

MONTH YEAR PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>APALUTAMIDE</p> <p>Tablet 60 mg</p> <p>Erlyand®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>The treatment of non-metastatic, castration-resistant prostate cancer.</p>	<p>Apalutamide is not currently listed on the PBS</p>	<p>Resubmission 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 patients with non-metastatic castration-resistant prostate cancer who are at high risk of distant metastases.</p> <p>The PBAC considered that apalutamide provided a substantial benefit to some patients in delaying metastases; however, the magnitude of the survival benefit was uncertain. The PBAC considered that the incremental cost-effectiveness ratio (ICER) was high and uncertain, and that a price reduction would be required to bring the ICER into an acceptable range.</p>
			<p>Comparator: watchful waiting (placebo)</p>	<p>The PBAC considered watchful waiting (placebo) remains the appropriate comparator.</p>
			<p>Clinical claim: a statistically significant and clinically important improvement in survival compared with watchful waiting.</p>	<p>The PBAC considered that apalutamide provided a substantial benefit to some patients in delaying metastases; however, the magnitude of the survival benefit was uncertain.</p>
			<p>Economic claim: cost-utility analysis compared with watchful waiting.</p>	<p>The PBAC considered that the inclusion of an OS difference in the economic analysis was supported, though the magnitude of benefit remains uncertain. The PBAC considered that the ICER was underestimated in the model base case presented and a price reduction would be required to bring the ICER into an acceptable range.</p>
			<p>Sponsor's comment:</p>	<p>The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen-Cilag Pty Ltd) is disappointed with the PBAC's decision not to recommend the PBS listing of ERLYAND® (apalutamide) for the treatment of Australian men with high-risk non-metastatic castration-resistant prostate cancer.</p> <p>Janssen's priority is to ensure access to ERLYAND® so</p>

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				that Australian men with high-risk non-metastatic castration-resistant prostate cancer may benefit from treatment. We will review the reasons for the decision and continue to work with the PBAC and the Department of Health towards this goal.
<p>BEZLOTOXUMAB</p> <p>Solution concentrate for I.V. infusion</p> <p>1000 mg in 40 mL</p> <p>Zinplava®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>The prevention of recurrence of <i>Clostridium difficile</i> infection (CDI) in adult patients 18 years or older at high risk for recurrence of CDI who are receiving antibiotic therapy for CDI.</p>	<p>Bezlotoxumab is not currently listed on the PBS.</p>	<p>Resubmission to request a Section 100 Authority required listing for the treatment of patients at high risk (≥2 of 4 risk factors) of CDI.</p> <p>Comparator: Placebo</p> <p>Clinical claim: Superior comparative effectiveness and non-inferior comparative safety compared with placebo.</p> <p>Economic claim: Cost-effectiveness basis compared with standard of care (oral antibiotics).</p>	<p>The PBAC did not recommend the listing of bezlotoxumab on the PBS for the prevention of CDI on the basis of the proposed patient population being inadequately justified, its modest effectiveness, and concerns regarding safety, along with a high and uncertain incremental cost-effectiveness ratio (ICER) and uncertain financial estimates.</p> <p>The PBAC previously accepted that the comparator was placebo.</p> <p>The PBAC accepted the claim of superior comparative efficacy of bezlotoxumab compared with placebo, although the PBAC considered that the magnitude of benefit was modest.</p> <p>The PBAC did not accept the claim of non-inferior comparative safety as it considered there was an increased risk of exacerbation of congestive heart failure for patients treated with bezlotoxumab remained.</p> <p>The PBAC noted the base case ICER in the resubmission was highly sensitive to the assumed CDI recurrence rates and it was uncertain whether CDI recurrence rates reported in the MODIFY trials were applicable to the Australian setting. The PBAC further noted that the ICER was uncertain due to the assumed mortality benefit not being supported by the trial data and the reduced efficacy in the trials in patients aged less than 65 years. The PBAC noted the lower effective price proposed in the pre-PBAC response, however</p>

