

RECOMMENDATIONS MADE BY THE PBAC IN MARCH 2005

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
<p>ADALIMUMAB injection 40 mg in 0.8 mL, Humira®</p> <p>Abbott Australasia Pty Ltd Minor submission</p>	<p>Treatment for rheumatoid arthritis</p>	<p>Change to current PBS eligibility requirements for severe rheumatoid arthritis. Remove positive rheumatoid factor status.</p>	<p>The PBAC recommended that the rheumatoid arthritis restriction be amended by removing any reference to rheumatoid factor. The PBAC noted that, overall, there is suggestive evidence of weak treatment effect modification by rheumatoid factor status. At worst, being RF-ve results in a treatment effect to bDMARDs in terms of ACR20 and ACR50 response rates, but may result in an inferior treatment effect in terms of these response rates compared with being RF+ve. However, in view of the continuation rules in place for PBS-subsidised use of the bDMARDs, the level of response required to receive repeat treatment is the same for RF-ve and RF+ve patients and the lower response rate thus become less of an issue.</p>
<p>ANAKINRA injection 100 mg in 0.67 mL, pre-filled syringe, Kineret®</p> <p>Amgen Australia Pty Ltd Minor submission</p>	<p>Treatment for rheumatoid arthritis</p>	<p>Change to current PBS eligibility requirements for severe rheumatoid arthritis. Remove positive rheumatoid factor status.</p>	<p>The PBAC recommended that the rheumatoid arthritis restriction be amended by removing any reference to rheumatoid factor. The PBAC noted that, overall, there is suggestive evidence of weak treatment effect modification by rheumatoid factor status. At worst, being RF-ve results in a treatment effect to bDMARDs in terms of ACR20 and ACR50 response rates, but may result in an</p>

			<p>inferior treatment effect in terms of these response rates compared with being RF+ve. However, in view of the continuation rules in place for PBS-subsidised use of the bDMARDs, the level of response required to receive repeat treatment is the same for RF-ve and RF+ve patients and the lower response rate thus become less of an issue.</p>
<p>BALSALAZIDE capsule, 750 mg, Colazide[®]</p> <p>Pharmatel Fresenius Kabi Pty Ltd Major submission</p>	<p>Intestinal anti-inflammatory agent</p>	<p>Authority required listing for mild to moderate ulcerative colitis where hypersensitivity or intolerance to sulfasalazine exists.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared to mesalazine, with the equi-effective doses in acute therapy being balsalazide 6.75 g per day and mesalazine 2.4 g per day. In maintenance therapy, the equi-effective doses are balsalazide 4.5 g per day and mesalazine 1.5 g per day.</p>
<p>BIVALIRUDIN vial, 250 mg, Angiomax[®]</p> <p>CSL Limited Major submission</p>	<p>Anticoagulant</p>	<p>Authority required listing for patients undergoing percutaneous coronary intervention</p>	<p>The PBAC recommended authority required listing for patients undergoing non-emergency percutaneous coronary intervention, with the addition of a NOTE: 'Bivalirudin has not been evaluated in patients undergoing emergency percutaneous coronary intervention, ie as primary or salvage therapy for myocardial infarction.'" Listing was recommended on a cost-minimisation basis compared to heparin and glycoprotein (GP) IIb/IIIa inhibitor, with the equi-effective doses being bivalirudin 0.75mg/kg bolus IV followed by 1.75mg/kg/hr infusion for the duration of the procedure (plus provisional GP IIb/IIIa inhibitor in 7.2% of</p>

