent early breast cancer in post-menopausal women who are intolerant of tamoxifen.
ANGIOTENSIN CONVERTING ENZYME INHIBITOR COMBINATIONS and ANGIOTENSIN II RECEPTOR ANTAGONIST COMBINATIONS	Treatment of hypertension	Request to delete the NOTE prohibiting increased maximum quantities and repeats for these entries	The PBAC agreed to delete the NOTE in recognition of the variations in the TGA-recommended dosage regimens for the individual components of these combination products. Such a move was considered consistent with quality use of medicine principles and appropriate for compliance reasons.
ATAZANAVIR capsules,	Anti-retroviral drug used	Section 100 (Highly Specialised Drug)	The PBAC recommended listing as

150 mg, 200 mg, Reyataz® Bristol-Myers Squibb Pharmaceuticals Australia Pty Ltd	in the treatment of HIV infections	private hospital authority required for the treatment, in combination with 2 or more anti-retroviral drugs, of HIV infection in patients with CD4 cell counts of less than 500 per cubic millimetre, or viral load of greater than 10,000 copies per mL.	requested on a cost-minimisation basis compared with nelfinavir, with the equi-effective doses being atazanavir 400 mg once daily and nelfinavir 750 mg three times daily; and atazanavir 300 mg plus ritonavir 100 mg once daily and Kaletra (lopinavir 400 mg plus ritonavir 100 mg) twice daily.
CAPTOPRIL, oral solution, 5 mg per mL, Capoten® Bristol-Myers Squibb Pharmaceuticals Pty Ltd	ACE-inhibitor for hypertension and other cardiovascular diseases	Restricted benefit listing for hypertension, heart failure, myocardial infarction, diabetic nephropathy (type I IDDM) in patients unable to take the tablet form of an ACE inhibitor.	The PBAC recommended a restricted benefit listing for patients unable to take a solid dose form of an ACE inhibitor on the basis of acceptable cost-effectiveness in this patient group.
ENFUVIRTIDE, powder for injection, 90 mg in mL, Fuzeon® Roche Products Pty Limited	Anti-retroviral drug used in the treatment of HIV infections	Section 100 (Highly Specialised Drug) listing for the treatment of HIV infection, in combination with other antiretroviral agents, in antiretroviral experienced patients with treatment failure characterised by: evidence of HIV replication, despite ongoing therapy; or treatment-limiting toxicity to previous antiretroviral agents.	The PBAC recommended listing for last-line treatment of HIV infection on the basis of acceptable cost effectiveness compared with standard medical management for "Treatment of HIV infection, in combination with other antiretroviral agents, in antiretroviral experienced patients with treatment failure characterised by: (a) evidence of HIV replication, despite ongoing therapy; or (b) treatment-limiting toxicity to previous antiretroviral agents. Patients must have failed previous treatment with 3 different antiretroviral regimens. At least one of each of the following classes of antiretroviral drugs must have been attempted: (i) at least one non-nucleoside reverse transcriptase inhibitor; and (ii) at least one nucleoside reverse transcriptase inhibitor; and

			(iii) at least one protease inhibitor."
ETANERCEPT, powder for injection, 25 mg, Enbrel® Wyeth Australia Pty Limited	A biological disease modifying anti-rheumatic drug for psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis	Authority required listing for the treatment of severe active ankylosing spondylitis in patients who have failed to achieve an adequate response to defined standard therapies.	The PBAC recommended listing for ankylosing spondylitis on a cost-minimisation basis compared with infliximab for the treatment of this condition. Link to draft restriction recommended by PBAC
FONDAPARINUX SODIUM, 2.5 mg pre-filled syringe, Arixtra® Sanofi-Synthelabo Australia Pty Ltd	An anti-thrombotic used to prevent thromboembolic events ie blood clots	Authority required listing for prevention of venous thromboembolic events (VTE) in patients undergoing major hip surgery and major knee surgery.	The PBAC recommended an authority required listing on a cost-effectiveness basis compared with enoxaparin for the prevention of venous thromboembolic events in patients undergoing major hip surgery, and total knee replacement.
FOSAMPRENAVIR tablet, 700 mg and oral solution 50 mg per mL, Telzir® GlaxoSmithKline Australia Pty Ltd	Anti-retroviral drug used in the treatment of HIV infections	Section 100 (Highly Specialised Drug) private hospital authority required listing for treatment, in combination with ritonavir and other antiretroviral agents of HIV infection in patients with (a) CD4 cell counts of less than 500 per cubic millimetre, (b) viral load of greater than 10,000 copies per mL.	The PBAC recommended listing as requested in combination with 2 or more antiretroviral drugs on a cost-minimisation basis with fosamprenavir in combination with ritonavir compared to nelfinavir.
GALANTAMINE HYDROBROMIDE, prolonged release capsules, 8 mg, 16 mg and 24 mg, Reminyl® Janssen-Cilag Pty Ltd	Treatment of mild to moderately severe dementia of the Alzheimer type	Authority required listing with same restriction as galantamine hydrobromide immediate release tablets.	The PBAC recommended listing as requested, with the 8 mg, 16 mg and 24 mg once daily products considered equivalent to the 4 mg, 8 mg and 12 mg twice daily products, respectively.