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				considered the resulting ICER unreliable for the aforementioned reasons.
<p>DENOSUMAB</p> <p>Injection 120 mg in 1.7 mL</p> <p>Xgeva®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>The prevention of skeletal related events in patients with multiple myeloma and in patients with bone metastases from solid tumours.</p>	<p>Denosumab is currently PBS listed for giant cell tumour of bone, bone metastases from breast cancer or from castrate resistant prostate cancer, and osteoporosis in patients with a bone mineral density T-score of -2.5 or less.</p>	<p>Resubmission to request an extension of the current Authority Required (STREAMLINED) listing to include patients with multiple myeloma who have renal impairment.</p> <p>Comparator: zoledronic acid and pamidronate.</p> <p>Clinical claim: non-inferior comparative effectiveness for prevention of skeletal related events, superior comparative safety due to a lower incidence of renal adverse events.</p> <p>Economic claim: cost-utility compared with zoledronic acid, with cost-offsets for infusion costs.</p> <p>Sponsor's comment:</p>	<p>MSD is disappointed in the PBAC outcome and will continue working to provide access for Australian patients with CDI.</p> <p>The PBAC did not recommend extending the current listing of denosumab to include the treatment of patients with multiple myeloma who have renal impairment.</p> <p>The PBAC accepted that zoledronic acid and pamidronate were appropriate comparators.</p> <p>Although the clinical evidence indicated likely non-inferiority to zoledronic acid for the outcome of skeletal-related events, the PBAC considered there was an inadequate basis for accepting the claim of superior safety compared with zoledronic acid.</p> <p>The PBAC considered that the incremental cost-effectiveness based on renal adverse events avoided was not reasonable, as the analysis did not adequately capture the differences in safety profiles between the therapies.</p> <p>No comment</p>
<p>DUPILUMAB</p> <p>Injection 300 mg in 2 mL single use pre-filled syringe</p>	<p>The treatment of moderate to severe atopic dermatitis (AD) in adult patients who are candidates for chronic</p>	<p>Dupilumab is not currently listed on the PBS.</p>	<p>Resubmission to request an Authority Required listing for the treatment of chronic, moderate to severe AD in patients who have had an inadequate response to topical therapies.</p>	<p>The PBAC did not recommend dupilumab for the treatment of adult patients with moderate-to-severe AD who are inadequately controlled on topical therapies.</p> <p>The PBAC acknowledged the effectiveness of dupilumab in a therapeutic area of high clinical need, however considered that dupilumab was not cost-</p>

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<p>Dupixent®</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>systematic therapy.</p>			<p>effective at the price proposed in the resubmission. The PBAC also considered that the criteria for defining the patient population for initial and continuing treatment did not appropriately consider the extent of disease in terms of the body surface area affected.</p> <p>The PBAC considered that the estimated financial implications were very high and uncertain, and that a Risk Sharing Arrangement would be necessary to manage the uncertainty in patient estimates, likely treatment duration and the potential for use outside the proposed restriction.</p>
			<p>Comparator: standard of care (SoC)</p>	<p>The PBAC considered that the resubmission appropriately used SoC as the main comparator.</p>
			<p>Clinical claim: superior efficacy and similar safety compared with SoC.</p>	<p>The PBAC considered that the claim of superior comparative effectiveness of dupilumab compared with SoC for patients with moderate to severe AD was reasonable based on Eczema Area and Severity Index-75 response and Investigator’s Global Assessment score. The PBAC considered that the claim of non-inferior comparative safety was not adequately supported by the data due to a higher incidence of conjunctivitis and injection-site reaction events in dupilumab patients. The PBAC noted that the long-term efficacy and safety for dupilumab beyond 52 weeks is unknown.</p>
			<p>Economic claim: cost-utility analysis compared with SoC.</p>	<p>The PBAC considered that the resubmission’s base-case incremental cost-effectiveness ratio (ICER) of \$15,000–\$45,000 per QALY gained was uncertain and appeared to be significantly underestimated due to assumptions in the model such as the cost for non-responders, maintenance of response, and the 10 year</p>

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				time horizon. The PBAC considered that the true ICER was likely to be unacceptably high at the proposed price.
<p>DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL</p> <p>Solution concentrate 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>Durvalumab is indicated for use:</p> <ul style="list-style-type: none"> • in patients with locally advanced or metastatic urothelial carcinoma who: <ul style="list-style-type: none"> ○ have disease progression during or following platinum-containing chemotherapy. ○ have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum- 	<p>Durvalumab is not currently listed on the PBS.</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following platinum-based CRT.</p> <p>Comparator: The resubmission nominated placebo, representing ‘watch-and-wait’ monitoring plus best supportive care, as the main comparator.</p> <p>Clinical claim: Superior effectiveness, with similar quality of life, and</p>	<p>Sanofi is disappointed with the PBAC’s decision not to recommend dupilumab but welcomes the Committee’s recognition of the need for a safe and effective treatment for patients with moderate-to-severe atopic dermatitis unresponsive to current therapies, and its acknowledgement of dupilumab’s effectiveness. Sanofi remains committed to working with the PBAC to enable access for Australian patients to this effective and innovative therapy.</p> <p>The PBAC did not recommend the Authority Required (STREAMLINED) listing of durvalumab for the treatment of Stage III unresectable NSCLC in patients whose disease has not progressed following CRT, on the basis of a high, uncertain cost-effectiveness ratio. The PBAC was also concerned about the high cost and very high estimated financial implications associated with listing the treatment. The PBAC acknowledged the clinical need for a consolidation treatment in Stage III, unresectable NSCLC, however considered that at the price proposed durvalumab was not cost-effective in this treatment setting. The PBAC considered the patient estimates were overestimated, and the cost-offsets for subsequent lines of immunotherapy were underestimated.</p> <p>The PBAC agreed that this was the appropriate comparator.</p> <p>The PBAC considered that the claim of superior comparative effectiveness and inferior comparative</p>

