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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ADALIMUMAB, injection, 40 mg in 0.8 mL pre-filled syringe,40 mg in 0.8 mL pre-filled pen, Humira® Abbott Australasia Pty Ltd Major submission	Chronic plaque psoriasis	An extension to the current Authority Required listing to include treatment of severe chronic plaque psoriasis.	The PBAC recommended listing adalimumab on the PBS for the treatment of severe chronic plaque psoriasis on a cost-minimisation basis with efalizumab or etanercept at TGA-recommended steady state continuous doses (ie adalimumab 40 mg fortnightly, efalizumab 1 mg weekly and etanercept 50 mg weekly are equi-effective).
AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN, sachets, 20 g, 30, GA Gel® Vitaflo Australia Pty Ltd. Minor submission	Medicinal food	Restricted Benefit listing for use in Glutaric Aciduria Type 1, without limiting use to patients less than 7 years of age.	The PBAC recommended a Restricted Benefit listing for proven glutaric aciduria type 1 for use in patients aged from 6 months to 10 years on the basis of acceptable cost-effectiveness.
APOMORPHINE HYDROCHLORIDE, injection 50 mg in 5 mL, Apomine® Hospira Pty Ltd Minor submission	Parkinson disease	Section 100 (Highly Specialised Drug) listing for new strength of apomorphine for the same restriction as the currently listed strength (20 mg in 2 mL).	The PBAC recommended the listing of apomorphine injection 50 mg in 5 ml at the same price per mg as the 20 mg per 2ml injection.
ARGININE with CARBOHYDRATE, sachets 4 g containing 500 mg arginine, 30, Arginine Amino Acid Supplement® Vitaflo Australia Pty Ltd. Minor submission	Medicinal food	Restricted Benefit listing for the dietary management of urea cycle disorders excluding arginase deficiency and other inborn errors of protein metabolism.	The PBAC recommended a Restricted Benefit listing for urea cycle disorders at the price requested on the basis of acceptable cost-effectiveness.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ARSENIC TRIOXIDE, solution for I.V. infusion, 10 mg in 10 mL, Phenasen® Phebra Pty Ltd Major submission	Anti- cancer drug	Authority Required listing for relapsed or refractory acute promyelocytic leukaemia (APL) in patients who meet certain criteria.	The PBAC recommended the Authority Required listing of arsenic trioxide for the treatment of relapsed APL in patients who are arsenic naïve at induction on the basis of high clinical need and acceptable but uncertain cost-effectiveness compared to all-trans retinoic acid (ATRA) and intensive chemotherapy .
ATAZANAVIR, capsule 100 mg (as sulfate), Reyataz® Bristol-Myers Squibb Australia Pty Ltd Minor submission.	HIV drug	A Section 100 (Highly Specialised Drug) listing of a new strength of 100 mg.	The PBAC recommended listing as requested.
