March 2007 PBAC Outcomes – Positive Recommendations

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Adalimumab, injection 40 mg solution in 0.8 mL pre-filled pen, Humira Pen®, Abbott Australasia Pty Ltd Minor submission	Rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis	Change the delivery system from a pre-filled syringe to a pre-filled pen.	The PBAC recommended listing of a new delivery system of adalimumab for the same indications as the currently listed product.
Amino acid formula with vitamins and minerals without phenylalanine, oral liquid, 87 ml x 30, and 174 mL x 30, PKU Cooler® 10 and 20, Vitaflo Australia Pty Ltd Minor submission	Nutrient for inborn error of metabolism	List new pack sizes and change name of PKU Express Liquid to PKU Cooler and additional pack sizes ie PKU Cooler 10 (87mL) and PKU Cooler 20 (174 mL).	The PBAC recommended listing of these new pack sizes on a cost neutral basis according to the price of the currently listed PKU Express Liquid 130 mL x 30. The PBAC also noted the name change from 'PKU Express Liquid' to 'PKU Cooler' for all three products, on the basis of differentiating the liquid from the powder product.
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine 130 mL liquid in foil pouch x 30 x 4 cartons, MSUD Express Cooler®, Vitaflo Australia Pty Ltd Minor submission	Nutrient for inborn error of metabolism	Restricted benefit for maple syrup urine disease.	The PBAC recommended listing as requested on a gram for gram of protein pricing basis, at the new price agreed for products to treat maple syrup urine disease.
Amlodipine maleate, tablets, 5 mg and 10 mg, Amlo 5®, Amlo 10®, Spirit Pharmaceuticals Pty Ltd Minor submission	Blood pressure drug	Listing as an unrestricted benefit.	The PBAC recommended listing on a cost minimisation basis compared with amlodipine besylate at comparable strengths (ie 5 mg of amlodipine base provided as the maleate salt is equivalent to 5mg of amlodipine as the besylate salt. The PBAC considered that these products should be "a" flagged to allow substitution to occur according to current dispensing practice.

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ANTICHOLINESTERASES Donepezil hydrochloride, tablets, 5 mg, 10 mg, Aricept®, Pfizer Pty Ltd Galantamine hydrochloride, prolonged release capsules 8 mg (base), 16 mg (base), 24 mg (base), Reminyl®, Janssen-Cilag Pty Ltd Rivastigmine hydrogen tartrate, capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), 6 mg (base), oral solution 2 mg (base) per mL, 120 mL, Exelon®, Novartis Pharmaceuticals Minor submission	Alzheimer's disease	Request from Medicare Australia to add to the restriction wordings to ensure that a baseline ADAS-Cog score is provided with the initial application if this measurement is to be used to demonstrate improvement in cognitive function for continuing treatment.	The PBAC agreed to amend the restrictions by addition of the sentence "If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purposes of fulfilling the criteria for continued PBS supply" to address the problems encountered with continuing treatment applications where the ADAS-cog score is not provided with the application for initial treatment.
Apomorphine hydrochloride, injection, 20 mg in 2 mL, Apo-go®, Mayne Pharma Limited Minor submission	Parkinson's disease	Temporary replacement listing due to unavailability of currently listed product.	The PBAC agreed to list this product at the price requested on the basis of clinical need while the currently listed product is not available.
Apomorphine hydrochloride, solution for infusion, 5 mg per mL, pre-filled syringe, 10 mL, Apomine PFS®, Mayne Pharma Limited Minor submission	Parkinson's disease	Additional strength for patients who require higher dosages.	The PBAC recommended listing this product at the price requested based on clinical need, for patients who have higher dosage requirements.

