

**NOVEMBER 2016 PBAC MEETING – POSITIVE RECOMMENDATIONS**

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE</p> <p>Bottles containing oral powder 34 g, 30</p> <p>PKU EASY® SHAKE &amp; GO</p> <p>AMINO ACID FORMULA with FAT, CARBOHYDRATE without PHENYLALANINE</p> <p>Tablet: modified release, 70.8 g protein per 100 g, 110 g</p> <p>PKU EASY® MICROTABS</p> <p>PROTEIN FORMULA with AMINO ACIDS, CARBOHYDRATES, VITAMINS and MINERALS without PHENYLALANINE, and SUPPLEMENTED with DOCOSAHEXAENOIC ACID</p> <p>Oral liquid 130 mL, 30</p> <p>PKU EASY®</p> <p>Orpharma Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Phenylketonuria</p>	<p>To request an increase in maximum quantities for PKU EASY SHAKE &amp; GO, PKU EASY MICROTABS, and PKU EASY.</p>	<p>The PBAC recommended the requested increase to the maximum quantities of PKU Easy®, PKU Easy Shake &amp; Go®, and PKU Easy Microtabs® for the treatment of phenylketonuria to align with other similar products on the PBS.</p>
<p>APOMORPHINE</p>	<p>Parkinson disease</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) listing of an additional</p>	<p>The PBAC recommended the listing of apomorphine 100 mg in 20 mL vial on the PBS noting that the listing would</p>

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<p>Injection containing apomorphine (as hydrochloride), 100 mg in 20 mL vial</p> <p>Apomine®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>		<p>strength of apomorphine.</p>	<p>reduce the number of ampoules needed to obtain the required dose per patient for continuous infusion, at the same price per milligram as the currently listed forms of apomorphine 10mg/mL.</p>
<p>BLINATUMOMAB</p> <p>Injection 38.5 microgram [1 vial] and inert substance solution [10 mL vial]</p> <p>Blinicyto®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to recommended listing</p> <p>(Minor Submission)</p>	<p>Relapsed or refractory Philadelphia-chromosome negative B-precursor acute lymphoblastic leukaemia</p>	<p>Resubmission to request a revision to the July 2016 PBAC recommendation.</p>	<p>The PBAC recommended the listing of blinatumomab for relapsed or refractory Philadelphia chromosome negative, B-precursor acute lymphoblastic leukaemia on the basis of the previous recommendation in July 2016, with the revised price proposed in the minor submission and removal of the recommended Managed Entry Scheme (MES). The PBAC reaffirmed that its recommendation was on the basis that blinatumomab should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy).</p> <p>The PBAC noted that the key input for the proposed MES was the proportion of patients alive two years after starting blinatumomab or standard care from the TOWER clinical trial, however as patients in the TOWER trial will not be followed for survival for two years the required data will not be collected.</p> <p>The PBAC noted that the incremental cost effectiveness ratio (ICER) calculated using the revised price, the 12 month survival data from the TOWER trial and the previously evaluated economic model was \$45,000 - \$75,000 per quality adjusted life year gained. In July 2016, the PBAC considered that this ICER was high but acceptable in this patient population.</p>
<p>BRENTUXIMAB VEDOTIN</p>	<p>Hodgkin lymphoma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing</p>	<p>The PBAC recommended a written Authority Required Section 100 (Efficient Funding of Chemotherapy) listing of</p>