			patients) and heparin 65U/kg bolus followed by further dose if low aPTT with abciximab 0.25mg/kg IV bolus followed by 0.215 mcg/kg/min for 12 hours OR eptifibatide acetate 180mcg/kg IV bolus followed by 2.0mcg/kg/min for 18 hours.
BRIMONIDINE 2 mg per mL (0.2%) – TIMOLOL 5 mg per mL (0.5%) eye drops, Combigan® Allergan Australia Pty Ltd Major submission	Antiglaucoma eye drop	Restricted benefit listing for reduction of elevated intra-ocular pressure in patients with open-angle glaucoma and ocular hypertension, who are not adequately controlled with timolol maleate 0.5% eye drops.	Consistent with its policy on fixed dose combination products, the PBAC recommended listing on a cost-minimisation basis compared to concomitant brimonidine tartrate 0.2% and timolol maleate 0.5%, as the data indicated that, on balance, Combigan had similar effectiveness and safety to this comparator.
CALCIUM FOLINATE, injection, equivalent to 100 mg folinic acid in 10 mL, Leucovorin® Pfizer Pty Ltd Minor submission	Fluouracil modulator	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this strength of calcium folinate to accommodate protocols that use 200 mg/m ² .
CARMELLOSE eye drops 0.25% and gel 1%, preservative free TheraTears® lubricant eye drops and liquid gel Contact Lens Centre Australia Ltd Minor submission	Lubricant eye drop	Authority Required Severe dry eye syndrome in patients who are sensitive to preservatives in multi-drops eye drops.	The PBAC recommended listing on a cost minimisation basis compared to the other ocular lubricant eye drops presented in single dose units, with the equi-effective doses being on a unit for unit basis.
DIPHtheria and TETANUS VACCINE ADSORBED, DILUTED	Immunisation	Unrestricted listing and Dr's bag listing	The PBAC had no objection to the Secretariat decision to list this

<p>FOR ADULT USE, injection 0.5 mL, pre-filled syringe, ADT[®]</p> <p>CSL Ltd Minor submission</p>			<p>presentation as a replacement for the ampoule presentation.</p>
<p>DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE, eye drops, 20 mg (base) -5 mg (base) per mL, (2%-0.5%), 5mL, Cosopt[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd Minor submission</p>	<p>Antiglaucoma eye drop</p>	<p>Restricted benefit listing for reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops. Reduction of elevated intra-ocular pressure in patients with ocular hypertension, who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.</p>	<p>The PBAC recommended the restriction be separated into the individual approvable indications to better meet HIC's electronic requirements and for consistency with the recommendation to list brimonidine tartrate 0.2% with timolol 0.5% eye drops.</p>
<p>ENTACAPONE, tablet, 200 mg, Comtan[®],</p> <p>Novartis Pharmaceuticals Australia Pty Ltd Minor submission</p>	<p>Treatment for Parkinson's disease</p>	<p>Authority required listing for Parkinson's disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of dose effect.</p>	<p>The PBAC recommended the change to the restriction wording, for consistency with the listing recommended in November 2004 for the combination product levodopa with carbidopa and entacapone, following agreement of the sponsor and the Australian Association of Neurologists.</p>
<p>EPIRUBICIN HYDROCHLORIDE, solution for IV injection, 100 mg in 50 mL, Epirubicin 100 mg, Mayne Pharma[®]</p> <p>Mayne Pharma Pty Ltd</p>	<p>Anti-cancer agent</p>	<p>Unrestricted listing</p>	<p>The PBAC had no objection to the Secretariat decision to listing this new strength of epirubicin hydrochloride.</p>

Minor submission			
<p>ESCITALOPRAM oral solution, 10 mg per mL, 28 mL, Lexapro Oral Solution®</p> <p>Lundbeck Australia Pty Ltd Minor submission</p>	Treatment for depression	Restricted Benefit for major depressive disorders	The PBAC recommended listing on the basis of acceptable cost-effectiveness at the price requested (the price advantage over the tablet formulation was not considered unreasonable for this relatively low volume item, consistent with the PBAC's acceptance of a price advantage for fluoxetine oral solution) with the same restriction as for the tablet forms for consistency with the oral solution formulation of fluoxetine. As with the oral solution formulation of fluoxetine, the PBAC recommended that the oral solution of escitalopram be included in the data collected for the purposes of the Pricing Authority's weighted average monthly treatment cost (WAMTC) calculations.
<p>ETANERCEPT vial powder for injection, 25 mg, Enbrel®</p> <p>Wyeth Australia Pty Ltd Major submission</p>	Treatment for rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis	Authority required listing for severe active psoriatic arthritis in patients who meet certain criteria.	The PBAC recommended listing on the basis of acceptable cost-effectiveness. Until acceptable comparative utility data across the two indications become available to justify reduced indices of disease severity, the PBAC recommended etanercept be listed for the psoriatic arthritis indication with the same indices of disease severity as apply to the rheumatoid arthritis indication for both the initial and continuing treatment restrictions.
ETANERCEPT vial powder for	See above	Remove requirement for patient to be	The PBAC recommended that the