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	<p>containing chemotherapy.</p> <ul style="list-style-type: none"> in patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT). 		<p>manageable safety compared with “watch and wait” monitoring in patients with Stage III NSCLC whose disease has not progressed following CRT.</p> <p>Economic claim: Cost-utility analysis compared with placebo. Rank preserving structural failure of time (RPSFT)-adjusted scenario analysis to adjust for the impact of subsequent therapy on overall survival.</p> <p align="center">Sponsor’s comment:</p>	<p>safety was reasonable.</p> <p>The PBAC also noted the clinical data presented was immature and considered the extent of clinical benefit with durvalumab was uncertain, given the applicability concerns with the Australian treatment setting, including the lower average age of participants included in the PACIFIC trial compared to the Australian population and the subsequent use of immunotherapies post-progression permitted in the trial, with subsidy currently limited to one course of programmed cell death (ligand) 1 therapy.</p> <p>The PBAC considered there was a number of issues with the resubmitted model, including: (i) lack of convergence of the progression-free survival and overall survival curves and (ii) time point of overall survival extrapolation.</p> <p>The PBAC also considered the results of the RPSFT-adjusted analysis did not completely mitigate the applicability as the assumptions underpinning the analysis were unverifiable.</p> <p>No comment</p>
<p>OBETICHOLIC ACID</p> <p>Tablet 5 mg Tablet 10 mg</p> <p>Ocaliva®</p> <p>Emerge Health Pty Ltd</p>	<p>Obeticholic acid is indicated for the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid</p>	<p>Obeticholic acid is not currently listed on the PBS</p>	<p>Resubmission 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 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 remained uncertain, the economic model remained highly uncertain and resulted in an incremental cost-effectiveness ratio (ICER) that was unacceptably high and the estimated financial impact was high.</p>

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New listing (Major Submission)	(UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.		Comparator: For UDCA-inadequate responders: UDCA plus placebo. For UDCA-intolerant patients: placebo	The PBAC previously accepted the nominated comparators as being appropriate.
			Clinical claim: Obeticholic acid plus UDCA was superior in terms of effectiveness compared with UDCA monotherapy in patients with a prior inadequate response to UDCA. Obeticholic acid monotherapy was superior in terms of effectiveness compared with placebo in patients who were intolerant to UDCA. Obeticholic acid plus UDCA and Obeticholic acid monotherapy were inferior in terms of safety compared to UDCA monotherapy in patients who had an inadequate response to UDCA and placebo in patients who were intolerant of UDCA respectively.	The PBAC considered that the clinical claim that obeticholic acid plus UDCA was superior in terms of effectiveness compared to UDCA monotherapy in patients who were UDCA-inadequate responders was reasonable. The PBAC considered that the magnitude of the clinical benefit remained uncertain given the relatively small sample size in POISE (n=200) and as over 50% of patients failed to meet the primary end point at 12 months. The PBAC considered that the clinical claim that Obeticholic acid as monotherapy was superior in terms of effectiveness to placebo in patients who were UDCA-intolerant was not adequately supported by the data due to the small size of the subgroup (n=16). The PBAC considered that the claim of inferiority in terms of safety was reasonable.
			Economic claim: Cost-utility analyses comparing Obeticholic acid plus UDCA with UDCA monotherapy and OCA monotherapy with placebo.	The PBAC considered that the economic model again lacked transparency, lacked clinical plausibility and was insufficient to inform decision-making. The PBAC considered that the ICERs remained unacceptably high at the requested price, especially considering the uncertainty surrounding the incremental clinical benefit.
			Sponsor's comment:	No comment
PEMBROLIZUMAB Solution concentrate	PEMBROLIZUMAB is indicated for use in <u>Melanoma</u> :	Unresectable Stage III or Stage IV malignant	Resubmission to request Section 100 (Efficient Funding of Chemotherapy Program) Authority Required	The PBAC did not recommend listing of pembrolizumab as an adjuvant treatment for completely surgically resected Stage IIIB, IIIC or IIID melanoma. The PBAC

