

NOVEMBER 2018 PBAC OUTCOMES – 1ST TIME DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ALEMTUZUMAB</p> <p>Solution concentrate for I.V. infusion 12 mg in 1.2 mL</p> <p>Lemtrada®</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Relapsing remitting multiple sclerosis (RRMS)</p>	<p>To request a change to the existing listing to allow for retreatment of RRMS with two additional courses of treatment in patients who have had an initial two courses of treatment.</p> <p>Sponsor Comment:</p>	<p>The PBAC did not recommend the request to increase the price per vial for alemtuzumab for relapsing remitting multiple sclerosis (RRMS) based on a claim of extended clinical benefit from two years to six years. The PBAC also did not recommend a change to the current listing to include an additional continuation restriction for the third and fourth courses of alemtuzumab for patients with RRMS who meet proposed re-treatment criteria.</p> <p>The PBAC did not accept the main comparator presented in the resubmission of two courses of PBS-funded alemtuzumab plus up to two additional courses of treatment as currently supplied by the sponsor. The PBAC noted that no comparative claims of efficacy or safety compared to fingolimod or natalizumab (or ocrelizumab or cladribine) were made in the resubmission. The PBAC concluded that the clinical evidence presented in the resubmission was insufficient to support the claimed extended clinical benefit of alemtuzumab to six years which formed the basis of the two requests.</p> <p>Sanofi will continue to explore options to address the issues raised by the PBAC in the hope of gaining recognition of the long-term benefit that Lemtrada provides and to be able to provide access to additional courses for patients who would benefit from further treatment.</p>
<p>APALUTAMIDE</p> <p>Tablet 60 mg</p> <p>Erlyand®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Castration resistant prostate cancer</p>	<p>To request an Authority Required listing for the treatment of non-metastatic castration resistant prostate cancer in combination with androgen deprivation therapy.</p>	<p>The PBAC did not recommend the listing of apalutamide for the treatment of non-metastatic castration-resistant prostate cancer. The PBAC considered that apalutamide provided a substantial benefit to some patients in delaying metastases but the survival benefit was uncertain as the trial data were immature. The PBAC noted the consumer comments and acknowledged the potential quality of life benefits associated with delaying metastasis and symptomatic progression. The PBAC considered that the appropriate treatment pathway is unclear as there are insufficient data demonstrating the degree of efficacy of abiraterone or enzalutamide after treatment with apalutamide. The PBAC considered that it is likely that other treatments, such as enzalutamide, are likely to enter the same market space as apalutamide. The PBAC advised that the incremental cost-effectiveness ratio was underestimated due to the estimated gain in overall survival being implausibly high in the economic analysis presented.</p>

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		Sponsor Comment:	Jansen was disappointed with the PBAC's decision not to recommend apalutamide (ERLYAND®). Janssen welcomes the PBAC'S acknowledgment of the substantial benefit in delaying metastases and maintain that apalutamide is associated with a survival advantage. Janssen will continue to work towards a listing for this important product in the treatment of prostate cancer.
