

Positive Recommendations made by the PBAC in September 2000

DRUG AND FORM	DRUG USE /TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION & COMMENTS
Amino acid formula with vitamins and minerals without phenylalanine (Phenex-1® and Phenex- 2®))	A food for inborn errors of metabolism	Restricted benefit listing for infants and very young children with proven phenylketonuria.	Recommended for listing as requested on the basis of acceptable cost-effectiveness.
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine (Ketonex-1®, Ketonex-2®)	A food for inborn errors of metabolism	Restricted benefit listing for maple syrup urine disease	Recommended for listing as requested on the basis of acceptable cost-effectiveness.
Amino acids with vitamins and minerals and long chain polyunsaturated fatty acids without phenylalanine (XP Analog LCP®)	A food for inborn errors of metabolism	Restricted benefit listing for infants and very young children phenylketonuria	Recommended for listing as requested on the basis of acceptable cost-effectiveness.
Brinzolamide eye drops 1% (Azopt®)	An eye drop for treatment of glaucoma	Restricted benefit listing for add-on (combination) therapy for the reduction in IOP in patients with open-angle glaucoma	Recommended for listing as an unrestricted pharmaceutical benefit with a price premium over beta-blockers and other 'add-on' eye drop therapies.
Bupropion tablet 150 mg (Zyban®)	A product to aid smoking cessation.	Authority required listing for use within a comprehensive treatment program for those who have unsuccessfully attempted to stop smoking with nicotine replacement therapy or in whom NRT is contra-indicated.	Recommended for listing with an authority required restriction "For use within a comprehensive treatment program with the goal of maintaining abstinence". The cost-effectiveness at the price proposed was considered acceptable.
Cyclosporin capsules 10 mg , 25 mg, 50 mg. 100 mg and oral solution 100 mg per mL	A new indication for a currently listed product for the treatment of nephrotic syndrome.	Section 100 listing for treatment by nephrologists or paediatric nephrologists of patients with	Recommended for listing under section 100 for treatment by nephrologists of nephrotic

(Neoral®)		nephrotic syndrome for induction and/or maintenance of remission, in whom steroids and cytostatic drugs have failed or are not tolerated, or are considered inappropriate, and when renal function is unimpaired.	syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired.
Diltiazem hydrochloride controlled delivery capsule 360 mg (Cardizem CD®)	For the treatment of hypertension.	Unrestricted listing	Recommended for listing as requested on the basis of the price being acceptable relative to the existing listed strengths of controlled delivery diltiazem hydrochloride.
Dorzolamide hydrochloride eye drops 20 mg per mL (2%) (Trusopt®)	An eye drop for glaucoma	Unrestricted listing	Recommended for listing as an unrestricted benefit with a price premium over beta-blockers and other 'add-on' eye drop therapies.
Enalapril maleate and hydrochlorothiazine tablet 20 mg/6 mg (Renitec Plus®)	Another combination treatment for high blood pressure	Restricted benefit listing for treatment of hypertension in patients who are not adequately controlled with either hydrochlorothiazide or enalapril maleate	Recommended for listing as a restricted benefit for treatment of hypertension in patients who are not adequately controlled with 20 mg enalapril maleate, on a cost-minimisation basis compared with enalapril maleate 20 mg and hydrochlorothiazide 12.5 mg.
Latanoprost eye drops 50 micrograms per mL (Xalatan®)	An eye drop for the treatment of glaucoma	Proposal to allow use in combination therapy by removal of the words "Monotherapy for the"	Recommended to be transferred to unrestricted listing, subject to price negotiations.
Leuprorelin acetate IM injection (modified release) set containing 1 vial powder for injection 30 mg	For carcinoma of the prostate	Authority required listing for advanced carcinoma of the prostate.	Recommended for listing as requested on the basis of the price being acceptable relative to the

and 1 ampoule diluent 2 mL (Lucrin Depot® 4 month injection)			existing listed strengths of modified release leuprorelin acetate.
Morphine sulfate capsules controlled release 30 mg, 60 mg, 90 mg and 120 mg (MS MONO®)	An opioid pain-killer	Restricted benefit for the treatment of opioid responsive, chronic severe pain.	Recommended for listing as a restricted benefit for chronic severe disabling pain not responding to non-narcotic analgesics, on a cost-minimisation basis, with the 30 mg once-daily presentation being equivalent to the 15 mg twice-daily presentation controlled release morphine sulfate and other strengths accordingly.
Paclitaxel injections (Taxol®)	A treatment for breast and ovarian cancer.	Additional authority required indication for the adjuvant treatment of node-positive breast cancer	Recommended for listing for adjuvant treatment of node-positive, oestrogen receptor negative, breast cancer administered sequentially to doxorubicin and cyclophosphamide, as paclitaxel was cost-effective only when used in node positive, oestrogen receptor negative breast cancer.
Ramipril capsule 10 mg (Tritace®)	Used for the treatment of hypertension, heart failure and for the prevention of progressive kidney failure	Unrestricted listing	Recommended for listing as requested on the basis of the price being acceptable relative to the existing listed strengths of ramipril.
Risedronate tablet 30 mg (Actonel®)	A bisphosphonate for use in the treatment of Paget's disease.	Authority required listing for symptomatic Paget's disease of bone	Recommended for listing as requested on a cost-minimisation basis with 2 months therapy with

			risedronate 30 mg being equivalent to six months therapy with alendronate 40 mg.
Risedronate tablet 5 mg (Actonel®)	A bisphosphonate for use in the treatment of osteoporosis.	Authority required listing for established osteoporosis in patients with fracture due to minimal trauma.	Recommended for listing for post-menopausal patients on a cost-minimisation basis with risedronate 5 mg daily being equivalent to alendronate 10 mg daily.
Risperidone tablet 0.5 mg and oral solution 1 mg per mL, 30 mL. (Risperdal®)	An anti-psychotic drug	Authority required listing for schizophrenia.	Recommended for listing on the basis of the price being acceptable relative to the existing listed strengths and sizes of risperidone.
Triglycerides-medium chain, formula (Monogen®)	A food for inborn errors of metabolism	Restricted benefit listing for infants and young children with long chain fatty oxidation disorders; chyle leakage; intestinal lymphangectasia; hyperlipoproteinaemia type1; fat malabsorption due to liver disease or short gut syndrome.	Recommended for listing as requested on the basis of acceptable cost-effectiveness.