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Aprepitant, pack with 1 capsule 125 mg and 2 capsules 80 mg, Emend®, Merck Sharp and Dohme (Australia) Pty Limited Minor submission	Anti nausea drug	To seek a change to the current restriction to allow authorisation of repeats for subsequent chemotherapy cycles at the time of initial application.	The PBAC recommended a change to the listing to allow repeats to be authorised to cover all future cycles of chemotherapy on the basis of efficiency. As the first dose of aprepitant is required one hour before chemotherapy for each cycle, this change will ensure patients have access to treatment at the appropriate time for all cycles, without having to obtain a further prescription.
Budesonide with eformoterol fumarate dihydrate, 100/6 and 200/6, Symbicort® turbuhaler, AstraZeneca Pty Ltd Major submission	Asthma drug	For ~~initiation of~~ single maintenance and reliever therapy in patients who experience asthma symptoms while receiving treatment with inhaled or oral corticosteroids or while receiving treatment with a combination of an inhaled corticosteroid and a long acting beta-2 agonist.	The PBAC recommended amending the current listing as a restricted benefit to include single maintenance and reliever therapy in patients who had frequent asthma symptoms while taking oral or inhaled corticosteroids or a combination of an inhaled corticosteroid and a long acting beta-2 agonist.
Budesonide with eformoterol fumarate dihydrate 400/12, Symbicort® turbuhaler, AstraZeneca Pty Ltd Minor submission	Asthma drug	Consequential amendment to recommendation for lower strength of this product.	Consequential to the recommendation to extend the current listings for Symbicort 100/6 and 200/6, the PBAC recommended that a NOTE precluding use of the 400/12 strength as 'maintenance and reliever' therapy be added to the current restriction.
Calcipotriol, cream, 50 micrograms per g (0.005%), 30 g, Daivonex®, CSL Biotherapies Pty Ltd Minor submission	Skin disorders	Restricted benefit listing for chronic stable plaque type psoriasis vulgaris.	The PBAC recommended listing on the basis of demonstrated equivalence to the currently listed calcipotriol ointment and recognition of patient preference for the cream.

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Cetuximab 2 mg/mL in 50 mL, Erbitux®, Alphapharm Pty Limited Major submission	Anti-cancer drug	Authority required for treatment in combination with radiotherapy of patients with UICC Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx in whom the use of cisplatin is either contraindicated or cannot be tolerated.	The PBAC recommended listing on the basis of acceptable cost-effectiveness against radiotherapy alone. The Committee accepted that loco-regional control was a more relevant end-point in head and neck cancers than in other cancers.
Ciprofloxacin ear drops, 3 mg per mL (0.3%), 5 mL, Ciloxan®, Alcon Laboratories (Australia) Pty Ltd Minor submission	Antibiotic	Request for a change to the restrction to align the age for treatment with the TGA indication to read: "Treatment of chronic suppurative otitis media in an Aboriginal and Torres Strait Islander person aged one month and older" The current restriction reads "aged one year and older".	The PBAC had no objection to the sponsor's request to change the age restriction included in the current listing from one year to one month, in line with the TGA registration.
Dasatinib tablets 70 mg, 50 mg , 20 mg Sprycel®, Bristol-Myers Squibb Pharmaceutical Australia Pty Ltd Major submission	Anti cancer drug	Section 100 Special Authority Program for the treatment of chronic myeloid leukaemia in adult patients expressing the Philadelphia chromosome or transcript, bcr-abl tyrosine kinase, who are resistant or intolerant to imatinib mesylate.	The PBAC recommended an authority required listing (exact mechanism to be determined) for the treatment of all phases of chronic myeloid leukaemia (CML) in patients not responding to imatinib because of resistance or intolerance, on a cost-effectiveness basis against imatinib.
Diphtheria and Tetanus Vaccine, diluted for adult use, injection 0.5 mL in pre-filled syringe, 5, ADT Booster®, CSL Limited Minor submission	Vaccine	Listing of a replacement ADT vaccine.	The PBAC had no objection to the Secretariat amendment to the restriction recommended for ADT Booster out of session in August 2006 because of changes approved by the TGA to the draft product information following the meeting.

