

NOVEMBER 2016 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>CARBOHYDRATE FORMULA WITH MINERALS Oral liquid</p> <p>Sachet containing oral powder 21 g Sachet containing oral powder 31 g Sachet containing oral powder 42 g Sachet containing oral powder 52 g</p> <p>SOS10®, SOS15®, SOS20®, SOS25®</p> <p>Vitaflo Australia Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>Dietary management of proven inborn errors of protein or fat metabolism</p>	<p>To request a Restricted Benefit listing for proven inborn errors of protein or fat metabolism.</p> <p>Sponsor comment:</p>	<p>The PBAC did not recommend the listing of carbohydrate formula with minerals for the treatment of proven inborn errors of protein metabolism and proven inborn errors of fat metabolism. The PBAC noted the risks of potential product wastage due to a high maximum quantity, and the lack of clarity surrounding the indications which could potentially result in use outside of the intended patient population.</p> <p>The sponsor had no comment.</p>
<p>CARFILZOMIB</p> <p>Powder for I.V. infusion 30 mg Powder for I.V. infusion 60 mg</p> <p>Kyprolis®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Multiple myeloma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of multiple myeloma in patients failing one prior line of treatment.</p>	<p>The PBAC did not recommend the listing of carfilzomib for the treatment of relapsed or refractory multiple myeloma in combination with dexamethasone (Cd) or in combination with lenalidomide and dexamethasone (CLd) on the basis of high and uncertain incremental cost effectiveness ratios (ICERs).</p> <p>The PBAC noted that the sponsor requested listings for Cd alone (Scenario 1) and for both Cd and CLd (Scenario 2), but not for CLd alone. The PBAC noted the submission did not address the different patient populations likely to be treated with CLd versus Cd if both were available and considered the role of CLd versus Cd in clinical practice was unclear.</p> <p>The PBAC considered that the claim of superior comparative effectiveness of Cd over its comparator, bortezomib plus dexamethasone (Bd), for Scenario 1 was reasonable. The PBAC did not accept this claim for Scenario 2. The PBAC considered that if CLd was available, the population</p>

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			<p>most likely to receive Cd would be the subgroup of patients who could not tolerate or were refractory to lenalidomide, and noted that there was no conclusive evidence that Cd was of superior efficacy over Bd in this subgroup of patients.</p> <p>The PBAC considered that the claim of superior efficacy of CLd over its comparator, lenalidomide plus dexamethasone (Ld), was adequately supported by the data for the progression free survival outcome but not for the overall survival outcome, as the difference was not statistically significant when adjusted for multiplicity.</p> <p>The PBAC accepted the claim that Cd had a different safety profile compared with Bd, and that CLd was of inferior safety compared to placebo plus Ld. The PBAC noted that patients taking Cd had a significantly lower rate of peripheral neuropathy related adverse events, but that the rate of any grade 3 or higher treatment-related adverse events was not significantly different to Bd.</p> <p>The PBAC considered that the incremental cost per quality-adjusted life year gained was uncertain and high. The PBAC considered the modelled overall survival gains with carfilzomib to be uncertain because the data from the clinical trials are immature and the differences were not statistically significant. Furthermore, the PBAC noted concerns with a number of assumptions in the economic model which favoured carfilzomib and hence considered that the base case ICERs were likely to be substantially underestimated. The PBAC also noted that the overall financial impact of listing carfilzomib was high and likely underestimated.</p>
		Sponsor comment:	Carfilzomib (Kyprolis®) is an effective and well tolerated treatment for refractory or relapsed multiple myeloma and provides a useful addition to existing therapies. Amgen will continue to work with the PBAC to ensure that Australian patients with myeloma are able to access carfilzomib on the PBS as soon as possible.
FLUTICASONE with SALMETEROL Powder for inhalation containing fluticasone	Asthma and chronic obstructive pulmonary disease (COPD)	To request the Restricted Benefit listing for asthma and COPD, with an age restriction of 18 years and older.	The PBAC decided not to recommend a Restricted Benefit listing of a new brand of fluticasone with salmeterol, AirFluSal® Forspiro® 500, for the treatment of asthma and COPD due to the inability to back titrate the dose with a similar device. The PBAC was concerned that there was only a single high strength available with this delivery device which may cause patients to