<p>injection, 25 mg, Enbrel[®]</p> <p>Wyeth Australia Pty Ltd Minor submission</p>		<p>rheumatoid factor positive.</p>	<p>rheumatoid arthritis restriction be amended by removing any reference to rheumatoid factor. The PBAC noted that, overall, there is suggestive evidence of weak treatment effect modification by rheumatoid factor status. At worst, being RF-ve results in a treatment effect to bDMARDs in terms of ACR20 and ACR50 response rates, but may result in an inferior treatment effect in terms of these response rates compared with being RF+ve. However, in view of the continuation rules in place for PBS-subsidised use of the bDMARDs, the level of response required to receive repeat treatment is the same for RF-ve and RF+ve patients and the lower response rate thus become less of an issue.</p>
<p>EVEROLIMUS tablet, 250 microgram, 500 microgram, 750 microgram and dispersible tablet 250 microgram, Certican[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd Major submission</p>	<p>Immunosuppressive agent</p>	<p>Section 100 (Highly Specialised Drug) public and private hospital authority required and Section 85 authority required listings for prophylaxis and treatment of renal allograft rejection and cardiac allograft rejection.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared to the comparator regimens used in the submission, with the final price to be weighted by the volume of use across the renal and cardiac transplant indications (noting that a 86:14 ratio is forecast in the submission). In the renal transplant indication, the accepted comparator was a regimen with sirolimus, with equi-effective doses of everolimus 2.15 mg per day and sirolimus 6.4 mg per day. In the cardiac transplant indication, the accepted comparator was a regimen with mycophenolate mofetil, with equi-effective doses of everolimus 1.3 mg per day and mycophenolate mofetil 2.72 g per day.</p>

			The dose and cost of concomitant immunosuppressive agents were taken into account in the analysis.
<p>EZETIMIBE with SIMVASTATIN tablet, 10 mg – 40 mg and 10 mg – 80 mg, Vytorin[®]</p> <p>Merck Sharp & Dohme Pty Ltd Major submission</p>	Lipid lowering drug combination	<p>Authority required listing for (a) treatment of patients whose cholesterol levels are inadequately controlled with 40 mg or more of a statin and who have coronary heart disease or diabetes mellitus;</p> <p>(b) patients with homozygous familial hyperlipidaemia whose cholesterol levels are inadequately controlled with a statin on current lipid lowering treatment.</p>	<p>The PBAC recommended listing with an authority required restriction for patients who have been adequately controlled on a minimum of 3 months of concomitant treatment with PBS-subsidised ezetimibe and PBS-subsidised HMGCoA reductase inhibitor (statin) therapy at a dose of 40 mg per day or more. Consistent with its policy on fixed dose combination products, the PBAC recommended listing on a cost-minimisation basis compared to the sum of the corresponding strengths of the individual components. The PBAC considered that, because there is more than one statin listed on the PBS, but only simvastatin is included in the combination product, it would be more clinically appropriate to stabilise the patient on ezetimibe with the appropriate dose of statin before commencing the combination product.</p>
<p>GEMCITABINE vial, 200 mg and 1 g, Gemzar[®]</p> <p>Eli Lilly Australia Pty Ltd Major submission</p>	Antineoplastic agent	<p>Authority required listing for advanced epithelial ovarian cancer in combination with carboplatin after failure (> 6 months) of prior platinum-based therapy.</p>	<p>The PBAC recommended listing on a cost-minimisation basis, concluding that the combination of gemcitabine plus carboplatin is of similar effectiveness and safety compared to the combination of paclitaxel plus carboplatin. The equi-effective doses are gemcitabine 1.6 g on Days 1 and 8 plus carboplatin 400 mg on Day 1 for six 21-day cycles versus paclitaxel 280 mg on Day 1 plus</p>