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Etanercept, injection set containing 4 pre-filled syringes for injection 50 mg, injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL, (Enbrel®), Wyeth Australia Pty Ltd Minor submission	Psoriatic arthritis and ankylosing spondylitis	Inclusion of the 50 mg pre-filled syringe and 50 mg lyophilised vial for psoriatic arthritis and ankylosing spondylitis.	The PBAC recommended out of session the listing of the 50 mg pre-filled syringe and 50 mg lyophilised vial for psoriatic arthritis and ankylosing spondylitis. The PBAC noted the sponsor did not request the listing of the 25 mg pre-filled syringe on the PBS for these conditions because the pre-filled syringe would not be suitable for the majority of the potential population.
Ezetimibe, tablet 10 mg, Ezetrol®, Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Cholesterol lowering drug	Add to the listing the following after conditions (1) and (2), following a request from Medicare Australia to clarify the intent of the restriction. "The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application".	The PBAC had no objection to the Secretariat amending the restriction to repeat the phrase "The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application" immediately after conditions (1) and (2) in the restriction.
Ezetimibe with Simvastatin, tablets, 10 mg – 40 mg and 10 mg – 80 mg, Vytorin®, Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Cholesterol lowering drug	Add to the listing the following after conditions (1) and (2), following a request from Medicare Australia to clarify the intent of the restriction. "The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application".	The PBAC had no objection to the Secretariat amending the restriction to repeat the phrase "The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application" immediately after conditions (1) and (2) in the restriction.

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Fluticasone propionate with salmeterol xinafoate, oral presssurised inhalation 250 mcg-25 mcg (base) per dose,120, CFC-free formulation, Seretide MDI 250/25®, & powder for oral inhalation in breath actuated device 500 mcg-50 mcg (base) per dose,60, Seretide Accuhaler 500/50® , GlaxoSmithKline Australia Pty Ltd Major submission	Asthma and Chronic Obstructive Pulmonary Disease (COPD)	Restricted benefit for the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD) in patients with a history of repeated exacerbations.	The PBAC recommended a restricted benefit listing on a cost-minimisation basis with the equi-effective doses being fluticasone 500 mcg/salmeterol 50 mcg inhaled twice daily being equivalent to tiotropium bromide monohydrate 18 mcg inhaled once daily in the treatment of COPD. The recommended restriction reflects the wording of the TGA registered indication.
Glucose Indicator, blood electrode strips**,** Accu-Chek® Performa, Roche Diagnostics Australia Pty Ltd Minor submission	Testing strips for use by diabetics	Listing of test strips for a self-monitoring blood glucose system.	The PBAC recommended the listing of an additional brand of blood glucose test strips.
Glucose Indicator, blood reagent strips, Betachek G5®, National Diagnostic Products (Australia) Pty Ltd Minor submission	Testing strips for use by diabetics	Listing of test strips for a self-monitoring blood glucose system	The PBAC recommended the listing of an additional brand of blood glucose test strips.
Glucose Indicator, blood reagent strips, Glucoboy Blood Glucose Test Strip® 50, Diabetes Association of Australia Minor submission	Testing strips for use by diabetics	Listing of test strips for a self-monitoring blood glucose system	The PBAC recommended out of session the listing of an additional brand of blood glucose test strips.
Hydroxocobalamin, injection, 1 mg in 1 mL, (Goldshield Hydroxocobalamin®), Mayne Pharma Limited Minor submission	Vitamin B_{12} deficiency	Restricted benefit listing for the treatment of pernicious anaemia, other proven Vitamin B_{12} deficiencies and for prophylaxis after gastrectomy.	The PBAC recommended listing at the price requested on the basis of providing an alternative to the currently listed product which is in short supply.

