JULY 2010 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Alendronate sodium, tablet equivalent to 70 mg alendronic acid, Fosamax Once Weekly® Alendronate sodium with colecalciferol, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol, Fosamax Plus® Alendronate sodium with colecalciferol, tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol, Fosamax Plus 70 mg/140 mcg® Alendronate sodium with colecalciferol and calcium, pack containing 4 tablets equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.5 g (equivalent to 500 mg elemental calcium), Fosamax Plus D-Cal® Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Osteoporosis	Request an extension to the current Authority Required (STREAMLINED) listing to include the treatment of corticosteroid-induced osteoporosis (CIO) in patients on long term (≥ 3 months) high dose (≥ 7.5 mg per day prednisolone or equivalent) corticosteroid therapy and a bone mineral density (BMD) T-score ≤ -1.5.	The PBAC recommended listing on a cost-minimisation basis compared with risedronate. The equi-effective doses are 70 mg alendronic acid weekly and 35 mg risedronate sodium weekly.
Amino acid formula with vitamins and minerals without lysine and low in tryptophan, powder 500 g, XLYS, LOW TRY Maxamaid® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Request a change to the age restriction from a child less than 7 years to a child less than 9 years in the current restricted benefit listing for proven glutaric aciduria type1.	Recommended

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Amino acid synthetic formula with fat, carbohydrate, vitamins, minerals and trace elements, powder, 400 g, Neocate LCP plus MCT® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Authority Required listing for treatment of combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrolysate formulas in a child from birth to 1 year of age, where the child has been assessed by a suitably qualified allergist or paediatrician.	The PBAC recommended listing on the same cost-basis and with the same restrictions as Neocate LCP.
Amlodipine (as besylate) with valsartan and hydrochlorothiazide, tablets, 5 mg-160 mg-12.5 mg, 5 mg-160 mg-25 mg, 10 mg-160 mg-12.5 mg, 10 mg-160 mg-25 mg and 10 mg-320 mg-25 mg, Exforge HCT® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in patients who are already adequately controlled on the triple combination of amlodipine, valsartan and hydrochlorothiazide (as individual or combination therapies).	The PBAC recommended listing for hypertension in a patient who is not adequately controlled with any two of the drugs in the combination in accordance with the combination Guidelines, on a cost-minimisation basis compared with the constituent components at equivalent doses.
Amlodipine with valsartan, tablets, 5 mg (as besylate)-320 mg, 10 mg (as besylate)-320 mg, Exforge5/320®, Exforge 10/320® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in a patient who is not adequately controlled with either of the drugs in the combination.	The PBAC recommended listing two additional strengths of amlodipine with valsartan tablets, 5 mg-320 mg and 10 mg-320 mg, in accordance with the combination Guidelines, on a cost-minimisation basis compared with the corresponding strengths of the constituent components, amlodipine and valsartan given concomitantly.
Artemether with lumefantrine, tablet 20 mg-120 mg (dispersible), Riamet® Novartis Pharmaceutical Australia Pty Ltd	Anti-malarial	Authority Required listing of a new dispersible formulation under the current listing conditions for the treatment of suspected or confirmed malaria due to Plasmodium falciparum.	The PBAC recommended listing the dispersible tablet at the same price as the pack of 24 standard tablets.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Minor submission			
Brimonidine tartrate,eye drops 1.5 mg per mL (0.15%), 5 mL, Alphagan® P 1.5 Allergan Australia Pty Ltd Minor submission	Glaucoma	1. Unrestricted benefit listing of a new form and strength of brimonidine eye drops for lowering elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension. 2. Same listing requested on the Optometrical Schedule.	The PBAC recommended an unrestricted benefit listing in the General and Optometrical Schedules on a cost-minimisation basis against brimonidine 0.2 % eye drops.
Cetrorelix, powder for injection with diluent syringe, 250 microgram (as acetate), Cetrotide® Merck Serono Australia Pty Ltd Minor submission	Fertility drug.	Section 100 (IVF GIFT Treatment Program) listing for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques (ART).	The PBAC recommended listing on a cost minimisation basis with ganirelix. The equi-effective doses are cetrorelix 250 micrograms and ganirelix 250 micrograms.
Cetuximab, solution for IV infusion, 100 mg in 20 mL, 100 mg in 50 mL, 500 mg in 100 mL, Erbitux® Merck Serono Australia Pty Ltd Minor submission	Anti-cancer drug	Extend the current Authority Required listing to include initial and continuing treatment as monotherapy or in combination with chemotherapy following failure of chemotherapy in K-Ras wild type patients with metastatic colorectal cancer.	The PBAC recommended listing on the basis of high but acceptable cost-effectiveness compared with best supportive care. The PBAC recommended listing be limited to monotherapy or in combination with irinotecan based therapies based on clinical trial data regarding efficacy.