			carboplatin 500 mg on Day 1 for six 21-day cycles.
<p>GLUCOSE INDICATOR – BLOOD, reagent strips, 50, Sensocard[®]</p> <p>Point of Care Diagnostics Australia Pty Ltd Minor submission</p>	Blood glucose testing strip	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this product as an unrestricted benefit with a maximum quantity of 2 packs of 50 and 5 repeats.
<p>GLUCOSE INDICATOR – BLOOD, reagent strips, 51, Accu-chek Integra[®]</p> <p>Roche Diagnostics Australia Pty Ltd Minor submission</p>	Blood glucose testing strip	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this product as an unrestricted benefit with a maximum quantity of 2 packs of 51 and 5 repeats.
<p>IMATINIB MESYLATE, tablet, 100 mg and 400 mg (base), Glivec[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd Minor submission</p>	Treatment for chronic myeloid leukaemia (CML) and gastrointestinal stromal tumours.	<p>Amend the section 100 listing for the chronic phase of CML by addition of the following paragraph: Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy from the date the first application for initial treatment was approved.</p> <p>Add the following NOTE:</p> <p>Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily and maintained on a</p>	The PBAC recommended this change to ensure that patients receive the appropriate dose of imatinib to maximise their chances of achieving a major cytogenetic response (MCR). The NOTE to advise that patients will be granted no more than 18 months initial supply, whether they receive the recommended dose or not, was added because there is no evidence to suggest that patients on lower doses will achieve a MCR if continued beyond 18 months initial therapy.

		<p>minimum dose of imatinib mesylate of 400 mg (base) daily. Prescribing of lower doses should be carefully considered. Continuing therapy is dependent on patients demonstrating a response to imatinib therapy following the initial 18 months of treatment, irrespective of the daily imatinib dose received.</p>	
<p>INFLIXIMAB powder for IV infusion 100 mg, Remicade®</p> <p>Schering-Plough Pty Limited Minor submission</p>	<p>Treatment for inflammatory diseases such as rheumatoid arthritis and ankylosing spondylitis.</p>	<p>Change to current PBS eligibility requirements for severe rheumatoid arthritis. Remove positive rheumatoid factor status.</p>	<p>The PBAC recommended that the rheumatoid arthritis restriction be amended by removing any reference to rheumatoid factor. The PBAC noted that, overall, there is suggestive evidence of weak treatment effect modification by rheumatoid factor status. At worst, being RF-ve results in a treatment effect to bDMARDs in terms of ACR20 and ACR50 response rates, but may result in an inferior treatment effect in terms of these response rates compared with being RF+ve. However, in view of the continuation rules in place for PBS-subsidised use of the bDMARDs, the level of response required to receive repeat treatment is the same for RF-ve and RF+ve patients and the lower response rate thus become less of an issue.</p>
<p>INTERFERON BETA-1a, pre-filled syringe, 30 micrograms in 0.5 mL, 4 syringes, Avonex®</p> <p>Biogen Idec Australia Pty Ltd</p>	<p>Treatment for multiple sclerosis</p>	<p>Authority required listing as for the already listed formulation of this product.</p>	<p>The PBAC had no objection to the Secretariat decision to list the pre-filled syringe presentation of this already listed product, with the same authority required restriction, maximum quantity and number</p>