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Ibandronic acid, tablet, 150 mg, Bonviva®, Roche Products Pty Limited Major submission	Osteoporosis	Authority required for treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma.	The PBAC recommended listing on a cost-minimisation basis with alendronate for the treatment of established osteoporosis, with the equi-effective doses being ibandronic acid 150 mg/month and alendronate 70 mg/week.
Infliximab, powder for I.V. infusion, 100 mg, Remicade®, Schering-Plough Pty Ltd Major submission	Crohn's disease	Section 100 Authority required listing for the treatment of moderate to severe Crohn's disease in patients who have failed an adequate trial of conventional therapy.	The PBAC recommended the listing of infliximab for the treatment of patients with severe Crohn's disease (Crohn's Disease Activity Index ≥ 300) or patients with an ileostomy or colectomy due to Crohn's disease on the basis of high and acceptable cost-effectiveness compared to placebo. Acceptable cost-effectiveness was demonstrated at a dose of 5 mg/kg infliximab for three doses (weeks 0, 2 and 6) and when continuation of treatment beyond three doses was determined by remission (CDAI ≤ 150) at approximately 12 weeks from the commencement of treatment.
Influenza Vaccine, injection 0.25 mL, Vaxigrip Junior®, Sanofi Pasteur Pty Ltd Minor submission	Vaccine	Listing of a smaller syringe size of 0.25 mL as a restricted benefit for infants and children 6-35 months	The PBAC recommended listing as a restricted benefit on the basis of the dosage requirement for eligible children up to 35 months of age.

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Insulin Glargine, pre-filled disposable device, 100 units per mL, 3 mL, 5, Lantus SoloStar®, Sanofi Aventis Australia Pty Ltd Minor submission	Diabetes	New presentation of existing product.	The PBAC recommended out of session the listing of a new presentation of the cartridge formulation which involved the irreversible integration of the existing 3 mL cartridge into a fully disposable injection system.
Insulin glulisine (human analogue) 100 unit per mL, 3 mL, 5,Apidra®, Sanofi-Aventis Australia Pty Ltd Major submission	Diabetes	Unrestricted benefit.	The PBAC recommended listing as an unrestricted benefit on a cost-minimisation basis against insulin lispro, with the equi-effective doses being 1 unit of insulin glulisine and 1 unit of insulin lispro.
Lanreotide Acetate, injection 30 mg, Somatuline LA®; 60 mg, 90 mg and 120 mg (base) in single dose pre-filled syringe, Somatuline Autogel®, Ipsen Pty Ltd Minor submission	Peptide analogue used in the treatment of acromegaly and carcinoid syndrome	Replace the words “Patients with a histologically confirmed diagnosis of a functional carcinoid tumour” with “Functional carcinoid tumour causing intractable symptoms”. Replace the words “where surgery and radiotherapy are contraindicated” with “if the patient is unfit or unwilling to undergo surgery and where radiotherapy is contraindicated”. (for Somatuline Autogel only)	The PBAC had no objection the secretariat’s suggested change to the restriction wording for Somatuline Autogel for the treatment of carcinoid tumour on the basis that, according to expert opinion, it is often not possible to confirm diagnosis histologically due to the location of the tumour. The PBAC also recommended a change to the listing of lanreotide for the treatment of acromegaly to bring it into line with the recommended change for octreotide in this condition.
Leflunomide tablets, 10 mg and 20 mg, Arabloc®, Arava®, Sanofi-Aventis Australia Pty Ltd Major submission	Psoriatic arthritis and rheumatoid arthritis	Authority required for initiation by consultant physicians for the treatment of active psoriatic arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate or ineffective; ongoing leflunomide therapy for active psoriatic arthritis in patients for whom other disease	The PBAC recommended listing in severe active psoriatic arthritis on a cost-effectiveness basis compared to placebo for patients who have not responded to DMARD treatment and on the basis of clinical need.