GEFITINIB tablet, 250 mg, Iressa® AstraZeneca Pty Ltd.	A selective inhibitor of epidermal growth factor receptor tyrosine kinase used to treat locally advanced or metastatic non-small cell lung cancer.	Authority required listing for the treatment of patients with locally advanced or metastatic non small cell lung cancer, where disease progression has occurred following prior treatment with at least one chemotherapy agent and WHO performance status is ≤ 2.	The PBAC recommended an authority required listing on the basis of acceptable cost-effectiveness compared to docetaxel and best supportive care in patients with an activating mutation of the EGFR gene. The restriction follows: Treatment by a specialist as monotherapy of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where: (1) disease progression has occurred following treatment with at least one chemotherapy agent; and (2) there is evidence that the patient has an activating mutation of the epidermal growth factor receptor gene (EGFR) in tumour material. Such a mutation must be demonstrated by analysis of the DNA sequence of the EGFR gene. The following must be provided at the time of application: (1) details of prior chemotherapy including the name of drug(s) and date of the most recent treatment cycle; (2) details of the patient's WHO performance status; and (3) details of test results providing evidence of the patient's activating mutations in the EGFR receptor. NOTE: No application for increased maximum quantities and/or repeats will be authorised.
GLUCOSE INDICATOR – BLOOD,	For use by diabetics	Unrestricted listing	The PBAC had no objection to the

electrode strips, 50, GlucoCare® DiaCare International Pty Ltd.			Secretariat decision to list this product.
IMATINIB MESYLATE, tablets, 100mg and 400 mg, capsule, 100 mg, Glivec® Novartis Pharmaceuticals Australia Pty Ltd	A protein-tyrosine kinase inhibitor used to treat chronic myeloid leukaemia and gastrointestinal stromal tumours.	Extension of the definition of response used in the criteria for continuing treatment applied under the Special Authority Program for the treatment of patients with metastatic or unresectable malignant gastrointestinal stromal tumours (GIST) to allow patients with no tumour growth to continue with therapy.	The PBAC recommended the Section 100 listing of imatinib for the treatment gastrointestinal stromal tumour (GIST) be amended to omit the requirement that patients achieve any quantified response in order to be eligible for continuing PBS-subsidy for imatinib. The PBAC accepted that, compared with the follow-up data considered in December 2003, including the additional period of follow-up the data now indicate that there is no significant difference between partial response and stable disease at six months in terms of their ability to predict either time to disease progression or overall survival. This recommendation has been implemented. Please contact the HIC on 1800 242 679 for information. The wording of the restriction is yet to be finalised.
INFLIXIMAB, powder for infusion, 100 mg, Remicade® Schering-Plough Pty Ltd	Used to treat inflammatory diseases, such ankylosing spondylitis, rheumatoid arthritis and Crohn's disease	The HIC requested an amendment to the restriction for the treatment of rheumatoid arthritis to include a minimum weekly dose for concomitant methotrexate treatment.	The PBAC recommended that concomitant methotrexate treatment be at a minimum dose of 7.5 mg weekly.
IRINOTECAN injection, 40 mg in 2mL and 100 mg in 5 mL vials,	Used for the treatment of colorectal cancer	To seek an amendment to the current authority required listing for irinotecan	The PBAC recommended listing for metastatic colorectal cancer in patients

