

Positive Recommendations made by the PBAC at the December 1999 meeting.

Drug and Formulation	Drug use/type	Listing Proposed	PBAC Recommendation and Comments
Botulinum Toxin Type A, injection 100 unit (Botox [®])	Currently listed for use in blepharospasm.	Section 100 listing for the treatment of dynamic equinus foot deformity due to spasticity in juvenile cerebral palsy patients two years of age or older.	Recommended for listing on the basis of acceptable cost-effectiveness.
Cabergoline, tablets 1 mg, 2 mg and 4 mg (Cabaser [®])	For suppression of lactation, treatment of hyperprolactinaemia and Parkinson's disease.	Authority required listing for the treatment of Parkinson's disease.	Recommended as being of similar safety and efficacy to bromocriptine.
Epoetin alfa injection 500 units in 0.25 mL (Eprex [®])	Anaemia associated with chronic renal failure.	Section 100 listing for the treatment of anaemia requiring transfusion, associated with chronic renal failure, where treatment is initiated in a hospital with a renal dialysis unit.	Recommended for listing as requested.
Eprosartan Mesylate, tablets 300 mg (base) and 400 mg (base) (Teveten [®])	Hypertension	Restricted benefit listing for treatment of hypertension	Recommended as being of similar safety and efficacy to enalapril.
Etonogestrel, subdermal insert 68 mg (Implanon [®])	Contraceptive implant	Restricted benefit listing for use when long-term contraception is required.	Recommended as being of similar safety and efficacy to medroxyprogesterone acetate.
Fosinopril sodium with hydrochlorothiazide, tablets 10 mg-12.5 mg and 20 mg-12.5 mg (Monoplus [®])	Hypertension	Authority required (as per the application cf. Restricted benefit in Executive summary). For the treatment of hypertension. Treatment should not be initiated with these combinations.	Recommended for listing as a restricted benefit for treatment of hypertension in patients not adequately controlled with either hydrochlorothiazide or fosinopril sodium monotherapy.
Gabapentin tablet 800 mg (Neurontin [®])	Anti-epileptic	Authority required listing for the treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.	Recommended for listing as requested.
Ganciclovir capsule 500 mg (Cymevene [®])	Cytomegalovirus (CMV)	Section 100 listing for: <ul style="list-style-type: none"> Maintenance therapy, after 	Recommended for listing as requested.

		<p>stabilisation with intravenous ganciclovir, of sight-threatening cytomegalovirus retinitis in severely immunocompromised patients;</p> <ul style="list-style-type: none"> • Primary prophylaxis of cytomegalovirus disease in liver, heart and bone marrow transplant patients at risk of CMV disease. 	
Hydromorphone hydrochloride, oral liquid 1 mg per mL, 473 mL and injections 2 mg per mL, 10 mg per mL, 50 mg per 5 ml and 500 mg per 50 mL	Narcotic anagesic	<p>Restricted benefit listing (with caution and note as per morphine sulfate)</p> <ul style="list-style-type: none"> • Dilaudid oral liquid and injections: first line treatment for severe disabling pain not responding to non-narcotic analgesics. • Dilaudid tablets: second line treatment for severe disabling pain not responding to non-narcotic analgesics and where treatment with morphine sulfate SR tablets is inappropriate. 	<p>Oral liquid recommended for listing for severe disabling pain not responding to non-narcotic analgesics. Caution and note to apply as for morphine. Injections recommended as unrestricted benefits. Caution to apply.</p> <p>Recommended as being of similar safety and efficacy to morphine.</p>
Indapamide hemihydrate tablet (sustained release) 1.5 mg (Natrilix SR [®])	Diuretic	Unrestricted listing	Recommended as being similar to the immediate release product indapamide 2.5 mg.
Insulin Lispro with Insulin Lispro Protamine 100 units (25 units-75 units) per mL, 3 mL cartridges	Type 2 Diabetes	Unrestricted listing	Recommended on the basis that the product warrants a similar price premium to that of plain insulin lispro over plain insulin injection.
Interferon beta-1a (Rebif [®]) two strengths 6 million units) and 12 million units solutions for injection	Treatment of multiple sclerosis.	Authority required listing for subcutaneous administration for relapsing-remitting multiple sclerosis.	Recommended on the basis of similar safety and efficacy to Avonex and Betaferon.
Interferon beta-1a (Avonex [®])	Treatment of multiple sclerosis.	Change the restriction to delete the requirement for neutralising antibody testing.	Accepted on the basis that the effect of these antibodies on the effectiveness if treatment with interferon beta is unclear.