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		modifying anti-rheumatic drugs (including methotrexate) are inappropriate and/or ineffective.	
Letrozole tablet, 2.5 mg, Femara® Novartis Pharmaceuticals Australia Pty Limited Major submission	Anti cancer drug	To remove note restricting use in early breast cancer to a duration of 5 years.	The PBAC recommended the listing of letrozole for extended adjuvant treatment of early breast cancer after treatment with tamoxifen on the basis of high but acceptable cost-effectiveness compared to placebo (for no extension of hormonal treatment). The total duration of treatment in early breast cancer with letrozole should not exceed 5 years, and treatment should commence within 6 months of ceasing tamoxifen.
Levonorgestrel intrauterine drug delivery system 52 mg (20 mcg/24 hrs), Mirena® Schering Pty Limited Major submission	Hormone therapy	Restricted benefit listing for treatment of idiopathic menorrhagia when oral medical therapies for menorrhagia have been ineffective or are contraindicated.	The PBAC recommended listing as a restricted benefit as requested on a cost-minimisation basis compared to hysterectomy and on the basis that over a five year period, overall savings would result for cases where hysterectomy had not been undertaken during that time period.
Macrogol 3350, sachets containing powder for solution 13.125 g with electrolytes, 30, Movicol® Norgine Pty Limited Major submission	Laxative	Restricted benefit for paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies.	The PBAC recommended listing as requested. The PBAC recognised that access to macrogol 3350 by this patient group would meet an important clinical need, and that superiority over other oral therapies had been demonstrated in other conditions impairing bowel function sufficient to justify the price advantage for macrogol 3350 over these other oral therapies.

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Meningococcal Group C, conjugate vaccine, Meningitec®, Wyeth Australia Pty Ltd Minor submission	Meningitis	Inclusion on the National Immunisation Program of a new presentation.	The PBAC recommended out of session the listing of a new pre-filled syringe on the National Immunisation Program (NIP). The single dose vial presentation is no longer being manufactured and will be replaced globally by a pre-filled syringe.
Monovalent Human Rotavirus oral vaccine, oral, 1mL (reconstituted), Rotarix®, GlaxoSmithKline Pty Ltd Minor submission	Rotavirus gastroenteritis	Removal of reference to strain in the National Immunisation Schedule.	The PBAC agreed to change the recommended restriction for Rotarix® by removing the referral to strain G1P[8].
Montelukast sodium chewable tablets, 4 mg (base) 5 mg (base), Singulair®, Merck Sharp and Dohme (Australia) Pty Limited Minor submission	Asthma drug	A minor amendment to the listing to change “episodic” to “intermittent” for consistency with National Asthma Council Australia 2006 Asthma Management Handbook.	The PBAC had no objection to the request by the sponsor to change the wording of the restriction for the current PBS listing to maintain consistency with the recently updated Asthma Management Handbook (2006). The term ‘episodic’ is to be replaced with ‘intermittent’.

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Octreotide acetate injection 50 mcg, 100 mcg, 500 mcg, Sandostatin®; 10 mg, 20 mg, 30 mg, Sandostatin LAR®; Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Peptide analogue used in the treatment of acromegaly and carcinoid syndrome	Change wording in listing as a section 100 Highly Specialised Drug from "where surgery and radiotherapy are contraindicated" to "where patients are unfit or unwilling to undergo surgery or radiotherapy" Replace the words "Patients with a histologically confirmed diagnosis of a functional carcinoid tumour" with "Functional carcinoid tumour causing intractable symptoms".	The PBAC recommended a change to the listing of octreotide for the treatment of acromegaly to bring it into line with the TGA registered indication for patients unfit or unwilling to undergo surgery. The PBAC had no objection the secretariat's suggested change to the restriction wording for octreotide for the treatment of carcinoid tumour and VIPoma on the basis that, according to expert opinion, it is often not possible to confirm diagnosis histologically due to the location of the tumour.
Olanzapine, tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, Zyprexa®, Eli Lilly Australia Pty Ltd Minor submission	Antipsychotic drug	Change of pack size to coincide with the wafer presentations.	The PBAC agreed to the sponsor's request to harmonise the packaging of Zyprexa and Zyprexa Zydis by changing the Zyprexa pack size from 30 to 28.
Olmesartan medoxomil with hydrochlorothiazide tablets, 20 mg-12.5 mg, 40 mg-12.5 mg, 40 mg-25 mg, Olmetec Plus®, Schering-Plough Pty Limited Major submission	High blood pressure	Restricted benefit listing for hypertension in patients who are not adequately controlled with either hydrochlorothiazide or olmesartan monotherapy.	The PBAC recommended listing on a cost-minimisation basis compared with the corresponding strengths of the hydrochlorothiazide and olmesartan medoxomil components given concomitantly.
Pentavalent Human-Bovine Rotavirus oral vaccine, oral, 2mL, RotaTeq®, CSL Limited Minor submission	Rotavirus gastroenteritis	Removal of reference to strain in the National Immunisation Schedule.	The PBAC agreed to change the recommended restriction for RotaTeq® by removing referral to strains.