Camptosar® Pfizer Australia Pty Ltd		to allow use of the drug in the first line management of advanced colorectal cancer.	with a WHO performance status of 2 or less on a cost-minimisation basis compared to oxaliplatin.
OLANZAPINE tablets, 2.5 mg, 5 mg, 7.5 mg and 10 mg, Zyprexa®, wafers, 5 mg and 10 mg, Zyprexa Zydis® Eli Lilly Australia Pty Limited	Treatment for schizophrenia and bipolar disorder	Authority required listing for maintenance treatment of bipolar I disorder.	The PBAC recommended the listing as requested on the basis of acceptable cost-effectiveness compared with lithium.
PEGINTERFERON ALFA-2A pre-filled syringes, 180 µg, 135 µg, Pegasys® Roche Products Pty Limited	Used for the treatment of hepatitis C	Section 100 listing for the treatment of chronic hepatitis C virus (HCV) in patients 18 years or older who have compensated liver disease and who have received no prior interferon therapy and who have a contraindication to ribavirin.	The PBAC recommended listing on a cost-minimisation basis compared with peginterferon alfa-2b. The recommended restriction is as follows: Chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa therapy and have a contraindication to ribavirin, who satisfy all of the following criteria: 1. Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy). 2. Abnormal serum ALT levels in conjunction with documented chronic hepatitis C infection (repeatedly anti-HCV positive and/or HCV RNA positive). 3. No other forms of chronic liver disease. 4. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

			The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.
PRAMIPEXOLE, tablets, 125 microgram, 250 microgram, 1 mg, Sifrol® Boehringer Ingelheim Pty Limited	Used for the treatment of Parkinson's disease	Restricted benefit listing for treatment of Parkinson's disease as adjunctive therapy in combination with levodopa-decarboxylase inhibitor.	The PBAC recommended reinstatement of its previous recommendation of a restricted benefit listing for Parkinson's disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations. The recommendation was made on a cost-minimisation basis compared with bromocriptine.
RISPERIDONE, long-acting intramuscular injections, 25 mg, 37.5 mg, 50 mg, Risperdal® Consta® Janssen-Cilag Pty Ltd	Used for the treatment of schizophrenia.	Authority required listing for patients with schizophrenia who have had a relapse, or exacerbation in disease due to poor adherence with orally administered antipsychotic medication or treatment of schizophrenia in patients not satisfactorily controlled with other injectable antipsychotic therapy or treatment of schizophrenia in patients unable to tolerate other injectable antipsychotic therapy.	The PBAC recommended an authority required listing for schizophrenia. The PBAC recommended the simplified authority required listing based on an acceptance that applying the pricing relativity that IM haloperidol has over oral haloperidol to the weighted average monthly treatment cost of oral risperidone would represent an acceptable but high cost-effectiveness ratio.
ROFECOXIB tablets 12.5 mg and 25 mg, and oral suspension, 12.5mg per 5 mL and 25 mg per 5mL, Vioxx®	Used for treatment of osteoarthritis and rheumatoid arthritis	Additional restricted benefit listing for rheumatoid arthritis.	The PBAC recommended extension of the restricted benefit listing of rofecoxib as requested on the basis of acceptable

Merck Sharp & Dohme Pty Ltd			cost-effectiveness over traditional NSAIDs.
TRANDOLAPRIL, capsule, 4 mg, Gopten® Abbott Australasia Pty Ltd	Treatment of hypertension and other cardiovascular diseases	Unrestricted listing for a new strength of listed drug.	The PBAC had no objection to the Secretariat decision to list this product.
VALDECOXIB tablets 10 mg, 20 mg Valdyne® Pfizer Australia Pty Ltd	Treatment for osteoarthritis and rheumatoid arthritis	Restricted benefit listing for the symptomatic treatment of osteoarthritis and rheumatoid arthritis.	The PBAC recommended listing as requested on a cost-minimisation basis compared to celecoxib.
VALSARTAN tablets 40 mg, 80 mg and 160 mg Diovan® Novartis Pharmaceuticals Australia Pty Ltd	An angiotensin II antagonist used for the treatment of heart failure and hypertension.	Authority required listing for patients with mild to severe heart failure who are receiving conventional therapy but are intolerant to ACE inhibitors due to bradykinin-mediated adverse effects.	The PBAC recommended that valsartan be listed on a cost-minimisation basis compared with candesartan, with the equi-effective dose for the treatment of heart failure being valsartan 160 mg twice daily and candesartan 32 mg once daily. The conclusion regarding equi-effective doses is based on an indirect comparison of the results of the Val-HeFT trial with the results of the CHARM trial and its consistency with an indirect comparison of the PBAC's previous conclusions with respect to the equi-effective doses of valsartan and candesartan in hypertension.