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<p>Powder for I.V. infusion 50 mg</p> <p>Adcetris®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major submission)</p>		<p>for the treatment of relapsed or refractory Hodgkin lymphoma for patients who were autologous stem cell transplant (ASCT) naïve.</p>	<p>brentuximab vedotin for the treatment of relapsed Hodgkin Lymphoma patients who were ASCT naïve.</p> <p>The submission requested listing for brentuximab vedotin in two distinct ASCT naïve patient populations, in whom the treatment objective differs:</p> <ul style="list-style-type: none"> <li>• Palliative group - patients who are transplant-ineligible due to age or comorbidities (i.e. intent of treatment is palliative, potentially resulting in quality of life improvements), and</li> <li>• Salvage group - patients who are not currently eligible for ASCT due to substantial disease burden, but the aim of treatment with brentuximab vedotin is to achieve minimal residual disease in order to proceed to ASCT.</li> </ul> <p>The PBAC considered that while it was difficult to make a reliable estimate of the incremental benefit and harms on the basis of the naïve indirect comparison presented in the submission, brentuximab vedotin was well tolerated, and provided some improvement in efficacy over best supportive care.</p> <p>The PBAC considered that while brentuximab was cost-effective at the proposed price in the palliative group of patients, further price reduction and subsidisation caps on treatment cycles were required for it to be cost-effective in the salvage population, where the cost per additional patient proceeding to ASCT was inappropriately high and uncertain.</p>
<p>BRENTUXIMAB VEDOTIN</p> <p>Powder for I.V. infusion 50 mg</p> <p>Adcetris®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p>	<p>Hodgkin lymphoma</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory Hodgkin lymphoma following autologous stem cell transplant failure (ASCT).</p>	<p>The PBAC recommended a written Authority Required Section 100 (Efficient Funding of Chemotherapy) listing of brentuximab vedotin for the treatment of relapsed Hodgkin lymphoma post ASCT.</p> <p>In making this recommendation, the PBAC considered the cost-effectiveness of brentuximab vedotin in Hodgkin lymphoma patients post ASCT failure, its tolerability and its</p>

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<p>Change to listing (Major submission)</p>			<p>efficacy in serving as a 'bridge' to a potentially curative allogeneic stem cell transplantation in some patients.</p>
<p>CALCIPOTRIOL with BETAMETHASONE</p> <p>Foam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g</p> <p>Enstilar®</p> <p>LEO Pharma Pty Ltd</p> <p>New listing (Major submission)</p>	<p>Psoriasis</p>	<p>To request a Restricted Benefit listing for patients with chronic stable plaque type psoriasis vulgaris that is inadequately controlled with either a Vitamin D analogue or potent topical corticosteroid monotherapy.</p>	<p>The PBAC recommended the Restricted Benefit listing of calcipotriol with betamethasone foam spray for the treatment of chronic stable plaque psoriasis vulgaris subject to a cap on PBS expenditure. The PBAC noted the PBS cost was sensitive to the assumed number of packs per service and further recommended that the usage of calcipotriol with betamethasone foam spray be reviewed following listing.</p> <p>The PBAC noted the head-to-head randomised trial comparing the foam spray and gel which demonstrated the superior effectiveness of the foam spray over the gel. The PBAC noted itch was more commonly experienced by patients using the foam spray when compared to the gel, but considered that the safety profile of the foam spray was unlikely to be significantly different to that of the gel formulation.</p>
<p>CERITINIB</p> <p>Capsule 150 mg</p> <p>Zykadia®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request an Authority Required listing for anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic NSCLC patients with disease progression in patients meeting certain criteria.</p>	<p>The PBAC recommended a written Authority Required General Schedule listing of ceritinib for the treatment of ALK-positive NSCLC. In making this recommendation, the PBAC noted the effectiveness of ceritinib in an area of high clinical need with a relatively small population size, and its efficacy in heavily pre-treated metastatic NSCLC patients with a modest level of toxicity. The PBAC considered it likely that access to ceritinib would significantly improve quality of life in ALK-positive NSCLC patients compared with chemotherapy.</p>
<p>DACLIZUMAB</p> <p>150 mg/mL solution for injection, 1 mL pen-filled pen 150 mg/mL solution for injection, 1 mL</p>	<p>Relapsing-remitting multiple sclerosis</p>	<p>To request an Authority Required for relapsing-remitting multiple sclerosis.</p>	<p>The PBAC recommended the listing of daclizumab on the basis that a direct comparison with intramuscular interferon beta-1a (IFN β-1a) and indirect comparisons of daclizumab and fingolimod presented in the submission supported a conclusion that daclizumab is likely to be superior to IFN</p>

