

Positive Recommendations made by the PBAC in March 2001

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION & COMMENTS
Atorvastatin calcium tablet 80 mg LIPITOR®	A lipid lowering agent	Restricted benefit listing for use in accordance with the qualifying criteria for lipid-lowering drugs	Recommended for listing as requested.
Biphasic insulin aspart 3 mL cartridge 100 IU, and 3 mL prefilled syringe 100 IU NOVOMIX 30®	Diabetes	Unrestricted listing.	Recommended for listing as requested.
Botulinum toxin type-A lyophilised powder for intramuscular injection, 100 unit vial BOTOX®	To relieve muscle spasms and contractions.	Section 100 for the treatment of cervical dystonia (spasmodic torticollis) when other pharmacological treatments have failed or are inappropriate.	Recommended for listing on a cost-minimisation basis compared with the Dysport (1 unit of Botox is equivalent to 3 Ipsen units of Dysport) brand of botulinum toxin for treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.
Buprenorphine sublingual tablets 400 micrograms, 2 mg and 8 mg SUBUTEX®	For opiate dependence	Section 100 for the treatment of opiate dependence, including maintenance and detoxification (withdrawal) within a framework of medical, social psychological treatment.	Recommended for listing as requested, on the basis of acceptable, but high, cost-effectiveness.
Didanosine enteric coated capsules 125 mg, 200 mg, 250 mg and 400 mg VIDEX®	HIV/AIDS	Section 100 for the treatment of HIV infection in patients with CD4 cell counts < 500 per mm ³ , or viral load of > 10, 000 copies per mL.	Recommended for listing as requested.

Epoetin alfa injections 5000 IU per 0.5 mL, 6000 IU per 0.6 mL, 7000 IU per 0.7 mL, 8000 IU per 0.8 mL, 9000 IU per 0.9 mL in pre-filled syringes EPREX®	Treatment of severe anaemia	Section 100 for treatment of anaemia requiring transfusion, associated with chronic renal failure.	Recommended for listing as requested.
Esomeprazole tablet 20 mg and 40 mg NEXIUM®	A treatment for severe reflux disease (similar to omeprazole).	Authority required listing for severe refractory ulcerating oesophagitis proven by endoscopy.	Recommended for listing as requested on the basis that 20 mg esomeprazole is equivalent to 20 mg omeprazole. The PBAC would have no objection to a restricted benefit listing if the price was reduced to be equivalent to that of pantoprazole.
Gemcitabine hydrochloride sterile powder for reconstitution for intravenous injection 200 mg and 1g vial GEMZAR®	Treatment for certain types of cancer	Authority required for the treatment of patients with bladder cancer.	Recommended for listing in combination with cisplatin for locally advanced or metastatic bladder cancer, on the basis of acceptable cost-effectiveness.
Hydromorphone hydrochloride tablets 2 mg, 4 mg and 8 mg DILAUDID®	Opioid pain killer	Restricted benefit listing for severe disabling pain not responding to non narcotic analgesics.	Listed as requested with 1 mg hydromorphone being considered equivalent to 4 mg oxycodone.
Indapamide tablet 2.5 mg DAPA-TABS ® - Alphapharm Pty Ltd	Diuretic for hypertension	Company seeks to substantiate the price premium over hydrochlorothiazide.	The PBAC accepted that there is some evidence to suggest that indapamide is marginally superior to thiazide diuretics.
Indapamide tablet 2.5 mg NATRILIX®		To substantiate the price premium over hydrochlorothiazide.	The PBAC accepted that there is some evidence to suggest that indapamide is marginally superior to thiazide diuretics.
Lansoprazole sachet containing granules for oral suspension, 30 mg ZOTON®	For severe reflux disease and peptic ulcer	Authority required listing as for the capsule formulation of the drug	Recommended for listing as requested. The PBAC would have no objection to a restricted benefit listing if the price was reduced to be equivalent to that of pantoprazole.

Lercanidipine hydrochloride tablet 10 mg ZANIDIP®	Hypertension	Unrestricted listing.	Recommended for listing as requested on the basis that 20 mg lercanidipine is equivalent to 10 mg amlodipine
Oestradiol with dydrogesterone tablet 1 mg - 5 mg FEMOSTON-CONTI®	Hormone replacement therapy	Unrestricted listing	Recommended for listing as requested on a cost-minimisation basis compared with other combination hormone replacement therapies.
Rosiglitazone tablets 4 mg and 8 mg AVANDIA®	An oral treatment for diabetics	Authority required for use in combination with metformin or sulphonylureas, where either metformin or sulphonylurea therapy is contraindicated or not tolerated.	Recommended for authority required listing for use in combination with metformin or sulphonylureas in type 2 diabetic patients whose blood glucose concentrations are inadequately controlled despite diet, exercise and maximal tolerated doses of metformin or sulphonylureas and in whom combination therapy with metformin plus sulphonylureas is contraindicated or not tolerated, on the basis of acceptable cost-effectiveness.
Tramadol hydrochloride sustained release tablet 100 mg, 150 mg, and 200 mg TRAMAL SR®	A sustained release pain reliever	Restricted benefit listing where aspirin and/or paracetamol alone are inappropriate or have failed.	Recommended for listing as requested on the basis of acceptable cost-effectiveness.