ATOVAQUONE with PROGUANIL HYDROCHLORIDE, tablet, 250 mg-100 mg (base), Malarone® GlaxoSmithKline Australia Pty Ltd Minor submission	Anti-malarial	Authority Required (STREAMLINED) listing for the treatment of suspected or confirmed Plasmodium falciparum malaria in adults and children aged 3 years and older.	The PBAC recommended an Authority Required listing of atovaquone with proguanil hydrochloride for treatment of suspected or confirmed Plasmodium falciparum malaria where quinine containing regimens are inappropriate. The PBAC did not recommend a Streamlined authority due to concerns regarding use for prophylaxis.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
BIMATOPROST with TIMOLOL MALEATE, eye drops, 0.3 mg -5 mg (base) per mL (0.03%-0.5%), 3 mL, Ganfort® Allergan Australia Pty Ltd Major submission	Anti-glaucoma	Restricted benefit listing for open-angle glaucoma or ocular hypertension not adequately controlled with timolol maleate 0.5%, latanoprost or bimatoprost eye drops.	The PBAC recommended the restricted benefit listing of bimatoprost with timolol maleate as requested, in accordance with the combination guidelines on a cost-minimisation basis compared with its constituent components, bimatoprost 0.03% and timolol maleate 0.5% eye drops given concomitantly. The PBAC further recommended changing the wording of the restrictions for all PBS-listed timolol with prostaglandin/prostamide analogue combinations so that patients who are on a timolol/prostaglandin or prostamide analogue combination do not have to return to monotherapy with timolol prior to a change in the combination eye drop (See latanoprost with timolol, and travoprost with timolol below) Listing was also recommended in the Optometric section.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX, lyophilised powder for I.M. injection 100 units Botox® Allergan Australia Pty Ltd Minor submission	Spasticity disorder	Medicare Australia requested amendment to the Section 100 (Botulinum Toxin Program) restriction recommended at the November 2008 meeting allowing use in the treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient.	The PBAC agreed the previously recommended restriction wording for use in this condition should be replaced with the following: Treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient aged from 2 to 17 years inclusive; Continuing PBS-subsidised treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient. The PBAC also recommended a change to the restriction for initiation of treatment for post stroke spasticity of the upper limb in adult patients by replacing the words '3 to 6 months post-stroke' with '3 months post-stroke'. A consequential amendment to the Clostridium botulinum submission consideration (see below).
CEFUROXIME AXETIL, granules for oral suspension, 125 mg per 5 mL, 70 mL, Zinnat® GlaxoSmithKline Australia Pty Ltd Minor submission	Antibiotic	Unrestricted benefit listing.	The PBAC recommended listing cefuroxime granules for oral suspension on the PBS on the basis of clinical need for the paediatric population and acceptable cost-effectiveness.
CEPHAZOLIN, powder for injection, 500 mg and 1 g, Cefazolin Sandoz®, Sandoz Pty Ltd; Kefzol®, Aspen Pharmacare Australia Pty Ltd; Hospira Pty Ltd; Minor submission	Antibiotic	A regional health service requested the removal of the requirement that positive bacteriological evidence confirm the antibiotic is appropriate prior to prescribing under the PBS.	The PBAC recommended extension of the Restricted Benefit listing of cephazolin to included 'cellulitis', to allow the treatment of the infection without requiring positive bacteriological evidence to confirm the causative agent.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
CLOSTRIDIUM BOTULINUM type A toxin-haemagglutinin complex, lyophilised powder for I.M. injection, 500 units/vial, Dysport® Ipsen Pty Ltd Minor submission	Spasticity disorder	To request a change to the current Section 100 (Botulinum Toxin Program) restriction for initiation of botulinum for post stroke spasticity of the upper limb in adult patients to replace to words '3 to 6 months post-stroke' with '3 months post-stroke'.	The PBAC recommended the change for clarity. The wording of '3 to 6 months post-stroke' may have implied that treatment was only permitted during this 3 to 6 month period.
DASATINIB, tablet, 100 mg, Sprycel® Bristol-Myers Squibb Australia Pty Ltd Minor submission	Anti-cancer drug	An Authority required listing of a new 100 mg strength.	The PBAC recommended listing as requested.