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syringe Zinbryta® Biogen Australia Pty Ltd New listing (Minor submission)			<p>β-1a and non-inferior to fingolimod, with regards to comparative efficacy.</p> <p>The PBAC considered that daclizumab may be inferior to IFN β-1a with regards to comparative safety, but was unable to draw a meaningful conclusion compared with fingolimod on the basis of the indirect comparisons.</p>
EPOPROSTENOL Injection 500 microgram Injection 1.5 mg Flolan® GlaxoSmithKline Australia Pty Ltd New listing (Minor submission)	Pulmonary arterial hypertension	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a new pH 12 diluent and delisting of the infusion administration set.	The PBAC recommended the listing of the Flolan® brand of epoprostenol with a new diluent formulation and without the administration set. In making this recommendation, the PBAC noted assurances from the sponsor that administration sets would be supplied to patients through an alternative method at no additional cost to the patient.
ERIBULIN Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL Halaven® Eisai Australia Pty Ltd Change to listing (Major submission)	Soft tissue sarcoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic liposarcoma following chemotherapy.	<p>The PBAC recommended the listing of eribulin, on the basis that it should be available under Section 100 (Efficient Funding of Chemotherapy), for the treatment of patients with unresectable liposarcoma who have received prior chemotherapy for advanced or metastatic disease.</p> <p>The PBAC accepted the submission's claim that eribulin was of superior comparative effectiveness over dacarbazine, but considered that eribulin was of inferior safety to dacarbazine. The PBAC did not accept the submission's claim that the median overall survival achieved with eribulin is 7.2 months greater than dacarbazine, on the basis that this result was derived from a subgroup analysis of liposarcoma patients which was underpowered to detect a difference in overall survival between treatment arms. Further, the results were not adjusted for multiplicity. The PBAC also noted that most of the survival gain in the</p>

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			<p>liposarcoma subgroup (6.0 months) occurred post-progression and considered that this was not biologically plausible, in addition to being inconsistent with the results of the intention-to-treat (ITT) analysis. The PBAC considered that the results from the ITT analysis were a more reliable estimate of eribulin's true magnitude of clinical benefit (2.0 months) and that a price reduction was required to ensure the cost-effective PBS-listing of eribulin.</p> <p>In making its decision to recommend listing at a reduced price, the PBAC recognised the unmet clinical need for additional treatment options for liposarcoma patients and noted that the overall financial impact of listing eribulin would be low.</p>
<p>FOSAPREPITANT</p> <p>Powder for I.V. infusion 150 mg</p> <p>Emend® IV</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>Nausea and vomiting</p>	<p>Resubmission to request a General Schedule and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) Authority Required (STREAMLINED) listing of an intravenous formulation of fosaprepitant for the management of nausea and vomiting associated with cytotoxic chemotherapy.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) listing of fosaprepitant for the management of nausea and vomiting associated with cytotoxic chemotherapy, on a cost-minimisation basis against aprepitant (one-day regimen). The PBAC considered that the equi-effective doses were 150 mg fosaprepitant and 165 mg aprepitant.</p>
<p>GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALS</p> <p>Sachet containing oral powder 35 g</p> <p>PKU Sphere®</p> <p>Vitaflo Australia Pty Ltd</p> <p>New listing</p>	<p>Phenylketonuria</p>	<p>To request a Restricted Benefit listing for the dietary management of phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU SPHERE® as a Restricted Benefit for phenylketonuria for patients aged 10 years and older, on a cost minimisation basis against the comparator Camino Pro® Bettermilk at an equivalent price per gram of protein.</p>