<p>BUPRENORPHINE</p> <p>Injection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringe Injection 24 mg in 0.48 mL pre-filled syringe Injection 32 mg in 0.64 mL pre-filled syringe Injection 64 mg in 0.18 mL pre-filled syringe Injection 96 mg in 0.27 mL pre-filled syringe Injection 128 mg in 0.36 mL pre-filled syringe</p> <p>Buvidal®</p> <p>Camurus AB</p> <p>New listing (Major Submission)</p>	Opiate dependence	<p>To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.</p> <p>Sponsor comment:</p>	<p>The PBAC did not recommend the listing of prolonged buprenorphine injection for treatment of patients with opiate dependence. The PBAC acknowledged that there may be additional benefits of treatment with prolonged buprenorphine compared to existing treatments for some patients, however it considered that the claim of superior comparative effectiveness was not adequately supported by the evidence provided, and therefore that the price premium over existing treatments was not justified.</p> <p>The Company refers to published scientific data and the ("label") regarding the comparative effectiveness of the prolonged buprenorphine injection. Whilst disappointed with the PBAC's decision on the initial application, the Company remains positive and convinced of the benefit of the prolonged release of this patient group, and will continue to seek PBS reimbursement based on the advice from PBAC.</p>

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<p>CARFILZOMIB</p> <p>Powder for injection 30 mg Powder for injection 60 mg</p> <p>Kyprolis®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Multiple myeloma</p>	<p>To request an amendment to the restriction for pomalidomide (sponsored by Celgene Pty Limited) to allow the use of any proteasome inhibitor (bortezomib or carfilzomib) prior to treatment with pomalidomide.</p>	<p>The PBAC decided not to recommend a change to the pomalidomide restriction to allow the use of any proteasome inhibitor (bortezomib or carfilzomib) prior to treatment with pomalidomide, rather than bortezomib, specifically. The PBAC noted the proposed change to the pomalidomide restriction was not supported by trial evidence, and there is a risk of loss of cost-effectiveness for pomalidomide use. The PBAC also noted that no costings were provided for the change to the pomalidomide restriction and that no evidence was presented for there being a major need for this change from the patient or clinical community. The PBAC considered that while there is merit in the request, deficiencies in stakeholder consultation, evidence and cost assessment precluded a positive recommendation. The PBAC noted the request for change was not from the sponsor of pomalidomide, and that any such change would require consultation with the sponsor.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX</p> <p>Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units</p> <p>Dysport®</p> <p>Ipsen Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Spasticity of the lower limb</p>	<p>To extend the current Section 100 (Botulinum Toxin Program) listing to include the treatment of patients with moderate to severe spasticity of the lower limb following an acute event.</p> <p>Sponsor Comment:</p>	<p>The PBAC did not recommend the PBS listing of Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) for the treatment of adult patients with moderate to severe spasticity of the lower limbs following an acute event. Although considering that there was a clinical need, the PBAC did not recommend Dysport® on the basis of uncertain clinical effectiveness, a high and uncertain incremental cost-effectiveness ratio (ICER) which was based on a flawed economic evaluation and uncertain financial impact estimations.</p> <p>The PBAC considered that Dysport® was not superior compared to placebo in terms of effectiveness in the treatment of focal spasticity of the lower limb following an acute event. Although the key trial demonstrated a small, statistically significant improvement in Modified Ashworth Scale (MAS) score at Weeks 4 and 12, the results were not clinically significant as they did not exceed the predefined minimal clinically important difference (MCID) of at least one MAS point. The PBAC also noted the non-significant difference in the proportion of responders. The PBAC further noted that there were no significant differences between Dysport® and placebo in terms of walking speed at Week 4 or 12 in the key trial, Study 140. The PBAC considered that Dysport® was inferior in terms of safety compared to placebo.</p> <p>The PBAC considered that the premise of the economic evaluation was flawed as it modelled an improvement in walking speed, which was based on a post-hoc subgroup analysis of a non-statistically different outcome, and a consequential improvement in quality of life, which was not demonstrated in the trial, for patients treated with Dysport®. This resulted in a highly uncertain ICER.</p> <p>The PBAC, noting the advice from DUSC, considered that the utilisation estimates were uncertain.</p> <p>The sponsor had no comment.</p>