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<p>propionate 500 micrograms with salmeterol (as xinafoate) 50 micrograms per dose</p> <p>Airflusal® Forspiro® 500/50</p> <p>Sandoz Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>		<p>Sponsor comment:</p>	<p>remain on a clinically inappropriately high dose. The PBAC concluded that there was no clinical need to list this new brand of fluticasone with salmeterol on the PBS.</p> <p>The sponsor is disappointed with the PBAC outcome for Airflusal® Forspiro® 500/50. We respectfully disagree with the concerns raised. From a safety and efficacy perspective, these concerns have been thoroughly addressed with the Therapeutic Goods Administration, including advisory statements that lower strength presentations are available for the patient to titrate back to, either as a dry powder formulation or a metered dose inhaler. The sponsor will continue to work with the PBAC to ensure Airflusal® Forspiro® 500/50 will be available to Australian patients for the treatment of Asthma and COPD.</p>
<p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Relapsed or refractory mantle cell lymphoma</p>	<p>To request an Authority Required listing for the treatment of relapsed or refractory mantle cell lymphoma.</p>	<p>The PBAC did not recommend the listing of ibrutinib on the PBS for the treatment of mantle cell lymphoma on the basis of high and uncertain cost-effectiveness at the requested price. The PBAC considered the magnitude of the clinical benefit was uncertain. This was because the comparator in the randomised trial (temsirolimus) was not relevant to Australian clinical practice, and the assumption that the efficacy of temsirolimus was the same as for rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP), the nominated comparator for the submission, was based on naïve indirect comparisons. Further, the PBAC were of the view that a number of the assumptions used in the estimation of the cost-effectiveness were optimistic, and noted that the incremental cost-effectiveness ratio (ICER) was therefore likely to be higher than estimated in the submission.</p> <p>The PBAC considered that the claim of superior comparative effectiveness on the basis of a naïve indirect comparison to R-CHOP was reasonable based on the endpoint of progression free survival. However, the magnitude of the benefit was considered to be uncertain. The PBAC noted that a statistically significant gain in overall survival was not demonstrated in the MCL-3001 trial.</p> <p>The PBAC considered that the claim of superior comparative safety over R-CHOP was not adequately supported by the data. The PBAC noted that ibrutinib appears to be associated with a reduced risk of neutropenia, however also noted the emerging data suggesting ibrutinib may be associated with an increased risk of atrial fibrillation.</p>

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			The PBAC considered the incremental cost-effectiveness ratio of \$75,000-\$105,000 to be uncertain and unacceptably high at the requested price.
		Sponsor comment:	Janssen is disappointed that the PBAC did not recommend ibrutinib for the treatment of relapsed or refractory MCL. Janssen agrees with the PBAC that there is a clinical need for effective and well tolerated treatments for relapsed or refractory MCL. The submission presented a phase 3 randomised trial which demonstrates that ibrutinib can address this unmet clinical need. However, consistent with its position for relapsed or refractory chronic lymphocytic leukaemia, Janssen is concerned by the conservative assumptions required by the PBAC which underestimates the significant benefit and value of ibrutinib. Janssen are engaging with the PBAC to work towards a resolution.
<p>ICATIBANT</p> <p>Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe</p> <p>Firazyr®</p> <p>Shire Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major submission)</p>	Hereditary angioedema	<p>To request assessment of the cost-effectiveness of icatibant in the context of the current Australian Society of Clinical Immunology and Allergy (ASCI) treatment algorithm and June 2016 DUSC review.</p> <p>Sponsor comment:</p>	<p>The PBAC rejected the submission's claim that the additional use of icatibant reported by DUSC was cost effective on the basis that the revised model presented did not provide a reliable basis for the assessment of cost effectiveness.</p> <p>Furthermore, the PBAC considered that the submission did not provide adequate justification to support the requested increase to the financial caps.</p> <p>Shire will continue to work with the PBAC and the Department of Health on the review of icatibant utilisation.</p>
<p>IRINOTECAN</p> <p>I.V. injection containing nanoliposomal irinotecan 43 mg in 10 mL</p> <p>Onivyde®</p> <p>Baxalta Australia Pty Ltd now part of Shire</p>	Metastatic pancreatic cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with 5-fluorouracil (5-FU) and folinic acid, for the treatment of patients with metastatic pancreatic cancer previously treated with a gemcitabine based regimen.	<p>The PBAC did not recommend the listing of irinotecan (nanoliposomal) on the basis of an unacceptably high incremental cost for a modest and uncertain incremental clinical benefit. The PBAC acknowledged the high clinical need for effective and well-tolerated therapies for metastatic pancreatic adenocarcinoma, particularly in the context of the poor prognosis for this condition.</p> <p>The PBAC considered that the most relevant comparators are oxaliplatin-containing regimens such as mFOLFOX6 (oxaliplatin plus 5-FU/folinic acid) and capecitabine. The PBAC considered that in principle (even though it is not widely used in Australian practice). 5-FU/folinic acid could be</p>