Deferiprone, oral solution, 100 mg per mL, 250 mL, Ferriprox® Orphan Australia Pty Ltd Minor submission (Out of session)	Iron overload in patients with thalassaemia	To ratify the proposed maximum quantity and repeats for the Highly Specialised Drug Streamlined Authority listing for Public hospitals of deferiprone oral solution.	Recommended
Degarelix, powder for subcutaneous injections (modified release), 80 mg and 120 mg, (as acetate) with solvent, syringe and needles, Firmagon®	Anti-cancer drug	Authority Required listing for the treatment of locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.	The PBAC recommended an Authority Required (STREAMLINED) listing on a cost-minimisation basis compared with leuprorelin acetate 7.5 mg powder for I.M. injection.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Ferring Pharmaceuticals Pty Ltd Major submission			
Denosumab, injection, 60 mg in 1 mL, single use pre-filled syringe, Prolia® Amgen Australia Pty Ltd Major submission	Osteoporosis	Authority Required (STREAMLINED) listing for: 1. the treatment of osteoporosis in women aged 70 years of age or older with a BMD T score of -3.0 or less, and 2. the treatment of established post-menopausal osteoporosis in patients with fracture due to minimal trauma.	The PBAC recommended an Authority Required listing on a cost minimisation basis compared with zoledronic acid. The equi-effective doses are denosumab 60 mg administered every six months and zoledronic acid 5 mg administered once per year.
Epoetin lambda, injection, 1000 units in 0.5 mL, 2000 units in 1.0 mL, 3000 units in 0.3 mL, 4000 units in 0.4 mL, 5000 units in 0.5 mL, 6000 units in 0.6 mL, 8000 units in 0.8 mL and 10,000 units in 1.0 mL, pre-filled syringes, Novicrit® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Anaemia	S100 (Highly Specialised Drugs Program) for the treatment of anaemia requiring transfusion, where Hb level of less than 100 g per L and intrinsic renal disease is the primary cause of anaemia as assessed by a nephrologist.	The PBAC recommended listing on a cost-minimisation basis with epoetin alfa.
Exenatide, pre-filled injection pen, 5 micrograms per dose, 10 micrograms per dose, Byetta® Eli Lilly Australia Pty Ltd Minor submission	Diabetes	1. Request the PBAC allow patients to switch between agents in three classes namely gliptins, glitazones and glucagon-like peptides (exenatide only at present) without having to requalify with respect to glycosylated haemoglobin levels (HbA1c) be applied to the listing of exenatide. 2. Request for an Authority required (STREAMLINED) listing.	The PBAC recommended the restriction wording for exenatide and all currently PBS-subsidised dipeptidyl peptidase 4 inhibitors (gliptins) and thiazolidinediones (glitazones) be modified to allow patients to switch between agents in these three classes without having to requalify with respect to glycosylated haemoglobin levels (HbA1c). The PBAC rejected the Authority required (STREAMLINED) listing as it is a first in class agent with clinicians having little

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
			clinical experience with its use and place in therapy. However, the PBAC agreed to review the listing in 12 months time.
Glucose indicator-blood test strips, 100, Accu-Chek® Advantage Sensor Comfort Roche Diagnostics Australia Pty Ltd Minor submission (Out of session)	Diabetes	1. Unrestricted listing for Accu-Chek® Advantage Sensor Comfort test strips. 2. Restricted Benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangement where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	The PBAC recommended listing at the same price as the currently listed test strips.
Glucose indicator-blood test strips, 50, OneTouch Verio® Johnson & Johnson Medical Pty Ltd Minor submission (Out of session)	Diabetes	1. Unrestricted listing for OneTouch Verio test strips. 2. Restricted Benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangement where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	The PBAC recommended listing at the same price as the currently listed test strips.
Hydromorphone hydrochloride, tablets, 4 mg, 8 mg, 16 mg, 32 mg and 64 mg (modified release), Jurnista® Janssen-Cilag Pty Ltd Minor submission	Pain relief	To seek a change to the current pack size from 10 to 14, for all the five strengths of hydromorphone hydrochloride tablets.	The PBAC recommended listing at the same price per tablet as the 10 tablet packs.