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<p>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>- unresectable or metastatic melanoma in adults;</p> <p>- adjuvant treatment of melanoma with lymph node involvement who have undergone complete resection.</p> <p><u>Non-small cell lung cancer (NSCLC):</u></p> <p>- first-line treatment of metastatic NSCLC whose tumours express programmed death-ligand 1 (PD-L1) with a greater than or equal to 50% tumour proportion score (TPS), with no epidermal growth factor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations;</p> <p>- in combination with pemetrexed and platinum chemotherapy, as first-line treatment of metastatic non-squamous NSCLC, with no EGFR or</p>	<p>melanoma;</p> <p>Relapsed or refractory Hodgkin lymphoma;</p> <p>Previously untreated Stage IV (metastatic) NSCLC ;</p> <p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer</p>	<p>(STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III malignant melanoma.</p> <p>This was updated to exclude patients with Stage IIIA disease (i.e. for Stage IIIB, IIIC and IIID melanoma only) during evaluation.</p>	<p>acknowledged that there was a high 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 with placebo. However, the PBAC considered that due to the limited duration of follow-up in the key trial, KN054, the magnitude of the clinical benefit was uncertain. The PBAC considered that the modelled incremental benefit, in terms of overall survival, was substantially overestimated and, as a result, the economic model did not provide a reliable basis for assessing the cost-effectiveness of pembrolizumab. The PBAC also remained concerned about the high overall financial opportunity cost.</p>
			<p>Comparator: Observation/placebo</p>	<p>The PBAC reaffirmed that standard of care (routine follow-up) was the appropriate main comparator for pembrolizumab as adjuvant treatment for melanoma. Nivolumab was also considered for the same indication at the July 2019 meeting and was a near market comparator. Dabrafenib plus trametinib was also considered for adjuvant treatment of patients with BRAF mutant melanoma at the July 2019 meeting and was a near market comparator for the BRAF mutant subgroup of patients.</p>
			<p>Clinical claim: In patients with resected Stage III melanoma, pembrolizumab is superior to placebo in terms of efficacy. In terms of safety, pembrolizumab has inferior but manageable safety.</p>	<p>The PBAC again considered that the claim that pembrolizumab was superior compared to placebo in terms of recurrence free survival was reasonable, but due to the immaturity of the data considered that the magnitude of the treatment effect was highly uncertain. In terms of overall survival, the PBAC considered that further evidence was required to quantify the relationship between recurrence free and overall survival with PD-1 inhibitor therapy.</p>

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	<p>ALK genomic tumour aberrations; - in combination with carboplatin and either paclitaxel or nab-paclitaxel, as first-line treatment of metastatic squamous NSCLC; - advanced NSCLC whose tumours express PD-L1 with a greater than or equal to 1% TPS and who have received platinum-containing chemotherapy. <u>Head and Neck Squamous Cell Cancer (HNSCC):</u> - recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy. <u>Classical Hodgkin Lymphoma (cHL):</u> - adults with relapsed or refractory cHL following autologous stem cell transplant (ASCT) or, following at least two prior</p>		<p>Economic claim: The base case incremental cost-effectiveness ratio (ICER) of \$23,970 over a 10-year horizon is well within generally accepted thresholds for cost-effectiveness in the Australian setting.</p> <p align="right">Sponsor's comment:</p>	<p>The PBAC noted that the resubmission described pembrolizumab as inferior compared to placebo in terms of safety, but that the safety profile was manageable. The PBAC considered that this was reasonable.</p> <p>Overall, the PBAC considered that the ICER presented remained highly uncertain, variable and was most likely underestimated.</p> <p>MSD is disappointed with this outcome and will work with the PBAC to ensure that eligible patients have PBS access for pembrolizumab in adjuvant melanoma as soon as possible.</p>

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	<p>therapies when ASCT or multi-agent chemotherapy is not a treatment option.</p> <p><u>Primary Mediastinal B-Cell Lymphoma (PMBCL):</u></p> <ul style="list-style-type: none"> - adult and paediatric patients with refractory PMBCL, or who have relapsed after 2 or more prior lines of therapy. <p><u>Urothelial carcinoma:</u></p> <ul style="list-style-type: none"> - locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy and whose tumours express PD-L1 [Combined Positive Score greater than or equal to 10], or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status; - locally advanced or metastatic urothelial carcinoma who have received platinum- 			