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<p>New listing (Major submission)</p>			<p>considered representative of the efficacy and toxicity of mFOLFOX6.</p> <p>The submission was primarily based on one head-to-head, open label trial comparing irinotecan (nanoliposomal) with 5-FU/folinic acid: NAPOLI 1 (n=236). The PBAC considered that irinotecan (nanoliposomal) was modestly superior in terms of efficacy compared with 5-FU/folinic acid, with an increase in median overall survival of approximately nine weeks.</p> <p>The submission also presented a naïve indirect comparison of irinotecan (nanoliposomal) and oxaliplatin-containing regimens. The PBAC considered that the results of the naïve indirect comparison were not reliable but overall considered that the claim of superior comparative effectiveness compared with oxaliplatin-containing regimens was adequately supported. The PBAC considered that limitations associated with the reliability of the indirect comparison meant that there could not be confidence in the relative efficacy between irinotecan (nanoliposomal) and oxaliplatin-containing regimens. The PBAC considered the incremental benefit of irinotecan (nanoliposomal) over 5-FU/folinic acid observed in NAPOLI-1 (nine week gain in median overall survival) to be the upper limit of a plausible incremental benefit of irinotecan (nanoliposomal) over oxaliplatin-containing regimens.</p> <p>The PBAC considered that the estimated incremental cost-effectiveness ratio for irinotecan (nanoliposomal) compared with mFOLFOX6 was likely underestimated and unacceptably high at \$105,000 to \$200,000 per quality adjusted life year gained. Accordingly, the PBAC considered that irinotecan (nanoliposomal) was not sufficiently cost-effective to justify a recommendation for listing on the PBS, at the requested price.</p>
		<p>Sponsor comment:</p>	<p>Shire will work with the PBAC and Department of Health so that Australian patients may access nanoliposomal irinotecan via the PBS.</p>

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<p>OBINUTUZUMAB</p> <p>Solution for I.V. infusion 1000 mg in 40 mL</p> <p>Gazyva®</p> <p>Roche Products Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Follicular lymphoma (FL)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as re-induction treatment and maintenance therapy in patients with rituximab-refractory FL.</p> <p>Sponsor comment:</p>	<p>The PBAC did not recommend obinutuzumab for PBS listing for the treatment of rituximab-refractory FL, on the basis of uncertain cost-effectiveness and concerns about the economic model used in the submission.</p> <p>The PBAC considered that obinutuzumab plus bendamustine followed by obinutuzumab maintenance was of superior efficacy and inferior safety compared with bendamustine monotherapy. However, the PBAC noted that obinutuzumab had an overall tolerable safety profile, and that the benefits of its use outweighed its toxicities.</p> <p>The PBAC was concerned that some assumptions used in the economic analysis were not appropriate. The PBAC considered that due to the issues with the economic model, the incremental cost effectiveness ratio presented in the submission's base case analysis was highly uncertain and was likely to be significantly underestimated.</p> <p>Roche is pleased the PBAC recognised the need for effective PBS subsidised treatments for rituximab refractory FL.</p> <p>The sponsor welcomes the opportunity to work with the Department of Health and the PBAC in order to ensure Australian patients achieve access to obinutuzumab in this area of high unmet need.</p>
<p>PEMBROLIZUMAB</p> <p>Powder for injection 50 mg</p> <p>Keytruda®</p> <p>Merck Sharp and Dohme (Australia) Pty Ltd</p> <p>Change to listing</p> <p>(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 for the treatment of programmed death ligand 1 (PD-L1) positive NSCLC in patients refractory to platinum based chemotherapy.</p>	<p>The PBAC decided not to recommend that pembrolizumab be listed on the PBS for the treatment of PD-L1 positive NSCLC on the basis of unfavourable and uncertain cost-effectiveness. The PBAC recognised that there is a clinical need for new treatments for patients with NSCLC, and that there is a clinical place for pembrolizumab in this population.</p> <p>The PBAC also considered that the use of the proposed ≥50% tumour proportion score (TPS) threshold from PD-L1 testing to help determine eligibility of patients with NSCLC to receive pembrolizumab was not adequately justified. The PBAC noted that there were important unresolved issues regarding PD-L1 testing which have consequences for this codependent submission. As these issues were relevant to MSAC, PBAC decided that it should await MSAC's assessment before first drawing any conclusions on the usefulness of PD-L1 testing as a means of selecting patients for treatment with pembrolizumab.</p>