ENOXAPARIN SODIUM, injection, 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe, Injection, 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe, Solution for injection, 40 mg (4,000 i.u. anti-Xa) in 0.4 mL, Injection, 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe, Injection,80 mg (8,000 i.u. anti-Xa) in 0.8 mL pre-filled syringe, Injection, 100 mg (10,000 i.u. anti-Xa) in 1 mL pre-filled syringe, Clexane® Sanofi-Aventis Australia Pty Ltd Minor submission	Antithrombotic agent	A change to the maximum quantity and repeats for all strengths of enoxaparin from 10 with 1 repeat to 20 with nil repeats.	The PBAC recommended the maximum quantity and repeats for the 20 mg and 40 mg strengths be amended as requested. The PBAC considered the listings for the 60 mg, 80 mg and 100 mg injections should remain unchanged on the basis of uncertain clinical need, and the potential for significant wastage as these strengths are not prescribed for venous thromboembolism (VTE) prophylaxis, but are used in the treatment of VTE.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
EPOPROSTENOL SODIUM, powder for I.V. infusion 500 micrograms and 1.5 mg (base) with diluent, Flolan® GlaxoSmithKline Australia Pty Minor submission	Pulmonary hypertension	To request a change to the current restriction to allow only second line use in patients with primary pulmonary hypertension (PPH) WHO function class III while retaining first line use in patients with PPH WHO function Class IV.	The PBAC recommended the restrictions for epoprostenol in PPH Class III patients be amended as requested, to limit availability of epoprostenol to PPH Class III patients who have failed to respond to a prior PBS-subsidised therapy.
ETANERCEPT, injection set containing 4 vials powder for injection, 25 mg and 4 pre-filled syringes solvent 1 mL, injection set containing 4 vials powder for injection, 50 mg and 4 pre-filled syringes solvent 1 mL, injections, 50 mg in 1 mL single use pre-filled syringes, Enbrel® Wyeth Australia Pty Ltd Major submission	Chronic plaque psoriasis	To request amending the treatment regimen for etanercept in chronic plaque psoriasis to allow etanercept 50mg/week for 12 weeks of initial treatment to be followed by continuous treatment of 50mg/week, or, a flexible intermittent dosing regimen, for those patients who meet the continuation criteria.	The PBAC recommended amending the listing of etanercept to allow for continuous treatment in the management of chronic plaque psoriasis on the basis of cost-minimisation against efalizumab continuous treatment at the requested price. The equi-effective doses are etanercept 50 mg/week and efalizumab 1 mg/kg/week during both initial and maintenance treatment periods. The PBAC considered it was less clear that intermittent etanercept is as effective as efalizumab. However, the PBAC noted patients may currently have a break in therapy and later re-commence under the current listing criteria provided they are responding to treatment .
ETANERCEPT, single use pre-filled pen (auto-injector), 50 mg in 1 mL, 4, Enbrel® Wyeth Australia Pty Limited Minor submission	Immunomodulating agent	To request listing of an auto-injector (also known as pre-filled pen) presentation for etanercept 50 mg for all currently listed PBS indications, where 50 mg doses are required.	The PBAC recommended listing etanercept 50 mg in 1 ml single use pre-filled pen (auto-injector) for all the currently listed PBS indications.
ETRAVIRINE, tablet, 100 mg, Intelence® Janssen-Cilag Australia Pty Ltd Major submission	Antiretroviral agent	Section 100 (Highly Specialised Drug) listing for treatment in combination with other antiretroviral agents of HIV infection in patients who meet certain criteria and who have failed previous treatment with or have resistance to three different antiretroviral regimens.	The PBAC recommended the listing as requested on a cost-minimisation basis compared with raltegravir, with the equi-effective daily doses being etravirine 400 mg and raltegravir 800 mg.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
FILGRASTIM, injection, 300 micrograms in 1 mL, 300 micrograms in 0.5 mL single use pre-filled syringe, 480 micrograms in 1.6 mL, 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	Immunostimulant	To request removal of 'first-line' from the Private hospital authority required restriction wording for patients receiving chemotherapy for B-cell chronic lymphocytic leukaemia.	The PBAC recommended the removal of the wording "first-line" from the restrictions for filgrastim/pegfilgrastim for chronic lymphocytic leukaemia which was recommended at the November 2008 meeting as it was not the intent that filgrastim/pegfilgrastim use be limited to first-line therapy with fludarabine and cyclophosphamide.