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(Minor submission)			
<p>GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS</p> <p>Sachets containing oral powder 20 g</p> <p>PKU Restore®</p> <p>Cortex Health Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>Phenylketonuria</p>	<p>To request a Restricted Benefit for the dietary management of phenylketonuria.</p>	<p>The PBAC recommended the listing of PKU Restore® for the treatment of phenylketonuria on a cost minimisation basis against Camino Pro® at an equivalent cost per gram of protein equivalent.</p>
<p>HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE</p> <p>Oral semi-solid 100 g</p> <p>Keyo®</p> <p>Vitaflo Australia Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>Dietary management of conditions requiring a ketogenic diet</p>	<p>To request a Restricted Benefit listing as a dietary supplement for patients requiring a ketogenic diet.</p>	<p>The PBAC recommended the listing of Keyo® as a Restricted Benefit for a ketogenic diet on a cost minimisation basis against KetoCal 4:1 LQ at an equivalent price per kilojoule of energy.</p>
<p>INFLIXIMAB</p> <p>Powder for I.V. infusion 100 mg</p> <p>Renflexis®</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>New listing</p>	<p>Same as currently PBS subsidised indications for infliximab</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a biosimilar infliximab for all indications currently PBS subsidised for infliximab.</p>	<p>The PBAC recommended the listing of infliximab (Renflexis®) as a biosimilar of infliximab (Remicade®) on a cost minimisation basis with infliximab (Remicade) for all indications – rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis, Crohn’s disease, Fistulating Crohn’s disease and ulcerative colitis. The PBAC considered that the evidence presented in the submission supported the claims of comparative safety and effectiveness of Renflexis and Remicade.</p>

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(Major submission)			<p>The PBAC advised the Minister that it considered the Remicade and Renflexis brands of infliximab could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged) for the purposes of substitution by the pharmacist at the point of dispensing for all indications currently PBS-listed. The PBAC noted that the substitution process allows for patient and prescriber choice and is not automatic. For any individual prescription, a prescriber may choose to not permit brand substitution. If on the other hand, substitution has been permitted by the prescriber, the patient may choose which brand they wish to receive from the pharmacist.</p> <p>In forming its view on brand substitution ('a' flagging), the PBAC considered a range of factors including:</p> <ul style="list-style-type: none"> <li>• The key randomised clinical study in rheumatoid arthritis did not indicate differences in efficacy or safety of Renflexis compared with Remicade.</li> <li>• The clinical data provided in the submission did not suggest there were any identified populations where the risks of using the biosimilar product in place of the reference biologic were disproportionately high.</li> <li>• In the SB2-G31-RA transition-extension period which included 24 weeks of additional data, including a one-way switch from Remicade to Renflexis, the clinical evidence suggested no difference in efficacy, safety or immunogenicity between the biosimilar and the reference biologic. The proportion of patients who had at least one positive anti-drug antibodies result at week 78 was similar between for the Renflexis/Renflexis, Remicade/Remicade and Remicade/Renflexis groups.</li> <li>• The evidence presented in the SB2-G31-RA trial in treatment-naïve patients with rheumatoid arthritis initiating on either Remicade or Renflexis support a finding that Renflexis has equivalent effectiveness and equivalent safety compared to Remicade.</li> <li>• The Advisory Committee on Prescription Medicines (ACPM) has declared Renflexis a biosimilar for</li> </ul>

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			<p>Remicade. The ACPM was satisfied of the similar safety and efficacy of Renflexis and Remicade in rheumatoid arthritis, and that this could be extrapolated to ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn’s disease, refractory fistulating Crohn’s disease and ulcerative colitis. The ACPM also noted that there was no evidence to suggest the presence of anti-drug antibodies affected either the efficacy or safety of infliximab.</p> <p>The PBAC noted this submission sought listing of a second biosimilar brand of a biologic and that, in recommending an ‘a’ flag for Renflexis with Remicade, it is possible that switches between more than two brands of infliximab will occur in practice. The PBAC had no reason to consider this would affect patient outcomes.</p>
<p>IVACAFTOR</p> <p>Sachet containing granules 50 mg Sachet containing granules 75 mg</p> <p>Kalydeco®</p> <p>Vertex Pharmaceuticals (Australia) Pty Ltd</p> <p>Change to listing</p> <p>(Major submission)</p>	<p>Cystic fibrosis</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) listing of a new form of ivacaftor; and an extension to the current ivacaftor listing for patients aged 6 and above who have a G551D or other gating (class III) mutation in the cystic fibrosis transmembrane regulator (CFTR) gene to include patients aged 2-5 years.</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program), Authority Required listing of a new presentation of ivacaftor, in the form of granules, for treatment of cystic fibrosis CF in patients over the age of 2 years who have a G551D mutation or other class III gating mutations in the CFTR gene.</p> <p>The PBAC noted that limited efficacy data in the 2-5 years age group was provided. However, the PBAC also noted the ethical difficulties associated with getting clinical trial data in this setting. The PBAC noted that observational data from the Ivacaftor Long Term Safety Study showed a statistically significant improvement in the relative risk (RR) of hospitalisation in patients aged &lt;6 years (RR 0.68, 95%CI: 0.49-0.95). The PBAC recalled their earlier advice that the claim of superior efficacy over best supportive care in patients aged 2 to 5 years was biologically plausible and considered that, in this situation, the data provided was sufficient to support this claim.</p> <p>The PBAC noted that overall, the discounted cost/QALY gained was similar for the cohort aged 2-5 years and the</p>