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			<p>The PBAC concluded that pembrolizumab was more effective than its comparators, docetaxel and pemetrexed, in PD-L1 positive NSCLC, but that the magnitude of the gain in effectiveness over pemetrexed was less clear due to the need to conduct an indirect comparison.</p> <p>The PBAC considered that pembrolizumab would likely be better tolerated overall than docetaxel or pemetrexed, however, was more likely to increase the risk of immune-related adverse events.</p> <p>The PBAC considered that the incremental cost effectiveness ratio for pembrolizumab was high, and was likely to be significantly underestimated due to several issues with the economic model. The PBAC noted that the estimated overall net cost of PD-L1 testing and pembrolizumab for NSCLC to the Government would be substantial.</p>
		Sponsor comment:	The sponsor is disappointed and will continue to work with government to bring KEYTRUDA to appropriate patients as soon as possible.

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<p>ROMIDEPSIN</p> <p>Powder for I.V. infusion 10 mg</p> <p>Istodax®</p> <p>Celgene Pty Limited (submitted by Rare Cancers Australia)</p> <p>New listing</p> <p>(Major submission)</p>	<p>Relapsed or refractory peripheral T-cell lymphoma</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of relapsed or chemotherapy refractory peripheral T-cell lymphoma (PTCL).</p> <p>Sponsor comment:</p>	<p>The PBAC decided not to recommend the Section 100 Authority Required listing of romidepsin for the treatment of PTCL, as the clinical data and economic analysis presented did not provide a basis for the PBAC to assess its comparative clinical effectiveness and cost-effectiveness. The PBAC considered that the submission's approach to estimating cost-effectiveness was fundamentally flawed, could not provide sufficient certainty for decision making, and was unacceptable in the context of the magnitude of the predicted additional expenditure.</p> <p>In making this recommendation, the PBAC recognised the high and unmet clinical need for an additional or alternative effective therapy in a group of patients with advanced PTCL after the failure of prior systemic therapy.</p> <p>The PBAC noted that the key clinical evidence presented in the resubmission constituted two single-arm phase II studies (Study 0002, n=130 and Piekarz 2011, n=47) of romidepsin in PTCL. The PBAC considered the efficacy and safety data were difficult to assess in the absence of a comparative analysis. From the evidence presented in the resubmission, the PBAC considered that the romidepsin induced a durable response in a sizeable minority of patients with advanced PTCL; however, the magnitude of any benefit was uninterpretable due to the limited and biased nature of the data.</p> <p>Within the limits of interpretation of the economic model provided, the PBAC considered that a substantial reduction in price was likely to be required to establish cost-effectiveness. The PBAC would welcome a future submission with comparative data and a revised economic evaluation, prepared in accordance with the PBAC Guidelines.</p> <p>Rare Cancers Australia (RCA) is disappointed by the PBAC's decision, not to recommend romidepsin in the treatment of peripheral T-cell lymphoma on this occasion. It is RCA's sincere hope the manufacturer of romidepsin will go on to develop a successful resubmission, building on the PBAC's feedback and the good will forged between RCA and the DoH and the PBAC throughout the submission process.</p>