FRAMYCETIN SULFATE, eye and ear drops 5 mg per mL (0.5%), 8 mL, Soframycin® Sanofi-Aventis Australia Pty Ltd Minor submission	Antibiotic eye and ear drops	The Expert Advisory Panel on Optometric Prescribing requested an unrestricted listing in the Optometrical Schedule.	The PBAC recommended that framycetin eye drops 5 mg per mL be included in the Optometrical section as an unrestricted benefit. The unrestricted listing is consistent with the current General listing.
GEMCITABINE HYDROCHLORIDE, Powder for I.V. infusion, 2 g (base), DBL® Gemcitabine Hospira Pty Ltd Minor submission	Anti-cancer drug	Listing of a new strength of gemcitabine hydrochloride.	The PBAC recommended listing as requested.
GEMCITABINE HYDROCHLORIDE, solution concentrate for I.V. infusion, 200 mg (base) in 20 mL and 1g (base) in 100 mL, Gemcitabine Ebewe® InterPharma Pty Ltd. Minor submission	Anti-cancer drug	Listing of new presentations of gemcitabine hydrochloride.	The PBAC recommended listing as requested.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
GLUCOSE, I.V. infusion 139 mmol (anhydrous) per 500 mL (5%), 500 mL Pharmatel Fresenius Kabi Pty Ltd Minor submission	Solution for parenteral nutrition	Unrestricted General and Dental listing.	The PBAC recommended the listing of a new size of glucose 5% intravenous infusion as requested, with the price to be negotiated by the Pharmaceutical Benefits Pricing Authority (PBPA).
GLUCOSE, I.V. infusion 278 mmol (anhydrous) per 500 mL (10%), 500 mL Pharmatel Fresenius Kabi Pty Ltd Minor submission	Solution for parenteral nutrition	Unrestricted General listing of an additional strength of glucose (10%) for intravenous infusion.	The PBAC recommended listing as requested, with the price to be negotiated by the PBPA.
GLUCOSE, I.V. infusion, 139 mmol (anhydrous) per 500 mL (5%), 500mL; 69 mmol (anhydrous) per 250mL (5%), 250 mL; 28 mmol (anhydrous) per 100 mL (5%), 100 mL; B.Braun Glucose 5%® B.Braun Australia Pty Ltd Minor submission	Solution for parenteral nutrition	Unrestricted General listing for three new sizes of glucose 5% intravenous infusion.	The PBAC recommended the unrestricted listing the products, and inclusion of the 500 mL in the Dental section, with the price to be negotiated by the PBPA.
HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and low in PROTEIN and CARBOHYDRATE, powder 300 g, Ketocal® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted Benefit listing for patients with intractable seizures requiring treatment with a ketogenic diet, glucose transport protein defects, or pyruvate dehydrogenase deficiency.	The PBAC recommended listing as requested on the basis of acceptable cost-effectiveness.
HYPROMELLOSE, oral gel, 20 mg per g, 100 g, Aquae Gel® Hamilton Pharmaceutical Pty Ltd. Minor submission	Dry mouth	Addition of hypromellose oral gel to the Palliative Care section.	The PBAC recommended listing as requested

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ILOPROST TROMETAMOL, solution for inhalation, 20 micrograms (base) in 2 mL, Ventavis®, Bayer Schering Pharma Minor submission	Pulmonary hypertension	To request a change to the current Section 100 (Highly Specialised Drugs) listing to allow only second line use in patients with primary pulmonary hypertension (PPH) WHO Class III or pulmonary arterial hypertension (PAH) WHO Class III secondary to connective tissue disease while maintaining first-line use for patients with drug induced PPH, PPH WHO Class IV and PAH secondary to connective tissue disease WHO Class IV.	The PBAC recommended as requested that the restrictions for iloprost be amended to limit use in patients with PPH WHO Class III or PAH Class III secondary to connective tissue disease to those who had failed to respond to a prior PBS-subsidised therapy.