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			cohort aged 6+ years (\$105,000 - \$200,000).
<p>LEVODOPA with CARBIDOPA</p> <p>Intestinal gel containing levodopa 20 mg with carbidopa (as monohydrate) 5 mg in 1 mL</p> <p>Duodopa®</p> <p>Abbvie Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	Parkinson disease	To request a change in the Note section of the current Authority Required (STREAMLINED) restriction.	The PBAC recommended the removal of the wording ‘a positive clinical response to Duodopa® administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted’ from the Note section of the Section 100 (Highly Specialised Drugs Program) listing for levodopa with carbidopa on the basis that this is a clinical decision for the practicing physician.
<p>NADROPARIN</p> <p>Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL (2,850 I.U. anti-Xa) in 0.3 mL (3800 IU anti-Xa) in 0.4 mL (5700 IU anti-Xa) in 0.6 mL (7600 IU anti-Xa) in 0.8 mL (9500 IU anti-Xa) in 1 mL (11400 IU anti-Xa) in 0.6 mL (15200 IU anti-Xa) in 0.8 mL (19000 IU anti-Xa) in 1 mL prefilled syringe</p> <p>Fraxiparine® and Fraxiparine Forte®</p> <p>Aspen Pharmacare Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	Deep Vein Thrombosis (DVT) prophylaxis/ treatment Haemodialysis	To request an increase in maximum quantities for all strengths of the listed formulations.	The PBAC recommended a change to the PBS listing for all currently available strengths of nadroparin to increase the maximum quantity and repeats such that the same number of syringes can be dispensed per script as the current listings for the comparator, enoxaparin.
NETUPITANT with PALONOSETRON	Nausea and vomiting associated	Resubmission to request General Schedule and Section 100 (Efficient Funding of	The PBAC recommended listing netupitant with palonosetron fixed dose combination, as an Authority

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<p>Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)</p> <p>Akynzeo®</p> <p>Mundipharma Pty Ltd</p> <p>Change to listing</p> <p>(Major submission)</p>	<p>with emetogenic cancer chemotherapy</p>	<p>Chemotherapy – Related Benefits) Authority Required (STREAMLINED) listings for the treatment of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy.</p>	<p>Required (STREAMLINED) benefit on the General Schedule and under the Section 100 (Efficient Funding of Chemotherapy – Related Benefits) program, for the secondary prophylaxis of chemotherapy induced nausea and vomiting associated with moderately emetogenic chemotherapy and for primary prophylaxis of chemotherapy induced nausea and vomiting associated with carboplatin or oxaliplatin chemotherapy regimens.</p> <p>The recommendation was made on a cost-minimisation basis to aprepitant, where the equi-effective doses, based on the eviQ guidelines, were based on the assumption that each chemotherapy course would be treated with one capsule of netupitant 300 mg with palonosetron 500 micrograms or one capsule of aprepitant 165 mg plus a 5-HT<sub>3</sub> receptor antagonist.</p>
<p>NINTEDANIB</p> <p>Capsule 100 mg Capsule 150 mg</p> <p>Ofev®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Idiopathic pulmonary fibrosis (IPF)</p>	<p>Resubmission to request an Authority Required listing for use in patients with IPF.</p>	<p>The PBAC recommended the listing of nintedanib for the treatment of IPF under certain conditions. The PBAC was satisfied that nintedanib provides, for some patients, a significant improvement in effectiveness over best supportive care (BSC).</p> <p>Pirfenidone was considered to be a relevant secondary comparator for nintedanib. The PBAC considered nintedanib and pirfenidone to be similarly clinically effective.</p> <p>The PBAC concluded that the cost effectiveness of nintedanib would be acceptable in conjunction with risk sharing measures to provide additional certainty.</p>
<p>OLAPARIB</p> <p>50mg capsule, 4 x 112</p> <p>Lynparza™</p> <p>AstraZeneca Pty Ltd</p> <p>New listing</p>	<p>BRCA-mutated (BRCAm) platinum-sensitive relapsed (PSR) ovarian, fallopian tube or primary peritoneal cancer with high-grade serous features or a high-</p>	<p>Resubmission to request Authority Required (STREAMLINED) listing for the treatment of BRCAm PSR ovarian, fallopian tube or primary peritoneal cancer with high-grade serous features or a high-grade serous component.</p>	<p>The PBAC recommended the Authority Required listing of olaparib for the treatment of BRCAm PSR high grade serous ovarian cancer, high grade serous fallopian tube cancer and high grade serous primary peritoneal cancer. The PBAC was satisfied that olaparib provides, for some patients, a significant improvement in efficacy over best supportive care. The PBAC considered that while there remained some uncertainty as to the extent of the overall survival benefit associated with olaparib in the model, the</p>