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	containing chemotherapy.			
<p>REGORAFENIB</p> <p>Tablet 40 mg (as monohydrate)</p> <p>Stivarga®</p> <p>Bayer Australia Ltd</p> <p>New listing (Minor Submission)</p>	<p>The treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.</p>	<p>Regorafenib is not currently listed on the PBS</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable HCC who have progressed on first line treatment with a tyrosine kinase inhibitor (TKI).</p>	<p>The PBAC did not recommend the listing of regorafenib for the treatment of hepatocellular carcinoma for patients who have progressed on first line treatment with a TKI.</p>
			<p>Comparator: Best supportive care (BSC).</p>	<p>The PBAC previously accepted the comparator of BSC.</p>
			<p>Clinical claim: superior to BSC, providing a statistically significant and clinically significant increase in overall survival but a higher incidence of adverse events.</p>	<p>No additional clinical trial data was presented in the minor resubmission. The PBAC maintained that the claim of superior comparative effectiveness and the claim of inferior comparative safety were reasonable.</p>
			<p>Economic claim: cost-effectiveness analysis compared with BSC.</p>	<p>The economic analysis presented in the minor resubmission was unchanged from the previous resubmission with no change in the proposed price and hence incremental cost-effectiveness ratio.</p> <p>The PBAC reiterated its November 2018 advice that at the proposed price, the incremental cost-effectiveness ratio for regorafenib remained unacceptably high given the substantial toxicity and minor added benefit of regorafenib.</p>
<p align="center">Sponsor's comment:</p>	<p>Bayer is disappointed to receive a negative recommendation from the PBAC for the reimbursement of Stivarga® (regorafenib) in the treatment of HCC. Bayer maintains that the proposal was at a level of cost-effectiveness which was indicative of the current unmet need and low number of patients. Bayer will not be re-submitting for this indication in the future.</p>			
<p>ROMOSOZUMAB</p>	<p>The treatment of osteoporosis in</p>	<p>Romosozumab is not currently listed on the</p>	<p>Resubmission to request an Authority Required listing for the treatment of</p>	<p>The PBAC did not recommend the listing of romosozumab for the treatment of severe osteoporosis</p>

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<p>Injection 105 mg in 1.17 mL single use prefilled syringe</p> <p>Evenity®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>postmenopausal women at high risk of fracture.</p> <p>To increase bone mass in men with osteoporosis at high risk of fracture.</p>	<p>PBS</p>	<p>severe osteoporosis.</p>	<p>in patients who have experienced a prior fracture while on anti-resorptive therapy (later-line setting) due to concerns regarding the claim of comparative clinical effectiveness, the cardiovascular safety profile of the treatment and the uncertain size of the eligible patient population. The PBAC also considered the estimated financial implications were unacceptably high for a cost-minimisation analysis given it was not clear whether romosozumab would be cost-effective if it is used in a broader population than those patients who currently use teriparatide.</p>
			<p>Comparator: teriparatide</p>	<p>The PBAC considered the nominated comparator appropriate. However, if romosozumab is likely to be used in a much broader population than teriparatide, as predicted by the resubmission, the PBAC considered a comparison with anti-resorptives is relevant.</p>
			<p>Clinical claim: non-inferior comparative effectiveness and inferior comparative safety.</p>	<p>As there were no changes to the clinical evidence provided in the resubmission compared to the previous submission, the PBAC reiterated its November 2018 consideration that the claim of non-inferior comparative effectiveness was not adequately supported by the data. In addition, the PBAC considered that the addition of anti-resorptive therapy following cessation of romosozumab treatment was important to the claim of similar comparative efficacy with teriparatide and that it was difficult to ensure that patients received and adhered to subsequent anti-resorptive therapy.</p> <p>The PBAC considered that the claim of inferior comparative safety was reasonable.</p>
			<p>Economic claim: cost-minimisation analysis versus teriparatide.</p>	<p>The PBAC considered the cost-minimisation analysis presented did not adequately address the following areas of concern: the trial-based equi-effective doses</p>

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				<p>used; the additional costs for anti-resorptive therapy following cessation of romosozumab; and administration costs. The PBAC considered that the use of more conservative assumptions, resulting in a reduction in the proposed price for romosozumab, would be appropriate given the uncertainty with the clinical claim of non-inferior efficacy.</p> <p>The PBAC considered the estimated financial implications were unacceptably high for a cost-minimisation analysis.</p>
			Sponsor's comment:	No comment