IMATINIB MESYLATE, tablet, 100 mg and 400 mg (base), Glivec®, Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Acute lymphoblastic leukaemia	To request removal of the lifetime maximum of 24 months treatment from the current imatinib continuing treatment restriction for patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL).	The PBAC recommended changing the continuing treatment listing for imatinib for acute lymphoblastic leukaemia to allow up to a maximum of 24 months continuing treatment to be PBS-subsidised.
INSULIN LISPRO, injection (human analogue), 100 units per mL, 3 mL, 5, Humalog KwikPen®, INSULIN LISPRO—INSULIN LISPRO PROTAMINE SUSPENSION, injections (human analogue), 100 units (50 units-50 units) per mL, 3 mL, 5, Humalog Mix50 KwikPen® INSULIN LISPRO—INSULIN LISPRO PROTAMINE SUSPENSION, injections (human analogue), 100 units (25 units-75 units) per mL, 3 mL, 5, Humalog Mix25 KwikPen® Eli Lilly Australia Pty Limited Minor submission	Anti-diabetic agent	Unrestricted listing of pre-filled pens at the same price as the currently listed products.	The PBAC recommended listing as requested.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
IRINOTECAN HYDROCHLORIDE TRIHYDRATE, I.V. injection, 300 mg in 15 mL, Camptosar® Pfizer Australia Pty Ltd Minor submission	Anti-cancer drug	Listing of a new strength of irinotecan hydrochloride trihydrate.	The PBAC recommended listing as requested.
ISOLEUCINE with CARBOHYDRATE, sachets, 4 g, containing 1g isoleucine, 30, Isoleucine 1000 Amino Acid Supplement® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted Benefit listing of a new strength of isoleucine with carbohydrate for Maple Syrup Urine Disease (MSUD).	The PBAC recommended listing as requested, with an appropriate price premium to be determined by the PBPA.
LANSOPRAZOLE, tablet, (Oro-dispersible), 15 mg and 30 mg, 28, Zoton FasTabs® Wyeth Australia Pty Limited Minor submission	Proton pump inhibitor	Listing of a new formulation of lansoprazole.	The PBAC recommended listing as requested at the same price per mg as the currently listed products.
LATANOPROST with TIMOLOL MALEATE, eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL, Xalacom® Pfizer Pty Limited Minor submission	Anti-glaucoma	Consequential amendment (see bimatoprost with timolol above)	The PBAC recommended changing the wording of the restrictions for all PBS-listed timolol with prostaglandin/prostamide analogue combinations so that patients who are on a timolol/prostaglandin or prostamide analogue combination do not have to return to monotherapy with timolol prior to a change in the combination eye drop.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
MODAFINIL, tablet 100 mg, Modavigil® CSL Limited Minor submission	Narcolepsy	The Australasian Sleep Association and the Australian and New Zealand Association of Neurologists sought amendments to the diagnostic criteria for narcolepsy and clarification of the intolerance and contraindications to dexamphetamine contained in the modafinil restriction.	The PBAC considered the requested changes reasonable and appropriate. The recommended restriction wording for initial treatment follows: Authority Required Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where: (i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or (ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops. The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk: (a) a psychiatric disorder; (b) a cardiovascular disorder; (c) a history of substance abuse; (d) glaucoma; (e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information. Patients must meet the following definition of narcolepsy: Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and: (i) a definite history of cataplexy; or a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. or an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and (ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
MUPIROCIN, nasal ointment, 20 mg (as calcium) per gram (2%), 3g, Bactroban Nasal® GlaxoSmithKline Australia Pty Ltd Minor submission	Antibiotic ointment	To seek an Authority Required (STREAMLINED) listing for the treatment of nasal colonisation with Staphylococcus aureus in Aboriginal and Torres Strait Islander persons.	The PBAC recommended the listing of mupirocin as requested on the basis of acceptable cost-effectiveness.