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(Minor submission)	grade serous component		resultant incremental cost-effectiveness ratio (ICER) of \$45,000 – 75,000 obtained from a price reduction over previous submissions was considered to be acceptable. The sponsor has agreed to enter into a Risk Sharing Arrangement with the Department to help mitigate the remaining uncertainty in the modelling.
<p>OMALIZUMAB</p> <p>Injection 150 mg in 1 mL</p> <p>Xolair®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	Severe chronic idiopathic urticaria	Resubmission to request a reassessment of the recommended equi-effective dose of omalizumab compared with cyclosporin.	The PBAC recommended the equi-effective doses of omalizumab 300 mg and cyclosporin 4 mg/kg based on the untitrated trial doses for both drugs.
<p>OXYCODONE with NALOXONE</p> <p>Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg</p> <p>Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg</p> <p>Targin®</p> <p>Mundipharma Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	Chronic severe disabling pain	To request an Authority Required listing for two additional strengths of oxycodone with naloxone for the treatment of chronic disabling pain unresponsive to non-opioid analgesics.	The PBAC recommended the listing of two additional strengths of oxycodone with naloxone (oxycodone 60 mg with naloxone 30 mg and oxycodone 80 mg with naloxone 40 mg) on the General Schedule as a Restricted Benefit for chronic severe disabling pain.
<p>PALIPERIDONE</p> <p>I.M. injection (modified release) 175 mg (as palmitate) in pre-filled syringe</p>	Schizophrenia	To request an Authority Required (STREAMLINED) listing for the treatment of patients with schizophrenia who have been adequately stabilised with paliperidone	The PBAC recommended the Authority Required (STREAMLINED) listing of paliperidone once per three month injection (PP3M) for schizophrenia, on a cost minimisation basis with equivalent doses of paliperidone