Minor submission			of repeats.
LIGNOCAINE HYDROCHLORIDE injection 500 mg in 5 mL, Xylocard 500 [®] AstraZeneca Pty Ltd Change to listing Minor submission	Treatment of ventricular arrhythmias	Increase pack size from 5 to 10	The PBAC agreed to this request.
MESALAZINE tablet 500 mg, Salofalk [®] Orphan Australia Pty Ltd Minor submission	Immunosuppressant used to treat colitis	Extension of authority required for colitis (including ulcerative colitis and Crohn's disease) and Crohn's ileitis where hypersensitivity to sulfonamides exists or where intolerance to sulfasalazine exists.	The PBAC recommended extending the authority required listing at the price requested by the sponsor for colitis and Crohn's disease where hypersensitivity to sulfonamides exists; and colitis and Crohn's disease where intolerance to sulfasalazine exists. The PBAC was of the view that, as Crohn's disease covers both Crohn's colitis and Crohn's ileitis, the wording of the restriction should be as consistent as possible with that of mesalazine tablet 250 mg. However, the PBAC advised the Secretariat that it wished to conduct a review of the restrictions applying to the oral formulations of the aminosalicic acid derivatives at its next meeting.
METHYLPHENIDATE tablet, 10 mg, Ritalin [®] Novartis Pharmaceuticals Pty Ltd Major submission	Psychostimulant	Authority required listing for use in attention deficit hyperactivity disorder, in accordance with State/Territory Law.	The PBAC recommended listing on a cost-minimisation basis compared to dexamphetamine sulfate with the equi-effective doses being methylphenidate hydrochloride 10 mg and dexamphetamine sulfate 5 mg.

<p>METHYLPREDNISOLONE SODIUM SUCCINATE vial, 1 gram/ 16 mL, Solu-Medrol®</p> <p>Pfizer Australia Pty Ltd Minor submission</p>	<p>Corticosteroid</p>	<p>Unrestricted listing</p>	<p>The PBAC recommended the listing with pricing to be considered by the Pricing Authority using its usual criteria.</p>
<p>METOPROLOL SUCCINATE controlled release tablet, 23.5 mg - 47.5 mg – 95 mg, Toprol-XL Titration Pack®</p> <p>AstraZeneca Pty Ltd Minor submission</p>	<p>Treatment for heart failure</p>	<p>Add titration pack comprising 15 tablets each of the 23.5 mg, 47.5 mg and 95 mg existing strengths</p>	<p>The PBAC recommended listing on a cost minimisation basis compared to the sum of the individual components.</p>
<p>OXALIPLATIN vial, 50 mg and 100 mg, Eloxatin®</p> <p>Sanofi-Synthelabo Australia Pty Ltd Major submission</p>	<p>Antineoplastic agent</p>	<p>Authority required listing as adjuvant treatment, in combination with 5-fluorouracil and folinic acid, of Stage III (Duke's C) colon cancer after complete resection of the primary tumour.</p>	<p>The PBAC recommended listing on the basis of a high, but acceptable, cost-effectiveness ratio. Based on the data presented, the PBAC considered that oxaliplatin in combination with 5-fluorouracil and folinic acid improves the disease-free survival of patients with Stage III colon cancer and is likely to improve the overall survival.</p>
<p>PARACETAMOL, modified release tablet, 665 mg, Panadol Osteo® and Duatrol SR®,</p> <p>GlaxoSmithKline Consumer Healthcare Minor submission</p>	<p>Analgesic</p>	<p>Restricted benefit listing for relief of persistent pain associated with osteoarthritis.</p>	<p>The PBAC had no objection to the Secretariat decision to list with a maximum quantity of 192 tablets (2x96) rather than 180 tablets as had been recommended by the PBAC at its November 2004 meeting.</p>