ONDANSETRON, syrup, 4 mg per 5 mL, 50 mL, Zofran® syrup 50 mL GlaxoSmithKline Australia Pty Ltd Minor submission	Antinauseant	To request a similar Restricted Benefit listing for the syrup for the management of nausea and vomiting associated with cytotoxic chemotherapy as for as the currently PBS listed formulations.	The PBAC recommended listing as requested on the basis of acceptable cost-effectiveness.
OXYBUTYNIN, transdermal patches, 36 mg (releasing approximately 3.9 mg per 24 hours), Oxytrol® Hospira Australia Pty Ltd Minor submission	Urinary incontinence	Re-submission for a Restricted Benefit listing for the treatment of a patient with urge urinary incontinence or urgency due to detrusor irritability in a patient who cannot tolerate or swallow oral oxybutynin.	The PBAC recommended a Restricted Benefit listing for the treatment of detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin on the basis of acceptable cost effectiveness over placebo at the reduced price offered.
PANTOPRAZOLE SODIUM SESQUIHYDRATE, granules, (equivalent to 40 mg pantoprazole), Somac® Nycomed Pty Ltd Minor submission	Proton pump inhibitor	Listing of a new formulation of pantoprazole.	The PBAC recommended listing as requested at the same price as the currently listed 40 mg product.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
PEMETREXED DISODIUM, powder for I.V. infusion, 100 mg and 500 mg (base), Alimta® Eli Lilly Australia Pty Ltd Major submission	Anticancer drug	An extension to the current Authority Required PBS listing to include first line treatment of locally advanced or metastatic non-small-cell-lung cancer (NSCLC) with non-squamaous cell histology (adenocarcinoma and/or large cell carcinoma) in combination with cisplatin.	The PBAC recommended listing pemetrexed for the treatment of locally advanced or metastatic non small cell lung cancer in combination with cisplatin (first-line therapy) on a cost-minimisation basis compared with gemcitabine based on the clinical data presented. The PBAC did not recommend differentiating treatment on the basis of histology at this time, as it considered the evidence supporting this was insufficient.
POLY-L-LACTIC ACID, powder for intradermal injection, 150 mg, Sculptra® Sanofi-Aventis Australia Pty Ltd Minor submission	Injectable polymer to restore lost facial volume	Re-submission for an Authority Required listing for the treatment of a patient with facial lipoatrophy caused by antiretroviral therapy in HIV positive patients.	The PBAC recommended the Authority Required listing of poly-L-lactic acid for the treatment of severe facial lipoatrophy caused by therapy for HIV infection on the basis of clinical need and high and uncertain but acceptable cost effectiveness compared to placebo.
PRAZIQUANTEL, tablet, 600 mg, Biltricide® Bayer Australia Ltd Minor submission	Anthelmintic	To request a section 85 listing for the treatment of schistosoma infections due to various types of blood fluke.	The PBAC recommended Authority Required (STREAMLINED) listing of praziquantel tablets for the treatment of schistosomiasis on the basis of acceptable cost-effectiveness.
QUETIAPINE FUMARATE, tablets, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel® AstraZeneca Pty Ltd Major submission	Bipolar disorder	To extend the current Authority Required listing to include maintenance treatment of patients with bipolar 1 disorder in combination with a mood stabiliser for the prevention of recurrence of manic, depressive or mixed episodes.	The PBAC recommended the listing of quetiapine fumarate for the maintenance treatment of bipolar I disorder, in combination with lithium or sodium valproate on the basis of cost-minimisation with olanzapine and where the equi-effective doses are quetiapine 506.8 mg per day and olanzapine 8.6 mg per day ie a dose relativity of 58.9:1.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
RANIBIZUMAB, solution for intravitreal injection, 2.3 mg in 0.23 mL, Lucentis® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Antineovascularisation agent	Listing a new (lower) fill volume of 0.23 mL at the same price as the current product.	The PBAC recommended listing as requested
RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL, pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, Actonel Combi D® RISEDRONATE SODIUM, tablet, 75 mg, Actonel® 75 mg Sanofi-Aventis Australia Pty Ltd Minor submission.	Anti-resorptive agent for osteoporosis	An Authority Required (STREAMLINED) listing for risedronate 75 mg and the combination product Actonel Combi D for the treatment of corticosteroid-induced osteoporosis under the same listing conditions and at the same price as recommended at the July 2008 PBAC meeting for risedronate 5 mg and 35 mg tablets and risedronate sodium 35 mg with calcium carbonate 1.25 g (Actonel Combi®).	The PBAC recommended listing as requested.