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<p>I.M. injection (modified release) 263 mg (as palmitate) in pre-filled syringe                      I.M. injection (modified release) 350 mg (as palmitate) in pre-filled syringe                      I.M. injection (modified release) 525 mg (as palmitate) in pre-filled syringe</p> <p>Invega® Trinza™</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>		<p>modified release injection.</p>	<p>once monthly injection (PP1M). In making its recommendation, the PBAC considered that PP3M was non-inferior in comparative efficacy and safety to PP1M.</p> <p>The PBAC considered there was a clinical place for PP3M, as it would provide an extended duration long acting injectable treatment with less frequent dosing compared with other PBS listed therapies and may contribute to improvements in patient comfort, carer burden and access for patients in rural and remote areas.</p>
<p>PARITAPREVIR with RITONAVIR with OMBITASVIR</p> <p>Tablet containing 75 mg paritaprevir with 50 mg ritonavir with 12.5 mg ombitasvir</p> <p>Technivie®</p> <p>AbbVie Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Chronic hepatitis C virus (HCV) infection</p>	<p>To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for paritaprevir with ritonavir with ombitasvir, in combination with ribavirin, for the treatment of patients with genotype 4 chronic HCV infection.</p>	<p>The PBAC recommended the Authority Required General Schedule and Section 100 listing of paritaprevir with ritonavir and ombitasvir, in combination with ribavirin for the treatment of treatment naïve and treatment experienced genotype 4 CHC infection on a cost-minimisation basis with grazoprevir with elbasvir ± ribavirin.</p>
<p>PEGVISOMANT</p> <p>Powder for injection 10 mg                      Powder for injection 15 mg                      Powder for injection 20 mg</p> <p>Somavert®</p> <p>Pfizer Australia Pty Ltd</p>	<p>Acromegaly</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of acromegaly in patients who have had inadequate response to surgery and/or radiation and/or other medical therapies.</p>	<p>The PBAC recommended the listing of pegvisomant as a Section 100 (Highly Specialised Drugs Program), Authority Required benefit for the treatment of acromegaly on a cost-minimisation basis to pasireotide. The PBAC considered that although the clinical evidence indicated that a greater proportion of patients achieved insulin-like growth factor-1 (IGF-1) normalisation with pegvisomant compared to pasireotide, octreotide or lanreotide, the naïve indirect comparison presented was inadequate to support a claim of superior effectiveness. The PBAC also noted that</p>