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<p>CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX</p> <p>Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units</p> <p>Dysport®</p> <p>Ipsen Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Spasticity of the upper limb</p>	<p>To extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of patients with moderate to severe spasticity of the upper limb following an acute event, and to remove the current restriction on the number of treatment periods in a lifetime</p>	<p>The PBAC did not recommend an extension of the current PBS listing for Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) for treatment of moderate to severe focal spasticity of the upper limb following a stroke, to include spasticity following an acute event other than stroke, on the basis of uncertain clinical benefit, uncertain cost-effectiveness, and high and uncertain financial impact.</p> <p>The PBAC considered that the benefit of Dysport® compared to placebo in the treatment of focal spasticity of the upper limb following an acute event other than stroke could not be assessed as these patients were poorly represented in the key trial. The PBAC considered that the subgroups of patients with spasticity following a traumatic brain injury were very small and analyses were post-hoc and not powered to detect statistical significance. The PBAC noted that no evidence was presented for upper limb spasticity due to other aetiologies such as spinal cord injury, hypoxia or infection.</p> <p>The PBAC, noting that the submission did not make a claim regarding the safety of Dysport®, considered that Dysport® was inferior compared to standard of care/placebo.</p> <p>The PBAC recalled that it accepted a cost per responder analysis of less than \$15,000 when considering Dysport® for the treatment of upper limb focal spasticity following a stroke (November 2007, Dysport® PSD). The PBAC noted that the cost per responder, when response was defined as a MAS improvement of greater than one using the historical MAS coding convention, was considerably higher. The PBAC also noted that the estimated cost per responder was driven by response in stroke patients making the applicability of the results to patients with upper limb spasticity following an acute event other than stroke uncertain.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>CRISABOROLE</p> <p>Ointment containing crisaborole 20 mg per g, 60 g</p> <p>Staquis®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Atopic dermatitis</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of mild to moderate atopic dermatitis in patients who have failed to achieve satisfactory disease control with, or are contraindicated to, topical corticosteroids.</p>	<p>The PBAC did not recommend the listing of crisaborole for the treatment of mild to moderate atopic dermatitis due to omission of a relevant comparator, uncertainty regarding the appropriate place in therapy, uncertain comparative efficacy and highly uncertain cost effectiveness.</p>
		<p>Sponsor Comment:</p>	<p>Pfizer Australia is pleased that the PBAC acknowledged the value of treatments for atopic dermatitis and is committed to working with the PBAC to enable reimbursed access to crisaborole.</p>
<p>DURVALUMAB</p> <p>Solution for I.V. infusion 120 mg in 2.4 mL</p> <p>Solution for I.V. infusion 500 mg in 10 mL</p> <p>Imfinzi®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Non-small cell lung cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III non-small cell lung cancer.</p>	<p>The PBAC did not recommend the listing of durvalumab as an adjuvant (consolidation) treatment for Stage III non-small-cell lung cancer (NSCLC) in patients who have not progressed following chemoradiotherapy. The PBAC noted that some patients (~25%) are cured by chemo-radiotherapy and hence consolidation treatment with durvalumab would expose this group of patients to treatment without benefit. The PBAC however acknowledged that adjuvant treatment with durvalumab may reduce the risk of recurrence of NSCLC in some patients who have not been cured by chemo-radiotherapy. However, given the immaturity of the trial data and the unknown impact of subsequent treatment with an immunotherapy agent on progression, the extent of effect on overall survival could not be determined. The Committee considered that the uncertainty surrounding the magnitude of benefit of durvalumab in this setting resulted in a highly uncertain and potentially very high incremental cost-effectiveness ratio. The PBAC also noted the high total cost of subsidising durvalumab in this setting.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>FLUTICASONE PROPIONATE with EFORMOTEROL</p> <p>Pressurised inhalation containing fluticasone propionate 50 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses; Pressurised inhalation containing fluticasone propionate 125 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses; Pressurised inhalation containing fluticasone propionate 250 micrograms with formoterol fumarate dihydrate 10 micrograms per dose, 120 doses</p> <p>Flutiform® 50/5, 125/5, 250/10</p> <p>Mundipharma Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Asthma</p>	<p>To request the current Authority Required (STREAMLINED) listing be amended to a Restricted Benefit.