Interferon beta-1b (Betaferon [®])	Treatment of multiple sclerosis.	To be considered as similar in terms of activity of neutralising antibodies.	Recommended removal of requirement of testing as for Avonex.
Irbesartan with hydrochlorothiazide, tablets 150 mg-12.5 mg and 300 mg-12.5 mg. (Avapro HCT [®] , Karvezide [®])	Hypertension	Authority required for the treatment of hypertension in patients who are not adequately controlled with irbesartan monotherapy and who would benefit from fixed combination therapy.	Recommended for listing as restricted benefit for hypertension in patients who are not adequately controlled with hydrochlorothiazide or irbesartan monotherapy.
Irinotecan Hydrochloride, injections 40 mg and 100 mg (Camptosar [®])	Anti-cancer agent used in colorectal cancer	Authority required listing for treatment of metastatic colorectal cancer after failure of 5FU-based therapy in patients with WHO performance status 2 or less.	Recommended on the basis of advantages in efficacy over best supportive care and fluoruracil.
Naltrexone tablet 50 mg (ReVia [®])	Treatment of alcohol and opioid dependence	<ul style="list-style-type: none"> Authority listing for use within a comprehensive treatment program for alcohol dependence. NOTE: Authorities for increased maximum quantities and/or repeats will not be authorised Authority listing for use as adjunctive therapy in the maintenance of formerly opioid-dependent patients who have ceased the use of opioids such as diamorphine (heroin) and morphine and have been demonstrated to be opiate-free and are seeking abstinence. Prescribers must refer to the product information document. 	<p>Recommended for authority required listing for use within a comprehensive treatment program for alcohol dependence with a goal of maintaining abstinence, with a caution 'Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs'. 'Note' recommended as requested.</p> <p>Recommended for listing as being similar to acamprosate (Campral).</p>
Octreotide Acetate, modified release injections 10 mg, 20 mg and 30 mg (Octreotide LAR [®])	Long-acting preparation for treatment of acromegaly, carcinoid	<p>Section 100 listing for:</p> <ul style="list-style-type: none"> Certain patients with active acromegaly and who are controlled on Sandostatin subcutaneous; 	Recommended on the basis of similar safety and efficacy to the short-acting product. It was considered to be more acceptable to patients on the basis that injections are given monthly as opposed to three times

	syndrome and VIPomas.	<ul style="list-style-type: none"> Certain patients with a histologically confirmed diagnosis of a functional carcinoid tumour or vasoactive intestinal peptide-secreting tumour (VIPoma) and who are controlled on Sandostatin subcutaneous. 	daily for the short-acting product.
Oestradiol valerate and oestradiol valerate with cyproterone pack containing 16 tablets 2 mg and 12 tablets 2 mg - 1mg (Climen [®] 28)	Hormone replacement therapy.	Unrestricted listing.	Recommended on the basis of similar safety and efficacy to other listed hormone replacement therapy products.
Ofloxacin eye drops 0.3% (Ocuflax)	Antibacterial eye drops.	Restricted benefit listing for treatment of bacterial keratitis.	Recommended as being similar to ciprofloxacin eye drops in this indication.
Pantoprazole sodium sesquihydrate tablet 20 mg (base) (Somac [®])	Proton pump inhibitor used in the treatment of peptic ulcer and reflux oesophagitis.	<ul style="list-style-type: none"> Transferring the present 40 mg tablet from authority required to restricted benefit for the 'initial treatment of peptic ulcer'. Listing of a 20 mg strength tablet. Listing of both the 20 mg and 40 mg tablets as restricted benefits for the treatment of 'reflux oesophagitis' 	Recommended with same authority required restriction in this indication as the 40 mg strength on the basis of similar safety and efficacy to other low strength proton pump inhibitors.
Sotalol tablet 80 mg (Sotacor [®])	Severe cardiac arrhythmias.	Restricted benefit listing for severe cardiac arrhythmias.	Recommended for listing as requested.
Troglitazone tablets 200 mg and 300 mg (Rezulin [®])	Oral treatment for type 2 diabetics.	Authority required listing for type 2 diabetics whose blood glucose concentrations are not adequately controlled, despite the concomitant use of oral antidiabetic agents or where metformin is contraindicated. Therapy should be initiated in a diabetic clinic.	Recommended on the basis of acceptable cost-effectiveness in the patient group covered by the restriction.