Imatinib, tablets, 100 mg and 400 mg (as mesylate), Glivec® Novartis Pharmaceuticals Australia Pty Ltd Minor submission (Out of session)	Anti-cancer drug	To ratify the proposed removal of the remaining 'grandfather' wording for imatinib in the treatment of metastatic or unresectable malignant gastrointestinal stromal tumour (GIST).	Recommended
Inactivated influenza vaccine, injection containing A/Brisbane/59/2007,	Influenza vaccine	To request the PBAC recommend that Influvac Junior be designated a vaccine pursuant to Section 9B (7) of the National Health Act 1953 to allow the	Recommended

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
A/Brisbane/10/2007 and B/Florida/4/2006 like strains, 0.25 mL, pre-filled syringe, Influvac Junior® Abbott Products Pty Ltd Minor submission (Out of session)		sponsor to participate in future national tenders for supply via the National Immunisation Program (NIP).	
Lanthanum carbonate hydrate, chewable tablet, 500 mg, 750 mg and 1000 mg (base), Fosrenol® Shire Australia Pty Ltd Minor submission	Binds phosphate in patients with end stage kidney disease.	To request the PBAC change the current section 85 Authority Required listing for lanthanum to an Authority Required (STREAMLINED) listing. No change is requested to the section 100 listing.	Recommended
Long acting oral opioids on the PBS - Request to change the pack size Mundipharma Pty Ltd Minor submission		Mundipharma requests an increase in pack size to provide 14 days treatment for all PBS listed long-acting opioids should the PBAC approve a similar request for hydromorphone modified release tablets (Jurnista®)	Recommended
Losartan, tablets, 25 mg and 50 mg (as potassium), Cozavan® Alphapharm Pty Limited Major submission	Antihypertensive	Unrestricted Benefit listing for the treatment of hypertension.	The PBAC recommended listing on a cost-minimisation basis compared with irbesartan. The dose relativity accepted from the trials was 1:2.7.
Mesalazine, sachet containing prolonged release granules, 1 g per sachet, Pentasa ® Ferring Pharmaceuticals Pty Ltd Minor submission (Out of session)	Anti-inflammatory for bowel disease	Seek a change to the current pack size from 100 to 120 for mesalazine 1g granule sachets.	The PBAC recommended listing at the same price-to-pharmacist per sachet.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Mesalazine, suppositories (moulded), 1 g , 30, Salofalk® Orphan Australia Ltd Pty Minor submission	Anti-inflammatory for bowel disease	Restricted benefit listing for acute episodes of mild to moderate ulcerative proctitis.	The PBAC recommended listing on a cost minimisation basis with mesalazine suppositories (Pentasa®). The equi-effective doses are one mesalazine suppository (Salofalk®) and one mesalazine suppository (Pentasa®).
Mesalazine, tablet, 1 g (prolonged release), Pentasa ® Ferring Pharmaceuticals Pty Ltd Minor submission (Out of session)	Anti-inflammatory for bowel disease	Authority Required (STREAMLINED) listing of a new higher strength of mesalazine prolonged release tablets for the treatment of ulcerative colitis and Crohn disease.	The PBAC recommended listing on a cost-minimisation basis with mesalazine 1 g granules.
Metformin hydrochloride, tablet, 1000 mg (extended release), Diabex ® XR 1000 Alphapharm Pty Ltd Minor submission (Out of session)	Diabetes	Unrestricted listing of a new higher strength of metformin extended release tablets for the treatment of type II diabetes.	The PBAC recommended listing at the same price per mg as metformin XR 500 mg tablet.
Nicotine, transdermal patch releasing approximately 21 mg per 24 hours, 28, Nicabate P® GlaxoSmithKline Consumer Healthcare Minor submission	Smoking cessation aid	- To seek PBS listing of nicotine 21 mg patches, Nicabate P® - To request use of Nicabate P in a 2 week pre-quit clinical setting whilst the patient continues to smoke.	The PBAC recommended listing under the conditions recommended at the March 2010 PBAC meeting i.e for 12 weeks of therapy per year. The PBAC considered that insufficient data had been provided to support listing under different circumstances i.e in the pre-quit clinical setting.
Nicotine, transdermal patch, releasing 15 mg per 16 hrs, Nicorette Patch® Johnson&Johnson Pacific Pty Ltd Nicotine, transdermal patch, releasing 21 mg per 24 hours, Nicotinell Step 1 Patch®	Smoking cessation aid	Authority required listing for short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who meets certain criteria.	The PBAC recommended listing under the conditions recommended at the March 2010 PBAC meeting i.e for 12 weeks of therapy per year.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Novartis Consumer Health Australia Pty Ltd Minor submission (Out of session)			
Olmesartan medoxomil with amlodipine (as besylate), tablets, 20 mg-5 mg, 20 mg-10 mg, 40 mg-5 mg and 40 mg-10 mg, Sevikar® Schering-Plough Pty Ltd Major submission	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in patients who are not adequately controlled with either angiotensin II receptor antagonist or dihydropyridine calcium channel blocker monotherapy.	The PBAC recommended listing in accordance with the combination Guidelines, on a cost-minimisation basis compared with the corresponding strengths of the constituent components, amlodipine and olmesartan given concomitantly.