RISEDRONATE SODIUM, tablet, 150 mg, Actonel Once-a-Month® Sanofi-Aventis Australia Pty Ltd Minor submission	Anti-resorptive agent	Authority Required (STREAMLINED) listing for treatment of osteoporosis in a patient who meets certain criteria.	The PBAC recommended listing risedronate 150 mg tablets for the treatment of osteoporosis and corticosteroid-induced osteoporosis under the same listing conditions as those for currently listed risedronate products to be priced on a comparable annual cost with the lower strength tablets.
RIVAROXABAN, tablet, 10 mg, 15 tablet pack, 30 tablet pack, Xarelto® Bayer Australia Limited Major submission	Antithrombotic agent	Section 85 Authority Required (STREAMLINED) listing and a section 100 (Highly Specialised Drug) listing for the prevention of venous thromboembolism (VTE) in a patient undergoing hip or knee replacement.	The PBAC recommended listing rivaroxaban for the prevention of venous thromboembolism in a patient undergoing total replacement of the hip or knee on the basis of uncertain but overall acceptable cost-effectiveness compared to enoxaparin. Listing under section 100 was not recommended.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
SILVER SULPHADIAZINE, cream, 10 mg per g (1%), 50 g, Flamazine® Smith & Nephew Healthcare Minor submission	Antibiotic cream	Restricted benefit listing for the same conditions as silver sulphadiazine with chlorhexidine cream.	The PBAC recommended the listing of silver sulphadiazine cream on a gram for gram cost-minimisation basis compared with silver sulphadiazine with chlorhexidine cream (Silvazine®). The sponsor advised that there would be a short break of approximately 4-6 months in the supply of the Silvazine due to relocation of the global manufacturing site.
SITAGLIPTIN with METFORMIN HYDROCHLORIDE, tablet, 50 mg (as phosphate monohydrate) – 500 mg, 50 mg (as phosphate monohydrate) – 850 mg, 50 mg (as phosphate monohydrate) – 1g, Janumet® Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Diabetic drug	Authority required (STREAMLINED) listing for patients with Type II diabetes (i) where a combination of metformin and a sulfonylurea is contraindicated or not tolerated;or (ii) who have previously been authorised for treatment with, pioglitazone or rosiglitazone in combination with metformin.	The PBAC recommended listing sitagliptin with metformin on the PBS on a cost-minimisation basis compared with the individual components, sitagliptin and metformin in patients in patients inadequately controlled on metformin and where a combination of metformin and a sulphonylurea is contraindicated or not tolerated. The PBAC did not recommend a specific restriction that the sitagliptin/metformin combination be a replacement for pioglitazone or rosiglitazone in combination with metformin. The PBAC considered that the requested restriction was not appropriate, and doctors can currently stop therapy with a glitazone (when used in combination with metformin) and substitute sitagliptin for pioglitazone or rosigltazone under the current listing criteria.
SITAGLIPTIN, tablet, 25 mg, 50 mg and 100 mg (as phosphate monohydrate), Januvia® Merck Sharp & Dohme (Australia) Pty Ltd. Minor submission	Anti-diabetic agent	A change to the current Authority Required listing to an Authority Required (STREAMLINED) listing.	The PBAC recommended amending the listing as requested.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
SODIUM CHLORIDE, I.V. infusion I.V. infusion 77 mmol per 500 mL, (0.9%), 500 mL Pharmatel Fresenius Kabi Pty Ltd Minor submission	Solution affecting the electrolyte balance	Unrestricted General and Dental listing.	The PBAC recommended the unrestricted listing of a new size of sodium chloride 0.9% as requested with the price to be negotiated by the PBPA.