</p>	<p>The PBAC did not recommend amending the current Authority Required (STREAMLINED) listing of fluticasone propionate with formoterol fumarate dihydrate pressurised inhalation (fluticasone/formoterol) to a Restricted Benefit listing. The PBAC did not accept the minor submissions claim that fluticasone/formoterol should not be covered by PBAC decisions from the Post-Market Review of PBS Medicines Used to Treat Asthma in Children, as it is not TGA nor PBS-indicated for use in children below 12 years of age. The PBAC considered that concerns regarding high levels of initiation of asthma treatment with inhaled corticosteroid (ICS) plus long-acting β2-agonist (LABA) fixed dose combinations (FDC) rather than an ICS alone were relevant to both children and adults with the condition. As such the PBAC reaffirmed its March 2018 recommendation to increase the restriction level to Authority Required (STREAMLINED) for all ICS/LABA FDC inhalers to encourage prescribers to consider first line treatment with ICS alone in asthma management.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>OBETICHOLIC ACID</p> <p>Tablet 5 mg Tablet 10 mg</p> <p>Ocaliva®</p> <p>Emerge Health Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Primary biliary cholangitis</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with primary biliary cholangitis.</p>	<p>The PBAC did not recommend the listing of obeticholic acid (OCA) as a second-line agent in the treatment of primary biliary cholangitis (PBC). Although acknowledging the clinical need for effective PBC treatments, the PBAC considered that the magnitude of the clinical benefit was uncertain, the incremental cost-effectiveness ratio (ICER) was unacceptably high and unreliable and the estimated financial impact was high.</p> <p>Although the PBAC considered that the therapeutic claim of superior effectiveness for OCA plus ursodeoxycholic acid (UDCA) compared to UDCA monotherapy in patients who were inadequate UDCA responders was reasonable, it noted that the magnitude of the benefit was uncertain. The PBAC considered that the claim of non-inferior safety in this population was not reasonable.</p> <p>The PBAC could not assess the efficacy or safety of OCA monotherapy against placebo in patients who were intolerant to UDCA due to insufficient data.</p> <p>The PBAC considered that the economic model presented in the submission lacked transparency and clinical plausibility and was not sufficiently valid to inform decision making. The PBAC considered that the ICERs presented in the submission were unacceptably high, sensitive to changes in key variables and should be interpreted with caution.</p> <p>The PBAC noted the financial impact of OCA was high, particularly considering the uncertainty of the magnitude of the clinical benefit and the unreliability of the ICER.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Melanoma</p>	<p>To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as an adjuvant to complete surgical resection for Stage III or Stage IV malignant melanoma.</p>	<p>The PBAC did not recommend listing of pembrolizumab as an adjuvant treatment for completely resected Stage III melanoma. The PBAC acknowledged that there was a high unmet clinical need for effective therapies to reduce the risk of recurrence of resected Stage III melanoma, and considered that in some circumstances recurrence was less likely for those treated with pembrolizumab compared to placebo. However, the PBAC noted the prognosis for Stage III patients varied widely depending on staging subgroup and considered the appropriate population for treatment had not been identified in the submission.</p> <p>The primary outcome of the key trial, KN054, was recurrence free survival (RFS). The PBAC noted that the data were immature and, that at the median duration of follow-up (16 months), the median RFS for pembrolizumab had not been reached. The hazard ratio was 0.57 (95% confidence interval: 0.43, 0.74). The PBAC considered that the submission's claim that pembrolizumab was superior to placebo in terms of RFS, based on the interim analysis of KN054, was reasonable for the trial population. However, due to the immaturity of the trial data, the PBAC considered that the magnitude of the treatment effect was highly uncertain and the impact on overall survival was unknown. The PBAC considered the magnitude of RFS benefit for patients with Stage IIIA (metastases > 1 mm) was highly uncertain due to the small proportion of patients with this sub-stage of disease recruited into the trial.</p> <p>The PBAC considered, given the uncertainty in the magnitude of the clinical benefit and the limited duration of follow-up in the trial, that the incremental cost-effectiveness ratio (ICER) was highly uncertain, variable and likely to be underestimated. In addition, the estimated financial impact was very high and uncertain.</p>
