

Positive Recommendations Made by the PBAC at the March 2000 Meeting

Drug and Form	Drug Use/Type	Proposed Listing	Comments
Celecoxib capsules 100 mg and 200 mg  (Celebrex <sup>®</sup> )	Cox-2 inhibitor	Authority required listing for treatment of chronic arthropathies (including osteoarthritis) with an inflammatory component	Recommended for listing on the basis of acceptable cost-effectiveness with a restricted benefit restriction.
Cerivastatin sodium tablet 400 micrograms  (Lipobay <sup>®</sup> )	HMG CoA reductase inhibitor	Restricted benefit listing as for other PBS listed strengths of cerivastatin.	Recommended for listing as requested.
Clarithromycin tablet 500 mg (Klacid <sup>®</sup> )	Macrolide antibiotic	Unrestricted listing	Recommended for listing as requested.
Dofetilide capsules 125 mcg 250 mcg 500 mcg  (Tikosyn <sup>®</sup> )	Antiarrhythmic agent	Authority required listing for the management of atrial fibrillation or atrial flutter of at least one week's duration including the maintenance of sinus rhythm after reversion of atrial fibrillation or atrial flutter. Treatment is to be initiated as an in-patient in a hospital and monitoring as an in-patient is to be continued for at least three days.	Recommended for listing as requested based on comparison with sotalol and amiodarone.
Follitropin alfa 37.5 i.u. powder for injection with diluent  (Gonal-F <sup>®</sup> )	Gonadotropin	Restricted benefit listing (as applies to the other PBS listed strengths) for 1) treatment of anovulatory infertility in females under 41 years of age with no more than two live children by their present union; and  2) treatment of infertility in males due	Recommended for listing as requested.

		to hypogonadotropic hypogonadism, following failure of six months' treatment with human chorionic gonadotrophin (hCG) to achieve adequate spermatogenesis. Combined treatment with hCG should be given.	
Glimepiride tablets 1 mg 2 mg 4 mg  (Amaryl <sup>®</sup> )	Oral treatment for diabetes	Unrestricted listing	Recommended as an unrestricted benefit based on comparison with gliclazide
Insulin aspart 100 units per mL pre-filled syringe, cartridge and vial  (NovoRapid <sup>®</sup> )	Insulin analogue	Unrestricted listing	Recommended as an unrestricted benefit on the basis of comparison with insulin lispro.
Oestradiol and oestradiol with norethisterone acetate transdermal patch  (Estalis <sup>®</sup> 50/140 and Estalis <sup>®</sup> 50/250)	HRT	Restricted benefit listing for use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.	Recommended with the restriction requested on the basis of comparison with Estracombi.
Oestradiol with norethisterone acetate transdermal patch  (Aliatis <sup>®</sup> 50/140 and Aliatis <sup>®</sup> 50/250)	HRT	Restricted benefit listing for use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.	Recommended with the restriction requested on the basis of comparison with Estracombi
Pantoprazole sodium sesquihydrate sodium tablets 20 mg and 40 mg	Proton pump inhibitor	Amend current listing by increasing the number of repeats in severe refractory ulcerating oesophagitis from one to five	Recommended listing to be consistent with those for similar drugs

(Somac <sup>®</sup> )			
Repaglinide tablet 500 mcg 1 mg 2 mg  (NovoNorm <sup>®</sup> )	Oral treatment for type 2 diabetes	Treatment of type 2 diabetes or non-insulin dependent diabetic mellitus. <i>NovoNorm</i> treatment should be indicated when diet, physical exercise or weight reduction with other oral hypoglycaemic agents are not sufficient to control blood glucose levels. It should be used in combination with metformin when metformin alone has not given satisfactory blood glucose control.	Recommended on the basis of comparison with glibenclamide for treatment of type 2 diabetic patients.
Salmeterol/fluticasone Accuhaler 50/100 mcg/dose 50/250 mcg/dose 50/500 mcg/dose  (Seretide <sup>®</sup> MDI)	Combination inhalant preparation	Restricted benefit listing for patients with asthma, where use of a long-acting bronchodilator and an inhaled corticosteroid is appropriate.	Recommended on the basis of comparison with individual components as a restricted benefit for patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids and who are stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate.
Topiramate tablets 25 mg 50 mg 100 mg 200 mg and sprinkle capsules 15 mg and 25 mg  (Topamax <sup>®</sup> )	Antiepileptic	Change the restriction to – Treatment of partial epileptic seizures, primary generalised tonic clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not satisfactorily controlled by other antiepileptic drugs	Recommended as requested on the basis of comparison with lamotrigine on a mg per mg basis.
X Met Analog Powder 500 g	Food for medical condition	Restricted benefit listing for infants and very young children with proven homocystinuria that is not	Recommended for listing as requested.

		responsive, or not fully responsive, to pyridoxine therapy.	
X Met Maxamum <sup>®</sup> Powder 500 g	Food for medical condition	Restricted benefit listing for patients with proven homocystinuria that is not responsive, or not completely responsive to pyridoxine therapy.	Recommended for listing as requested.