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Perindopril arginine with Indapamide hemihydrate, tablet, 5mg-1.25mg, Coversyl Plus®, Servier Laboratories Pty Ltd Minor submission	High blood pressure	Restricted benefit listing of a new perindopril with indapamide combination product containing perindopril arginine.	The PBAC recommended out of session the listing of a new salt of perindopril in combination with indapamide with the same restriction, maximum quantity, repeats and price as the current perindopril erbumine combination product. The PBAC noted both the old and new products will be "a" flagged as interchangeable.
Phenoxybenzamine capsule,10 mg, Dibenyline®, Goldshield Healthcare (Australia) Pty Ltd Minor submission	Phaeo-chromocytoma	Temporary restricted benefit for phaechromocytoma and neurogenic urinary retention.	The PBAC noted advice from the sponsor of the difficulty in sourcing phenoxybenzamine and considered that it was clinically necessary to retain this drug on the PBS as it is the only drug subsidised for the treatment of phaeochromocytoma. The PBAC therefore recommended listing of a new pack size on the PBS.
Ramipril tablet, 10 mg Tritace®, Sanofi-Aventis Pty Ltd Minor submission	Cardiovascular disease	Listing as an unrestricted benefit.	The PBAC recommended listing as requested on a cost minimisation basis compared with ramipril capsule 10 mg and on the basis of demonstrated bioequivalence to the currently listed 10 mg capsule. The PBAC considered that these products should be "a" flagged to allow substitution to occur according to current dispensing practice.

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Ramipril with felodipine tablets 2.5mg-2.5mg and 5 mg-5 mg, Triasyn®, Sanofi-Aventis Australia Pty Ltd Major submission	High blood pressure	Restricted Benefit listing for the treatment of hypertension in patients who are not adequately controlled with either ramipril or felodipine monotherapy.	The PBAC recommended listing on a cost-minimisation basis compared with the corresponding strengths of the ramipril and felodipine components given concomitantly.
Ranibizumab 1.8 mg/0.3 mL and 3.0 mg/0.3 mL solution for intravitreal injection (Lucentis®) Novartis Pharmaceuticals Australia Pty Limited Major submission	Age Related Macular Degeneration	Authority Required for initial treatment of active neovascular (wet) age-related macular degeneration and continuing treatment of neovascular (wet) age-related macular degeneration (AMD), in patients previously treated with ranibizumab with evidence of continued disease activity as defined by a loss of 5 letters of visual acuity (ETDRS or one Snellen line equivalent) and or/or evidence of leakage of fluid, haemorrhage or lesion growth.	The PBAC recommended listing for the treatment of subfoveal choroidal neovascularisation (CNV) due to age related macular degeneration on a cost-effectiveness basis against verteporfin with PDT in predominantly classic disease, and against placebo in minimally classic or occult disease. Listing was recommended on the basis of acceptable cost-effectiveness.
Risedronate sodium 35 mg tablets x 4, 5 mg x 28 and Risedronate sodium 30 mg with calcium carbonate 1.25 g. Actonel® and Actonel Combi® Sanofi-Aventis Australia Pty Ltd Major submission	Osteoporosis	Authority required listing for the prevention of first fracture in patients aged ≥ 70 years with a bone mineral density (BMD) T-score ≤ -3.0 as determined by appropriate diagnostic tests.	The PBAC recommended extending the current listing to allow subsidised use in the primary treatment of osteoporosis on a cost-minimisation basis compared with alendronate. The equi-effective doses are risedronate 35 mg weekly and alendronate 70 mg weekly.
Rituximab solution for I.V. infusion 500 mg in 50 mL vials, Mabthera® Roche Products Pty Limited Major submission	Monoclonal antibody for use in lymphoma and rheumatoid arthritis	Section 100 Highly Specialised Drug listing for severe active rheumatoid arthritis (RA) in patients who have received prior treatment with a tumour necrosis factor antagonist (antiTNF).	The PBAC recommended listing, in combination with methotrexate, on a cost-minimisation basis as compared to etanercept and adalimumab for patients who have failed to demonstrate a response to at least one TNF inhibitor. The equi-effective doses are rituximab 1000 mg on Days 1 and 15 being equivalent to etanercept 25 mg twice weekly and adalimumab 40

