

March 2007 PBAC Outcomes - Deferrals

Drug and Sponsor	Drug Use and Type	Listing requested by sponsor	PBAC Recommendation
Amino acid formula with vitamins and minerals without phenylalanine (ADD INS [®]) Scientific Hospitals Supples c/- Nutricia Australia Minor submission	Nutrient for inborn error of metabolism	Listing as a restricted benefit for phenylketonuria	The PBAC decided to defer consideration of this item for use in the dietary management of phenylketonuria following advice from the Nutritional Products Working Party that it wished to investigate further the absence of inositol and choline from Add Ins.
		Sponsor's comment	Nutricia looks forward to working with the PBAC to resolve this issue.
Mupirocin, cream 20 mg per g (2%), ointment 20 mg per g (2%), Nasal Ointment 20 mg per g (2%) (Bactroban [®]) GlaxoSmithKline Australia Pty Ltd Minor submission	Topical antibacterial	Listing as an authority required benefit for the treatment of mild impetigo (ointment and cream), and for the elimination of nasal carriage of staphylococci (nasal ointment) in Aboriginal and Torres Strait Islander persons.	The PBAC deferred consideration of this submission pending the reconsideration of the listing request by the indigenous health Advisory Panel, in light of the concerns expressed by the Expert Advisory Group on Antimicrobial Resistance.
		Sponsor's comment	The sponsor looks forward to working with the PBAC to resolve this issue.
Strontium ranelate, sachet for oral susp, 2 g, (Protos [®]) Servier Laboratories (Australia) Pty Ltd Minor submission	To treat osteoporosis	Requesting an extension to the authority required listing to include women aged 70 years or older with low bone mineral density (BMD) T-score of -3.0 or less and without prevalent fracture.	The PBAC considered that the analyses of the indirect comparison in this minor submission required evaluation by the Pharmaceutical Evaluation Section and therefore deferred the submission for this to occur.
		Sponsor's comment	No comment
Sunitinib malate, capsules, 12.5 mg, 25 mg and 50 mg (Sutent [®]) Pfizer Australia Pty Ltd Major submission	Anti cancer drug	Authority required listing for the treatment of advanced renal cell carcinoma (RCC)	The PBAC deferred consideration of this item pending the provision of further economic analyses to demonstrate that sunitinib is a cost effective treatment for renal cell carcinoma.
		Sponsor's comment	The sponsor is working with the PBAC to resolve the issues.
Sunitinib malate, capsules, 12.5 mg, 25 mg and 50 mg (Sutent [®]) Pfizer Australia Pty Ltd Major submission	Anti cancer drug	Section 100 special authority required listing for the treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate due to resistance or intolerance.	The PBAC decided to defer consideration of the submission pending the provision of further information to demonstrate that sunitinib is a cost effective treatment for gastro-intestinal tumour after failure of imatinib.
		Sponsor's comment	The sponsor is working with the PBAC to resolve the issues.