Pneumococcal polysaccharide conjugate vaccine, 13 valent adsorbed, injection, 0.5 mL, pre-filled syringe, Prevenar-13® Wyeth Australia Pty Limited Major submission	Vaccine for Pneumococcal disease.	Listing on the National Immunisation Program as a replacement for Prevenar for vaccination against pneumococcal disease in infants.	The PBAC recommended listing under the same circumstances of use as the existing NIP listed pneumococcal 7-valent vaccine (7vPCV, Prevenar 7®).
Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel®; tablets (modified release), 50 mg, 200 mg, 300 mg and 400 mg, Seroquel XR® AstraZeneca Pty Ltd Major submission	Bipolar disorder	Authority Required (STREAMLINED) listing to include monotherapy treatment of bipolar disorder with the addition of a mood stabiliser (lithium or sodium valproate) as clinically appropriate, OR change the current PBS listing to the treatment of bipolar disorder.	The PBAC recommended extending the listing on a cost minimisation basis with olanzapine tablets. The equi-effective doses are 546 mg of quetiapine (as fumarate) and 12.5 mg of olanzapine.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Ribavirin and Peginterferon alfa-2a, packs containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms, Pegasys RBV® Roche Products Pty Ltd Major submission	Hepatitis C	Resubmission to extend the current S100 (Highly Specialised Drugs Program) to include the treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa who meet certain criteria.	The PBAC recommended extended the listing on a cost-minimisation basis with peginterferon alfa-2b with ribavirin (Pegatron), for 48 weeks of treatment.
Romiplostim, powder for injection, 100 micrograms, 250 micrograms and 500 micrograms, Nplate® Amgen Australia Pty Ltd Minor submission	Idiopathic thrombocytopenia purpura (ITP)	Resubmission to reassess the cost-effectiveness as the volume in the vial has changed.	The PBAC re-affirmed its previous recommendation to list on the basis of high but acceptable cost-effectiveness ratios.
Sevelamer hydrochloride, tablet, 800 mg, Renagel® Genzyme Australasia Pty Ltd Minor submission	Binds phosphate in patients with end stage kidney disease	Request a change of listing category from Authority Required to Authority Required (STREAMLINED).	Recommended

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Solifenacin, tablets, 5 mg and 10 mg, (as succinate), Vesicare® Orphan Australia Pty Ltd Major submission	Overactive bladder and symptoms of urge urinary incontinence	Resubmission for Restricted Benefit listing for the treatment of detrusor overactivity in a patient who cannot tolerate oral oxybutynin.	The PBAC recommended listing on a cost minimisation basis with transdermal oxybutynin. The equi-effective doses are 7.47 mg solifenacin and 3.9 mg transdermal oxybutynin.
Tacrolimus, capsules, 0.5 mg, 1 mg and 5 mg (prolonged release), Prograf XL® Janssen-Cilag Pty Ltd Minor submission	Immunosuppressant	Request to list a new prolonged release formulation of tacrolimus under the current listing conditions (organ and tissue transplantation).	The PBAC recommended listing on a cost-minimisation basis with immediate release tacrolimus on a mg:mg basis at the same price per mg.
Thalidomide, capsule, 50 mg, Thalomid® Lenalidomide, capsules, 5 mg, 10 mg, 15 mg and 25 mg, Revlimid® Celgene Pty Ltd Minor submission (Out of session)	Multiple myeloma	To request a change to the NOTE regarding risk management program for both thalidomide and lenalidomide Section 100 listings to read as follows: NOTE: Patients receiving xxxxx under the PBS listing must be registered in the i-access ™ risk management program.	Recommended
Trastuzumab, powder for I.V. infusion, 60 mg, Herceptin ® Roche Products Pty Ltd Minor submission (Out of session)	Anti-cancer	1. S100 (Authority Required) listing of a new lower strength of trastuzumab for the treatment of HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery in a patient who meets certain criteria. 2. Same listing is also requested on the Herceptin Program, administered by Medicare Australia for the treatment of HER2 positive metastatic breast cancer.	The PBAC recommended listing of the new lower strength of trastuzumab on a cost-minimisation basis with trastuzumab 150 mg. The PBAC also recommended trastuzumab 60 mg be made available to the Herceptin Program, administered by Medicare Australia.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMENDATION
Triptorelin, powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles, Diphereline® Ipsen Pty Ltd Minor submission (Out of session)	Anti-cancer	Authority Required (STREAMLINED) listing of a new higher strength of triptorelin 6-month sustained release formulation for locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.	The PBAC recommended listing on a cost-minimisation basis with the currently PBS-listed leuprorelin acetate (Eligard 6 month®).