<p>PERINDOPRIL with INDAPAMIDE tablet, 2 mg-625 microgram, Predonium[®]</p> <p>Servier Laboratories Australia Pty Ltd Major submission</p>	Anti-hypertensive	Unrestricted benefit listing (for hypertension)	Consistent with its policy on fixed dose combination products, the PBAC recommended listing on a cost-minimisation basis compared to the sum of the individual components.
<p>PERINDOPRIL with INDAPAMIDE tablet, 4 mg-1.25 mg, Coversyl Plus[®]</p> <p>Servier Laboratories Australia Pty Ltd Minor submission</p>	Anti-hypertensive	Amend restricted benefit listing to hypertension in patients not adequately controlled with indapamide hemihydrate and/or perindopril erbumine.	The PBAC recommended the change to allow patients receiving treatment with the combination tablet of perindopril with indapamide, 2 mg-625 microgram to receive treatment with this higher strength product.
<p>PIOGLITAZONE, tablet, 15 mg, 30 mg and 45 mg, Actos[®], Eli Lilly Australia Pty Ltd</p>		Amend the authority required listing for continuing dual therapy with insulin as follows: Continuation of therapy, in combination with insulin, in type 2 diabetic patients where the patient has previously been issued with an authority prescription for pioglitazone hydrochloride or rosiglitazone maleate.	The PBAC recommended this change following the recommendation to list rosiglitazone for use in dual therapy with insulin. This would allow patients who were initiated on rosiglitazone therapy to swap to pioglitazone plus insulin, without having to requalify for initial therapy.
<p>POLYGELINE 3.5% IV infusion, 500 mL, Haemacel[®]</p> <p>AFT Pharmaceuticals Pty Ltd Minor submission</p>	Plasma volume expander	Re-list an item deleted at request of previous sponsor	The PBAC recommended listing on the basis that the price to pharmacist proposed was the same as at the time of deletion and the same price as the alternative product, succinylated gelatin 20 g per 500 mL.

<p>PRAVASTATIN with ASPIRIN tablet, 40 mg -81 mg, Pravigard[®]</p> <p>Bristol-Myers Squibb Australia Pty Ltd Major submission</p>	<p>Lipid-lowering and anti-platelet drug combination</p>	<p>Restricted benefit listing for prevention of cardiovascular events in patients who have had a myocardial infarction or who have unstable angina pectoris and who meet lipid lowering drug criteria.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared to pravastatin sodium 40 mg, as proposed in the submission.</p>
<p>QUININE BISULFATE tablet, 300 mg, Quinbisul[®], Alphapharm Pty Ltd, QUININE SULFATE, tablet, 300 mg, Quinsul[®] Alphapharm Pty Ltd, Quinate[®], Aspen Pharmacare Australia Pty Ltd Minor submission</p>	<p>Treatment of malaria</p>	<p>Transfer from unrestricted listing to authority required listing for malaria.</p>	<p>The PBAC recommended the change to listing to ensure that PBS use is in accordance with the revised TGA-approved indications which have recently been amended to remove the indication relating to muscle cramps.</p>
<p>RISPERIDONE, tablet, 500 µg, 1 mg and 2 mg, Risperdal Quicklets[®],</p> <p>Janssen-Cilag Pty Ltd Minor submission</p>	<p>Treatment for schizophrenia and aggression in patients with dementia.</p>	<p>Authority required listing as for the corresponding strengths of the tablet formulation</p>	<p>The PBAC had no objection to the Secretariat decision to list this new presentation of risperidone on a cost-minimisation basis compared to the corresponding strengths of risperidone tablets.</p>
<p>ROSIGLITAZONE tablet, 4 mg and 8 mg, Avandia[®]</p> <p>GlaxoSmithKline Australia Pty Ltd Major submission</p>	<p>Used to manage diabetes</p>	<p>Extend the authority required listing to dual therapy with insulin, in insulin-treated type 2 diabetic patients whose blood glucose concentrations are inadequately controlled.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared to pioglitazone hydrochloride, with the equi-effective doses as proposed by the sponsor and as previously accepted by the PBAC for the current restrictions.</p>
<p>SIROLIMUS, tablet, 2 mg Rapamune[®]</p> <p>Wyeth Australia Pty Ltd</p>	<p>Immunosuppressant</p>	<p>Section 100 and authority required listing for prophylaxis and management of renal allograft</p>	<p>The PBAC had no objection to the Secretariat listing this strength of sirolimus with the same restriction as the 1 mg</p>