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<p>New listing (Major submission)</p>			<p>pegvisomant has a different safety profile to pasireotide, octreotide, and lanreotide. The PBAC considered that on the basis of the different safety profiles, the cost offsets applied to pasireotide for diabetes should not be applied to pegvisomant, but that as use of pegvisomant will require additional liver function testing, offsets for the cost of this testing should be applied to pegvisomant. The PBAC considered that the proposed equi-effective dose of 14.23 mg pegvisomant to 20, 40 and 60 mg pasireotide was highly uncertain and as such, an equivalent cost per day of treatment of pegvisomant compared to pasireotide, on a flat pricing basis, was appropriate.</p>
<p>PEMBROLIZUMAB Powder for injection 100 mg Keytruda® Merck Sharp &amp; Dohme (Australia) Pty Ltd New listing (Minor submission)</p>	<p>Melanoma</p>	<p>To request a Section 100 (Efficient funding of Chemotherapy) Authority Required (STREAMLINED) listing of an additional strength of pembrolizumab for unresectable stage III or stage IV malignant melanoma.</p>	<p>The PBAC recommended the listing of pembrolizumab 100 mg concentrated injection as a new form, under the same conditions, and at the same price per milligram, as the current PBS-listed pembrolizumab 50 mg powder for infusion for the treatment of metastatic melanoma.</p>
<p>SALBUTAMOL Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20 Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd Change to listing (Minor submission)</p>	<p>Asthma</p>	<p>To request a change to the pack size.</p>	<p>The PBAC recommended a change to the current general schedule listing of Ventolin Nebules® to decrease the pack size and increase the maximum quantity, in terms of packs, maintaining the current maximum quantity of 60 ampoules. The PBAC also recommended a change to the current emergency supply drug program listing of Ventolin Nebules® to decrease the pack size to 20 ampoules. The PBAC recommended that the note “Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution” be added to the administrative advice of the listing.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>SOFOSBUVIR with VELPATASVIR</p> <p>Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir</p> <p>Epclusa®</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p> <p>(Major submission)</p>	<p>Chronic hepatitis C virus (HCV) infection</p>	<p>To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for the treatment of chronic HCV infection, regardless of genotype. For patients with decompensated liver disease, the requested listing is in combination with ribavirin.</p>	<p>The PBAC recommended the Authority Required General Schedule and Section 100 listing of sofosbuvir with velpatasvir for the treatment of chronic HCV infection for patients with genotypes 1-6 and no cirrhosis. The PBAC also recommended the Authority Required General Schedule and Section 100 listing of sofosbuvir with velpatasvir +/- ribavirin for the treatment of chronic HCV infection for patients with genotypes 1-6 and cirrhosis.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment, as described above, that the cost-effectiveness of sofosbuvir with velpatasvir +/- ribavirin would be acceptable if it were cost-minimised against the relevant lowest priced alternative regimen in the General Statement for Drugs for the Treatment of Hepatitis C.</p> <p>The PBAC recommended that sofosbuvir/velpatasvir fixed dose combination enter the Risk Sharing Arrangement currently in place for other drugs used for the treatment of HCV infection.</p>
<p>SOMATROPIN</p> <p>Injection</p> <p>6 mg (18 i.u.) in 1.03 mL</p> <p>12 mg (36 i.u.) in 1.5 mL</p> <p>20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)</p> <p>Saizen®</p> <p>Merck Serono Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	<p>Severe growth hormone deficiency</p>	<p>To request an Authority Required listing for the treatment of growth disturbance (growth retardation) in pre-pubertal children due to chronic renal insufficiency (CRI).</p>	<p>The PBAC recommended the change to the listing of Saizen® to include an Authority Required listing for the treatment of short stature associated with CRI, on the basis that it should be available only under special arrangements under Section 100 (Human Growth Hormone Program), at an equivalent price per milligram as other brands of somatropin.</p>
<p>TENOFOVIR ALAFENAMIDE with EMTRICITABINE and RILPIVIRINE</p>	<p>Human immunodeficiency</p>	<p>Authority Required (STREAMLINED) listing for treatment of HIV infection.</p>	<p>The PBAC recommended the listing of tenofovir alafenamide with emtricitabine and rilpivirine in the</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>tenofovir alafenamide 25 mg + emtricitabine 200 mg + rilpivirine 25 mg, tablet, 30</p> <p>Odefsey®</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>virus (HIV)</p>		<p>form tenofovir alafenamide 25 mg + emtricitabine 200 mg + rilpivirine 25 mg on a cost minimisation basis with tenofovir disoproxil fumarate with emtricitabine and rilpivirine in the form tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg.</p>
<p>TENOFOVIR ALAFENAMIDE with EMTRICITABINE</p> <p>tenofovir alafenamide 10 mg + emtricitabine 200 mg tablet, 30 tenofovir alafenamide 25 mg + emtricitabine 200 mg tablet, 30</p> <p>Descovy®</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p> <p>(Minor submission)</p>	<p>Human immunodeficiency virus (HIV)</p>	<p>Authority Required (STREAMLINED) listing for treatment of HIV infection.</p>	<p>The PBAC recommended the listing of tenofovir alafenamide with emtricitabine in the forms tenofovir alafenamide 10 mg + emtricitabine 200 mg and tenofovir alafenamide 25 mg + emtricitabine 200 mg on a cost minimisation basis with tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg.</p>
<p>TRIGLYCERIDES MEDIUM CHAIN FORMULA</p> <p>Oral liquid solution, 500mL</p> <p>Nutrini Peptisorb Energy</p> <p>Nutricia Australia Pty Ltd</p>	<p>Dietary management of conditions requiring a source of medium chain triglycerides</p>	<p>To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides.</p>	<p>The PBAC recommended the listing of Nutrini Peptisorb Energy as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides for patients aged 1-10 years old on a cost minimisation basis against Peptamen Junior at an equivalent price per kilojoule of energy.</p>

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<b>DRUG, SPONSOR, TYPE OF SUBMISSION</b>	<b>DRUG TYPE OR USE</b>	<b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b>	<b>PBAC OUTCOME</b>
New listing (Minor submission)			
<p>VARENICLINE</p> <p>Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack Tablet 1 mg (as tartrate)</p> <p>Champix®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor submission)</p>	Nicotine dependence	To request the current Authority Required listing be changed to Authority Required (STREAMLINED).	<p>The PBAC recommended amending the listings of varenicline from Authority Required to Authority Required (STREAMLINED). The PBAC reaffirmed its previous consideration that varenicline is superior to bupropion, nicotine replacement therapy (NRT) and placebo with regard to comparative efficacy. The PBAC considered that varenicline may be non-inferior to NRT and placebo with regards to comparative safety.</p> <p>The PBAC considered that changing varenicline to a STREAMLINED Authority was unlikely to significantly impact the utilisation of varenicline. This conclusion was supported by the DUSC review of smoking cessation therapies that found no significant impact on utilisation trends following similar changes to bupropion and NRT listings.</p>