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			mg once every second week.
Somatropin recombinant human growth hormone, solution for injection, 10 mg (30iu) in 2mL cartridge, Nutropin AQ®, Ipsen Pty Ltd Minor submission	Human Growth Hormone	Listing of a new brand	The PBAC recommended out of session listing a new brand of somatropin under the Section 100 Human Growth Hormone Program.
Thyrotropin alfa-rch, kit containing 2 vials of powder for I.M. injection 1.1 mg, Thyrogen®, Genzyme Australasia Pty Ltd Major submission	Thyroid disease	Authority required listing for use in adult post-thyroidectomy patients, without known metastatic disease who are/will be maintained on hormone suppression therapy, in the ablation of thyroid remnant tissue with radioactive iodine. PBS-subsidised use is limited to once per lifetime.	The PBAC recommended listing to prepare for radio-iodine ablation on the basis of acceptable cost-effectiveness compared to withdrawing thyroid hormone therapy and thus inducing a longer period of hypothyroidism of 4-6 weeks prior to ablation.
Tiagabine hydrochloride monohydrate, tablet 2.5 mg, Gabitril®, Mayne Pharma Ltd Minor submission	Anti-epileptic drug	Addition of a lower strength tablet.	The PBAC recommended the listing of a lower strength of tiagabine hydrochloride with the same restriction as the currently listed products.
Tipranavir,soft capsules, 250 mg, Aptivus® Boehringer Ingelheim Pty Ltd Major submission	HIV-AIDS	Section 100 Highly Specialised Drug. Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of HIV infection in antiretroviral experienced adults with a) evidence of HIV replication and/or b) CD4 cell counts of less than 500 per cubic millimetre. Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with at least 1 non-nucleoside reverse transcriptase inhibitor, 1 nucleoside reverse transcriptase inhibitor, and 2 protease inhibitors. `	The PBAC considered that tipranavir offers a clinical advantage in the high risk salvage patient group for whom subsidy is sought and recommended listing on a cost-effectiveness basis over the comparator.
Topiramate tablets, 25 mg and 50 mg,	Anti-epileptic and	Authority Required listing for migraine prophylaxis in	The PBAC recommended listing on the

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Topamax® Janssen-Cilag Pty Ltd Major submission	migraine prophylaxis	adults who are experiencing an average of 3 or more migraines per month for a period of at least six months and meet certain criteria.	basis of acceptable cost-effectiveness compared to placebo for migraine prophylaxis in patients unable to take a beta-blocker and/or pizotifen.
Travoprost with timolol maleate, eye drops, 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (Duotrav®, Extravan®) Alcon Laboratories (Australia) Pty Ltd Major submission	Glaucoma	To widen the current restriction to read: Reduction of elevated intra-ocular pressure in patients with open angle glaucoma, who are not adequately controlled with beta-blockers or prostaglandin analogues; Reduction of elevated intra-ocular pressure in patients with ocular hypertension, who are not adequately controlled with beta-blockers or prostaglandin analogues.	Based on the data presented in the submission, the PBAC recommended expanding the current listing, on a cost minimisation basis as previously, to include patients not adequately controlled on timolol, travoprost or latanoprost.
Vancomycin Hydrochloride, powder for injection 1 g, Vancomycin Sandoz®, Sandoz Pty Ltd Minor submission	Antibiotic	Listing of a higher strength of a currently listed drug.	The PBAC recommended the listing of a higher strength of vancomycin hydrochloride.