		<p>Sponsor Comment:</p>	<p>MSD is disappointed with the rejection of pembrolizumab in this indication. MSD is committed to working with the PBAC to find a solution to make pembrolizumab available to these patients on the PBS.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the treatment of EGFR wildtype ALK translocation negative non-squamous NSCLC.</p>	<p>The PBAC did not recommend listing of pembrolizumab for the first line treatment of Stage IV NSCLC in combination with pemetrexed and platinum chemotherapy, on the basis that in patients with a programmed death ligand 1 (PD-L1) tumour proportion score (TPS) $\geq 50\%$ the available evidence does not support there being an additional benefit, in terms of efficacy, for combination treatment over pembrolizumab monotherapy and because the safety of combination treatment appears worse than monotherapy treatment in this patient group. In patients with a PD-L1 TPS $< 50\%$ there is uncertainty in the magnitude of the incremental benefit, if any, over the alternative therapy of chemotherapy followed by a PD-(L)1 inhibitor.</p> <p>Furthermore, the PBAC formed the view, based on the totality of the evidence now available, that PD-L1 expression status alone is insufficient in determining which patients with NSCLC should be offered PD-(L)1 inhibitor therapy. The PBAC considered that a listing that made pembrolizumab available to patients as a first line treatment for Stage IV NSCLC irrespective of PD-(L)1 status was appropriate but noted that this would require a reduction in the proposed price. The PBAC also noted the high estimated cost of subsidising pembrolizumab in this setting at the proposed price.</p>
		<p>Sponsor Comment:</p>	<p>MSD strongly disagrees with this decision and stands by the superior overall survival benefit of pembrolizumab in combination with chemotherapy when compared to chemotherapy alone as well as the relevance of the PD-L1 biomarker in non-squamous non-small cell lung cancer. MSD is very concerned about the impact this decision will have on patients with non-squamous non-small cell lung cancer who could have benefited from treatment.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Primary mediastinal B-cell lymphoma (PMBCL)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with relapsed or refractory PMBCL who meet certain conditions.</p>	<p>The PBAC did not recommend the listing of pembrolizumab for the treatment of relapsed or refractory primary mediastinal large B-cell lymphoma (PMBCL). The PBAC considered that the incremental effectiveness versus standard of care chemotherapies was uncertain because the pembrolizumab trial data were immature and the control data used in the submission were not contemporary. Thus, the cost-effectiveness was unknown.</p> <p>The PBAC considered there was a high unmet clinical need for effective treatments for relapsed or refractory PMBCL, particularly given the poor outcomes in patients with this condition. The PBAC advised that more mature trial data would help inform a resubmission.</p>
		<p>Sponsor Comment:</p>	<p>MSD is disappointed with the outcome of this submission but will continue to work with the PBAC and the Department of Health to ensure that patients with this rare lymphoma will have access to pembrolizumab on the PBS.</p>

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<p>PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 13-VALENT ADSORBED</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Prevenar-13®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Prevention of pneumococcal disease</p>	<p>To expand the current National Immunisation Program (NIP) listing to include:</p> <ul style="list-style-type: none"> - children aged 5 to 14 years; - adults aged 15 to 64 years with increased risk of pneumococcal disease; and - Aboriginal and Torres Strait Islander adults aged 25 years and older. <p>Sponsor Comment:</p>	<p>The PBAC decided not to recommend a change to the circumstances under which 13 valent pneumococcal conjugate vaccine (13vPCV) is available as a designated vaccine for the National Immunisation Program (NIP). Specifically, the PBAC decided not to recommend vaccination of individuals with an at-risk condition (aged ≥5 to <65 years) and Indigenous adults (aged ≥25 years) on the basis of unacceptably high and uncertain incremental cost effectiveness ratios (ICERs).</p> <p>In the absence of direct comparative evidence or an indirect statistical comparison for 13vPCV and 23vPPV, the PBAC accepted 13vPCV is likely to be superior to 23vPPV for the prevention of community acquired pneumonia (CAP) caused by the serotypes in 13vPCV but considered that the magnitude of superiority was uncertain. The PBAC further considered 13vPCV is likely to be superior for the prevention of IPD caused by the serotypes common to both vaccines and is inferior to 23vPPV for the prevention of IPD caused by serotypes contained only within 23vPPV (23v non-13v serotypes). The comparative clinical effectiveness of 13vPCV for the prevention of IPD is therefore dependent on the relative contribution of the serotypes in 13vPCV, compared with 23v-non-13v serotypes, over time. If 13vPCV serotypes are substantially reduced as a result of the infant 13vPCV vaccination program, 13vPCV may become inferior to 23vPPV for IPD. In this regard, the PBAC recalled that it recently recommended a change to the dosing schedule for the 13vPCV infant program which is expected to further decrease IPD rates [caused by those serotypes in 13vPCV] in the 0-4 year age group (March 2018 13vPCV PSD, paragraph 6.3).