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<p>TERIFLUNOMIDE</p> <p>Tablet 14 mg</p> <p>Aubagio®</p> <p>Sanofi-aventis Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Relapsing-remitting multiple sclerosis (RRMS)</p>	<p>To request the current Authority Required listing be changed to Authority Required (STREAMLINED).</p> <p>Sponsor comment:</p>	<p>The PBAC decided not to recommend amending the listing of teriflunomide to Authority Required (STREAMLINED), as it considered that the market for oral therapies for RRMS had not yet stabilised.</p> <p>The sponsor had no comment.</p>
<p>TRIFLURIDINE with TIPIRACIL</p> <p>Tablet containing 15 mg trifluridine with 6.14 mg tipiracil</p> <p>Tablet containing 20 mg trifluridine with 8.19 mg tipiracil</p> <p>Lonsurf®</p> <p>Servier Laboratories (Australia) Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Metastatic colorectal cancer (mCRC)</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of mCRC.</p>	<p>The PBAC did not recommend the listing of trifluridine with tipiracil on the PBS for the treatment of patients with mCRC who have been previously treated with, or are not considered suitable for, currently available therapies. This decision was made on the basis of a modest clinical benefit, high and uncertain incremental cost-effectiveness ratio, and concern that the extent of benefit as observed in the clinical trial would not be realised in clinical practice.</p> <p>The PBAC agreed with the submission's nominated comparator of best supportive care.</p> <p>The PBAC considered the submission's claim of superior efficacy of trifluridine with tipiracil over best supportive care to be adequately supported by the data, although considered the magnitude of the benefit to be modest. The PBAC considered the submission's claim of inferior safety of trifluridine with tipiracil compared to placebo to be reasonable. The PBAC noted the toxicity associated with trifluridine with tipiracil was predictable, with myelosuppression being the key adverse event.</p> <p>The PBAC questioned the applicability of the trial data to Australian clinical practice and noted that the magnitude of the benefit as observed in the trials may not be realised in clinical practice. This was because, on average, patients with a worse performance status may be treated and dose reductions or delays may be required because of neutropenia.</p>

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			The PBAC considered the cost-effectiveness ratios presented in the submission (\$75,000-\$105,000 per quality adjusted life year (QALY) gained) and the pre-PBAC response (\$45,000-\$75,000 per QALY gained) to be unacceptably high, and likely to be underestimated given the potential applicability issues and concerns regarding the model structure.
		Sponsor comment:	The sponsor had no comment.
VITAMIN, MINERAL, AND TRACE ELEMENTS with CARBOHYDRATE Sachet 6 g Fruitivits® Vitaflo Australia Pty Ltd Change to listing (Minor submission)	Dietary management of conditions requiring a highly restrictive therapeutic diet	To request a change to the restriction to include children aged 1 year or older.	The PBAC did not recommend amending the restricted benefit listing for Fruitivits® to include patients from 1 year of age as the product contains iron at only 56% of the nutrient reference value for patients aged 1-3 years.
		Sponsor comment:	The sponsor had no comment.
WARFARIN Tablet containing warfarin sodium, 1 mg Tablet containing warfarin sodium, 2 mg Tablet containing warfarin sodium, 5 mg Warfarin APOTEX®	Unrestricted	To request the listing of a new brand of warfarin (Warfarin APOTEX®) with an 'a-flag' to a currently listed brand of warfarin (Coumadin®).	The PBAC did not recommend the listing of Warfarin APOTEX® or for it to be marked as equivalent (i.e. 'a' flagged) to the Coumadin® brand of warfarin tablets in the context of potential safety and quality use of medicines issues identified. The PBAC noted the narrow therapeutic index and considerable safety risks associated with inadequate control of warfarin. The PBAC considered that the listing of additional brands for warfarin would increase the potential risk of significant adverse outcomes, and would likely cause confusion and distress to patients, particularly because of the lack of interchangeability between the currently listed Coumadin® and Marevan® brands.

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Apotex Pty Ltd New listing (Minor submission)		Sponsor comment:	The sponsor had no comment.