Minor submission		rejection.	tablet and oral solution 1 mg per mL, for maintenance therapy.
SULFASALAZINE, tablet 500 mg, Salazopyrin [®] and 500 mg (enteric coated), Salazopyrin EN [®] , Pharmacia Australia Pty Limited, Pyralin EN [®] , Kenral Division of Pharmacia Australia Pty Limited Minor submission	Disease modifying anti-rheumatic agent.	Transfer for restricted benefit to unrestricted listing.	The PBAC agreed to transfer the listing from a restricted benefit to an unrestricted listing, on the basis that this drug has been listed for a number of years and it is very unlikely to be used inappropriately.
SUMATRIPTAN fast disintegrating tablets, 50 mg, Imigran FDT [®] GlaxoSmithKline Australia Pty Ltd Minor submission	Treatment for migraine	Authority Required migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.	The PBAC noted that this additional tablet formulation has been registered on the basis of bioequivalence to the currently listed Imigran [®] tablet. This being the case, the PBAC was of the view that Imigran FDT [®] should simply be listed as an alternative brand of sumatriptan tablet 50 mg.
TEMOZOLOMIDE capsule 5 mg, 20 mg, 100 mg and 250 mg, Temodal [®] Schering-Plough Pty Limited Minor submission	Treatment for certain types of brain tumour	Change to current PBS eligibility requirements to allow use in glioblastoma multiforme concomitantly with radiotherapy, with a maximum quantity of 15 with 2 repeats (excluding 250 mg tablet), and for glioblastoma multiforme following radiotherapy, with a maximum quantity of 5 with 5 repeats (all strengths).	The PBAC recommended listing on the basis of acceptable cost effectiveness. The PBAC noted that, based on the more scientifically rigorous evidence submitted for this setting, temozolomide is probably more cost-effective than in the setting following recurrence despite incurring more costs per patient on average. The revised listing will allow use in glioblastoma multiforme at an earlier

			stage than allowed by the existing listing for recurrence of the condition. This was supported by an amendment to the TGA-approved indications for the product and is consistent with current trends in clinical practice.
<p>TETANUS VACCINE, ADSORBED, injection, 0.5 mL, pre-filled syringe, Tetox[®]</p> <p>CSL Ltd Minor submission</p>	Immunisation	Unrestricted listing and in Dental list and Doctor's Bag	The PBAC had no objection to the Secretariat decision to list this presentation as a replacement for the ampoule presentation.
<p>TESTOSTERONE gel sachet, 50 mg per 5 g (1%), Testogel[®]</p> <p>Schering Pty Ltd Major submission</p>	Hormone replacement	Authority required listing for testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.	The PBAC recommended listing on a cost-minimisation basis compared to testosterone patches, with the equivalent doses being the testosterone gel 50 mg per day gel and the testosterone patch releasing approximately 5 mg per day.
<p>THALIDOMIDE capsule, 50 mg, Thalidomide Pharmion Hard Capsule[®]</p> <p>Pharmion Pty Ltd Major submission</p>	Immunomodifier	Section 100 (Highly Specialised Drug) public and private hospital authority required listing for treatment of relapsed/refractory multiple myeloma patients who have failed at least one other treatment.	The PBAC recommended listing on the basis of a high, but acceptable cost-effectiveness ratio compared with a weighted average of a mixture of salvage treatments with autologous stem cell transplant and a number of standard chemotherapy regimens, provided the dose used in practice remains at no more

			than 200 mg per day.
<p>TRAMADOL oral drops, 100 mg per mL, Tramal[®]</p> <p>CSL Limited Minor submission</p>	Treatment for pain	Restricted Benefit and Dental listing for pain where aspirin and/or paracetamol alone are inappropriate or have failed.	The PBAC recommended listing on the basis of cost minimisation compared with the 50 mg immediate release capsule.
<p>VENLAFAXINE HYDROCHLORIDE, capsule, 37.5 mg (base) (modified release), Efexor-XR[®]</p> <p>Wyeth Australia Pty Ltd Minor submission</p>	Antidepressant	Restricted benefit listing for major depressive disorders	The PBAC had no objection to the Secretariat decision to list this new strength of modified release venlafaxine hydrochloride to assist patients with dose titration.