APRIL 2013 PBAC SPECIAL MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
EVEROLIMUS, tablets, 2.5 mg, 5 mg and 10 mg, Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Tuberous sclerosis	Consideration of a managed entry scheme (MES), as outlined in the Memorandum of Understanding between the Commonwealth and Medicines Australia, as part of an application to amend the PBS listing of everolimus to include the treatment of patients with tuberous sclerosis complex (TSC).	The PBAC recommended listing of everolimus as an Authority required benefit for treatment of visceral manifestations of tuberous sclerosis complex on the basis of high clinical need, greater clinical benefit compared to current treatment and high but acceptable cost effectiveness. On the basis of the information available to it at the April 2013 meeting, the PBAC considered that there was no longer a requirement for a managed entry scheme approach.
LINAGLIPTIN + METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg and 2.5 mg-1000 mg, Trajentamet® Boehringer Ingelheim Pty Ltd	Diabetes	Authority Required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA_{1c} is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).	The PBAC recommended listing of linagliptin+metformin fixed dose combination (FDC) tablets as an Authority Required (STREAMLINED) benefit in patients whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin (i.e. without the requirement for patients to be contraindicated or intolerant of sulfonylureas). From the findings of the DUSC utilisation analysis, with specific regard to gliptin+metformin FDCs, the PBAC noted that a significant proportion of patients initiated on a regimen containing a gliptin+metformin FDC had been supplied only metformin as pre-initiation treatment (i.e., they had not been supplied a sulfonylurea). While the PBAC acknowledged that a proportion of these patients may have a true contraindication to sulfonylureas, the PBAC considered that this proportion would be small, and the majority were probably supplied gliptin+metformin FDCs under circumstances that were outside the current PBS criteria and where the cost-effectiveness of the treatment regimen had not been established. The PBAC therefore recommended listing of linagliptin+metformin FDC on a cost minimisation basis with the individual components for the proportion of use previously determined to be cost-effective, and on a cost minimisation basis with metformin plus the average daily dose of a sulfonylurea for the proportion of use where cost-effectiveness has not been established.

RIFAXIMIN, tablet, 550 mg, Xifaxan® Norgine Pty Ltd	Liver disease	Consideration of a managed entry scheme (MES), as outlined in the Memorandum of Understanding between the Commonwealth and Medicines Australia, as part of an application for the PBS Authority required listing of rifaximin for prevention of hepatic encephalopathy.	The PBAC recommended listing of rifaximin on the basis of high clinical need, improved clinical benefit over the existing treatments and acceptable cost effectiveness. On the basis of the information available to it at the April 2013 meeting, the PBAC considered that there was no longer a requirement for a managed entry scheme approach.
SAXAGLIPTIN WITH METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg, 2.5 mg-1000 mg, Kombiglyze® Bristol-Myers Squibb Australia Pty Ltd	Diabetes	Authority required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA_{1c} is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).	The PBAC recommended listing of saxagliptin+metformin fixed dose combination (FDC) tablets as an Authority Required (STREAMLINED) benefit in patients whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin (i.e. without the requirement for patients to be contraindicated or intolerant of sulfonylureas). From the findings of the DUSC utilisation analysis, with specific regard to gliptin+metformin FDCs, the PBAC noted that a significant proportion of patients initiated on a regimen containing a gliptin+metformin FDC had been supplied only metformin as pre-initiation treatment (i.e., they had not been supplied a sulfonylurea). While the PBAC acknowledged that a proportion of these patients may have a true contraindication to sulfonylureas, the PBAC considered that this proportion would be small, and the majority were probably supplied gliptin+metformin FDCs under circumstances that were outside the current PBS criteria and where the cost-effectiveness of the treatment regimen had not been established. The PBAC therefore recommended listing of saxagliptin+metformin FDC on a cost minimisation basis with the individual components for the proportion of use previously determined to be cost-effective, and on a cost minimisation basis with metformin plus the average daily dose of a sulfonylurea for the proportion of use where cost-effectiveness has not been established.