Drug and Form	TGA Indication	Current PBS Listing	Listing Requested by Sponsor	PBAC Outcome and Comments
Exenatide, powder for injection, 2 mg vial with diluent,Bydureon® Bristol-Myers Squibb Australia Pty Ltd Minor submission	Type 2 diabetes	Authority required (Streamlined) Dual oral combination therapy with metformin or a sulfonylurea Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient 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 either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. Authority required (Streamlined) Triple oral combination therapy with metformin and a sulfonylurea Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than	Listing requested: Authority required (Streamlined) for 1) Dual combination therapy with metformin or a sulfonylurea. 2) Triple combination therapy with metformin and a sulfonylurea	The PBAC rejected the re-submission for exenatide 2 mg once weekly on the basis of no new data presented to support the claims of comparative effectiveness and safety and unclear cost-offsets. The Committee considered that new and updated clinical and safety data (i.e. updated literature, clinical trials, cardiovascular effects data) must be presented in the submission in order to assess the initial claim of non-inferior comparative safety.

		7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea.		
			Comparator: The re-submission nominated exenatide administered twice daily as the main comparator.	This was the appropriate comparator and had been previously accepted by the PBAC in July 2011
			Clinical claim: The re-submission maintained the claim of superior efficacy associated with exenatide 2 mg once weekly over exenatide 10 mcg twice daily.	The PBAC noted that the submission did not provide any new clinical safety data comparing the two formulations to address the uncertainty in the claim of non-inferior safety versus the twice daily injection. The PBAC recalled that in July 2011, the PBAC considered that the submission's claim of non-inferior safety of exenatide once weekly to the twice a day injection was inappropriate, as the long-term safety of exenatide once weekly was unknown.
			Economic claim: The re-submission proposed a new price for exenatide 2 mg once weekly using a cost-minimisation analysis with exenatide 10 mcg twice daily as a price comparator. The re-submission claimed that the cost-offsets to PBS were associated with the reduced	The PBAC did not accept the submission's claim in cost-offsets in needles and additional patient co-payments.

			number of needles required for patients on exenatide once weekly and an increase in patient co-payments received with exenatide once weekly supply for 28 days compared to exenatide twice daily supply for 30 days.	
			Sponsor's comments:	Bristol- Myers Squibb Australia is committed to working with the PBAC to ensure that Bydureon is made available on the PBS.
Linezolid, tablet 600 mg, oral liquid 20 mg per mL, injection 600 mg per 300 mL, Zyvox® Pfizer Australia Pty Ltd Major submission	Antibiotic	Not currently PBS listed.	Listing requested: Authority required listing for treatment of microbiologically proven, multi-resistant methicillin-resistant Staphylococcus species (MRSS) infection in patients where no other antimicrobial agents can be used or treatment of microbiologically proven VRE infection.	The PBAC rejected the PBS listing of linezolid on the basis of incorrect comparator, and consequent lack of comparative data against the therapies most likely to be replaced. The PBAC noted issues in relation to the restriction wording for the treatment of MRSS
			Comparator: The submission nominated standard therapy, defined as continuation of inadequate, unapproved or no further therapy	The PBAC did not accept the submission's claim that non-TGA registered treatments were not appropriate comparators. The PBAC considered that the therapy most likely to be replaced should be the comparator, irrespective of the regulatory status of the antibiotic.
			Clinical claim: The submission described linezolid as superior in terms of comparative effectiveness and	The PBAC did not consider that the submission's claims were supported, as no comparative data was presented. The PBAC considered there were

			inferior in terms of comparative safety compared to standard therapy.	insufficient data to conclude that linezolid was superior in terms of efficacy versus “unapproved” therapy, including antimicrobials that may be effective for MRSS or VRE but are not PBS-listed or not TGA indicated. In terms of comparative safety, the PBAC expressed concerns about the toxicity and risk of developing antimicrobial resistance with linezolid.
			Economic claim: The submission included a modelled economic evaluation with a cost effectiveness analysis based on the claim of superior efficacy.	The PBAC considered that the economic analysis was consistent with the clinical claim, but not consistent with the clinical evidence as no comparative data were provided.
			Sponsor’s comments:	Due to the high clinical need for new antibiotics, Pfizer is disappointed with the PBAC’s decision.
Mometasone furoate, hydrogel, 0.1% (1 mg per g), 15g, Zatamil® Ego Pharmaceuticals Pty Ltd Minor submission	Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses such as psoriasis and atopic dermatitis	Not currently PBS listed		The PBAC rejected the requested listing on the basis of inadequate evidence provided on comparative effectiveness and safety for the new hydrogel formulation of mometasone furoate compared with the currently PBS-listed cream, lotion and ointment formulations of mometasone furoate. The PBAC remained unconvinced that there was a significant clinical need for a new formulation of mometasone, with the availability of the cream, ointment and lotion formulations.

			Listing requested: Restricted benefit listing for a 15 g hydrogel formulation for the treatment of corticosteroid-responsive dermatoses	
			Comparator: No comparator was specified	The PBAC presumed that the currently PBS-listed cream, lotion and ointment formulations of mometasone were the comparators.
			Clinical claim: No clinical claim was presented	The PBAC noted that as in March 2013 the sponsor did not provide a clinical claim in reference to the presumed comparators, however, it requested the same price as the presumed comparator. The PBAC further noted that there were no data presented to support the non-inferiority of the various formulations.
			Economic claim: No economic analysis was presented	
			Sponsor's comments:	We are working with the PBAC to resolve the issues.
Quetiapine, tablets, 50 mg, 150 mg, 200 mg and 300 mg, Seroquel XR®	Bipolar disorder Treatment of depressive episodes	Authority required (Streamlined) listing for schizophrenia Authority required	Listing requested: Authority required (Streamlined) listing for recurrent major depressive disorder as augmentation to current	The PBAC rejected quetiapine as augmentation for treatment resistant major depression on the basis that non-inferior comparative effectiveness and safety with the comparator, lithium,

AstraZeneca Pty Ltd Major submission	associated with bipolar disorder Schizophrenia Major Depressive Disorder Generalised anxiety disorder	(Streamlined) listing for monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder Authority required (Streamlined) listing for maintenance treatment of bipolar I disorder	antidepressant therapy in patients treated by a psychiatrist or a general practitioner in consultation with a psychiatrist who have had inadequate response to two prior antidepressant therapies	had not been established. The PBAC noted that the restriction proposed in this resubmission specified that treatment must be as augmentation to current antidepressant therapy, following inadequate response to two prior antidepressant therapies. The PBAC considered the proposed restriction to be appropriate.
			Comparator: The re-submission nominates lithium as the main comparator.	The PBAC considered this reasonable and accepted lithium as the comparator.
			Clinical claim: This re-submission has revised the clinical claim to non-inferiority versus lithium augmentation. In terms of safety, the re-submission claim remains unchanged	Based on the data presented in this re-submission, the PBAC did not consider that the claim of non-inferior comparative effectiveness and safety was adequately supported.
			Economic claim: A cost-minimisation analysis based on a claim of non-inferiority is presented. The November 2011 submission presented a cost-effectiveness model.	The PBAC considered that the validity of the resubmission's economic results were affected by its reliance on results of one six-week open-label trial to indicate long-term constant efficacy in light of the lack of adequate follow-up and the missing data addressed by last observation carried forward (LOCF). The PBAC also considered that insufficient evidence was provided to demonstrate the applicability of the RUBY trial to the proposed PBS

				population
			Sponsor's comments	The sponsor has no comment