SODIUM CHLORIDE, I.V. infusion, 77 mmol per 500 mL (0.9%), 500 mL; 36 mmol per 250 mL (0.9%), 250 mL; 15 mmol per 100 mL (0.9%), 100 mL, B.Braun 0.9% Sodium Chloride® B.Braun Australia Pty Ltd Minor submission	Solutions affecting the electrolyte balance	Unrestricted General listing for three new sizes of sodium chloride 0.9% intravenous infusion.	The PBAC recommended the unrestricted listing of three new sizes of sodium chloride 0.9% intravenous infusion, and inclusion in the Dental section for the 500mL infusion, with the price to be negotiated by PBPA.
SODIUM LACTATE COMPOUND, I.V. infusion, 500 mL, B Braun Australia Pty Ltd Minor submission	Electrolyte replacement solution	An unrestricted benefit listing.	The PBAC recommended listing as requested, at a price to be negotiated with the PBPA.
SOY LECITHIN LIPOSOMAL, eye spray, 10 mg per mL (1.0 %), 100 sprays, Tears Again® BioRevive Pty Ltd Minor submission	Lubricant metered eye spray.	To seek a new listing for relief of dry eye.	The PBAC recommended the Authority Required listing of soy lecithin liposomal eye spray for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops on a cost-minimisation basis compared to single dose unit lubricant eye drops. Two sprays of soy lecithin were considered to be equi-effective to one single dose unit of carmellose sodium (Cellufresh®). Listing was also recommended in the Optometrical section.

March 2009 PBAC OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
TEMOZOLOMIDE, powder for I.V. injection 100 mg, Temodal® Schering Plough Pty Ltd Minor submission	Anti- cancer drug	Authority R equired listing for the same conditions as the capsules for patients who are unable to take a solid dose form of temozolomide	The PBAC recommended listing temozolomide powder for I.V. infusion for patients who are unable to take a solid dose form of temozolamide on a cost-minimisation basis with temozolomide capsule. The equi-effective doses were considered to be temozolomide 100 mg I.V equivalent to temozolomide 100 mg capsule.
THALIDOMIDE, capsule, 50 mg, Thalidomide Pharmion® Celgene Pty LtdCelgene Pty Ltd Major submission	Anti- cancer drug	To extend the current section 100 listing to include treatment of a patient newly diagnosed with multiple myeloma, or alternatively in a patient who is ineligible for treatment with high dose chemotherapy or a stem cell transplant.	The PBAC recommended an extension to the Section 100 listing for thalidomide to include the treatment of a patient newly diagnosed with multiple myeloma (first-line setting) on the basis of acceptable cost-effectiveness at the current price.
TRAVOPROST with TIMOLOL MALEATE, eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL, Duotrav® Alcon Laboratories (Australia) Pty Ltd Minor submission	Anti-glaucoma	Consequential amendment (see bimatoprost with timolol above)	The PBAC recommended changing the wording of the restrictions for all PBS-listed timolol with prostaglandin/prostamide analogue combinations so that patients who are on a timolol/prostaglandin or prostamide analogue combination do not have to return to monotherapy with timolol prior to a change in the combination eye drop.
VALINE with CARBOHYDRATE, sachets, 4 g, containing 1g valine, 30, Valine 1000 Amino Acid Supplement® Vitaflo Australia Pty Ltd. Minor submission	Medicinal food	Restricted Benefit PBS listing of a new strength of valine with carbohydrate for Maple Syrup Urine Disease (MSUD).	The PBAC recommended listing as requested, with an appropriate price premium to be determined by the PBPA.