</p> <p>The PBAC considered that the ICERs presented in the submission were unacceptably high and sensitive to the assumed duration and scope of protection with 13vPCV. The PBAC was therefore not confident that 13vPCV for the proposed population would be cost effective at the requested price.</p> <p>Pfizer Australia is disappointed that the PBAC did not recommend the NIP-listing of Prevenar 13 for individuals at increased risk of pneumococcal disease and remains committed to working with the PBAC to enable reimbursed access for this population.</p>

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<p>ROMOSOZUMAB</p> <p>Injection 105 mg in 1.17 mL pre-filled pen Injection 105 mg in 1.17 mL pre-filled syringe</p> <p>Evenity®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Osteoporosis</p>	<p>To request an Authority Required listing for the treatment of patients with severe osteoporosis.</p>	<p>The PBAC did not recommend the listing of romosozumab for the treatment of severe osteoporosis due to uncertainties in the clinical claims and the financial estimates and concerns regarding the safety profile. The PBAC considered that the cost-minimisation analysis and financial estimates for the comparison versus teriparatide (in the 'later-line' population) were unreliable. For the comparison versus alendronate (in the 'additional' population), the PBAC considered that the long-term comparative efficacy was uncertain, and the economic model was not a reliable basis for decision making. For both comparisons, the PBAC considered that romosozumab had inferior comparative safety (versus teriparatide or alendronate).</p> <p>The PBAC considered there is a clinical need for additional options for the treatment of severe osteoporosis in later-line settings given the more limited alternative therapies available in this setting. The PBAC considered the risk of cardiac adverse events with romosozumab may be more manageable in a small population of patients with a higher level of fracture risk and more limited alternative treatment options.</p>
		<p>Sponsor Comment:</p>	<p>Amgen will continue to work with the PBAC to make romosozumab available on the PBS for patients with severe osteoporosis.</p>

NOVEMBER 2018 PBAC OUTCOMES – 1ST TIME DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>VARICELLA ZOSTER RECOMBINANT VACCINE</p> <p>Injection [1 vial] (&) adjuvant substance diluent [0.5 mL vial], 1 pack</p> <p>Shingrix®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Prevention of herpes zoster</p>	<p>To request National Immunisation Program (NIP) listing for the prevention of herpes zoster in adults aged 60 years with a 5 year catch-up program for persons aged over 60 years.</p>	<p>The PBAC did not recommend the listing of the varicella zoster virus vaccine (HZ/su) on the National Immunisation Program (NIP) for the prevention of herpes zoster in adults aged 60 years, with a five year catch-up program. The PBAC considered that there was some uncertainty in the magnitude of the clinical benefit, that the incremental cost-effectiveness ratios (ICER) were highly uncertain and that the estimated financial impact was high and uncertain. Given the very large opportunity cost, the PBAC considered more conservative cost-effectiveness analyses were required.</p> <p>The PBAC noted that the submission did not include an evaluation of NIP-funded HZ/su vaccine at a lower age threshold of at least 50 years for Indigenous individuals (who have a greater burden of disease) or people who are immunocompromised as a result of underlying medical conditions or treatment (unmet need).</p> <p>The submission provided clinical and economic comparisons between the HZ/su vaccine and placebo for individuals aged 60 years and 80 years and between HZ/su and the live zoster virus vaccine (live-HZ) for those aged 70 years of age. The PBAC considered, based on the results of the two key trials (ZOE-50 and ZOE-70), that the HZ/su vaccine was more effective than placebo in individuals aged 60 years and 80 years. The PBAC also considered, based on the results of an indirect comparison, that HZ/su was more effective than the live-HZ vaccine. The PBAC considered that the magnitude and duration of the benefit for both comparisons was uncertain.</p> <p>In terms of the economic analyses, the PBAC had a number of concerns and considered that more conservative inputs should be modelled. The PBAC considered that a comparison of the HZ/su vaccine in 60 year olds with the HZ-live vaccine in 70 year olds would be required to assess the cost-effectiveness of the proposed new varicella-zoster vaccine program versus the current program.</p>
		<p>Sponsor Comment:</p>	<p>GSK will continue to work with the PBAC to gain NIP listing for Shingrix to enable access to this important vaccine for Australians.</p>