

**MARCH 2016 PBAC MEETING – POSITIVE RECOMMENDATIONS**

<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>
<p>ATOMOXETINE 10 mg capsule, 28 18 mg capsule, 28 25 mg capsule, 28 40 mg capsule, 28 60 mg capsule, 28 80 mg capsule, 28 100 mg capsule, 28</p> <p>Strattera®</p> <p>Request from pharmaceutical advisors at Department of Human Services</p> <p>Matters Outstanding</p> <p>(Other Submission)</p>	<p>Attention-deficit hyperactivity disorder</p>	<p>To amend the current restriction for atomoxetine to include lisdexamfetamine as an appropriate first line treatment, in addition to dexamphetamine and methylphenidate.</p>	<p>The PBAC considered the restriction for atomoxetine should be updated to include lisdexamfetamine as an appropriate first line treatment, in addition to dexamphetamine and methylphenidate.</p>
<p>AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE oral liquid, 20 x 500 mL</p> <p>PKU Baby®</p> <p>Orpharma Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for phenylketonuria.</p>	<p>The PBAC recommended listing amino acid formula with fat, carbohydrate, vitamins, minerals and long chain fatty acids without phenylalanine and supplemented with docosahexaenoic acid, oral liquid 500 mL, 20 (PKU Baby®) as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine, oral powder 400 g (PKU Anamix Infant®) at an equivalent price per gram of protein.</p>

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<p>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid: powder for, 30 x 20 g sachets</p> <p>PKU Go®</p> <p>Orpharma Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for phenylketonuria.</p>	<p>The PBAC recommended listing amino acid formula with vitamins carbohydrate, vitamins, and minerals and trace elements without phenylalanine, sachets containing oral powder 20 g, 30 (PKU Go®) as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against amino acid formula with vitamins and minerals without phenylalanine, sachets containing oral powder 24 g, 30 (PKU Gel®) at an equivalent price per gram of protein.</p>
<p>ADALIMUMAB 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes</p> <p>Humira®</p> <p>Abbvie Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Ulcerative colitis</p>	<p>Re-submission to request an Authority Required listing for the treatment of patients with moderate to severe ulcerative colitis.</p>	<p>The PBAC recommended the listing of adalimumab on the General Schedule for the treatment of moderate to severe ulcerative colitis on the basis of a clinical need for subcutaneous therapy for this condition. In making this recommendation, the PBAC considered that adalimumab is likely to be less effective than infliximab for this indication and that this should be reflected in the price of adalimumab. The PBAC recommendation was based on the following comparable doses: adalimumab 160 mg at week 0 and 80 mg week 2, then 40 mg fortnightly thereafter and infliximab 5 mg/kg (weeks 0, 2, and 6 then every 8 weeks thereafter).</p> <p>The clinical evidence presented to the PBAC was a comparison of five randomised controlled trials.</p>

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<p>APREPITANT 165 mg capsule, 1</p> <p>Emend®</p> <p>Merck Sharp and Dohme (Australia) Pty Limited</p> <p>Change to listing  (Minor Submission)</p>	<p>Chemotherapy induced nausea and vomiting</p>	<p>Re-submission to request an extension to the current Section 100 (Chemotherapy - Related Benefits) and General Schedule PBS listings to include use with carboplatin/oxaliplatin regimens from the first chemotherapy cycle without having a prior episode of chemotherapy induced nausea and vomiting.</p>	<p>The PBAC recommended listing aprepitant as an Authority Required (Streamlined) benefit on the General Schedule and under the Section 100 program Efficient Funding of Chemotherapy – Related Benefits, for use with carboplatin/oxaliplatin regimens from the first chemotherapy cycle, without having a prior episode of chemotherapy induced nausea and vomiting.</p> <p>In making its recommendation, the PBAC noted that the resubmission proposed a price for aprepitant for this indication that was cost-minimised to the price of aprepitant when used with moderately emetogenic chemotherapy, as per the PBAC’s advice from November 2015.</p> <p>The PBAC noted that no new clinical data was presented in the resubmission, and that the PBAC’s consideration of the clinical claim remained unchanged from November 2015.</p> <p>The original submission was based on a series of meta-analysis of four head-to-head trials.</p>

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<p>ARMODAFINIL 50 mg tablet, 30 150 mg tablet, 30 250 mg tablet, 30</p> <p>Nuvigil®</p> <p>TEVA Pharma Australia Pty Ltd</p> <p>New Listing</p> <p>(Minor Submission)</p>	<p>Narcolepsy</p>	<p>Re-submission to request an Authority Required listing for the treatment of narcolepsy.</p>	<p>The PBAC recommended an Authority Required listing for armodafinil for the treatment of narcolepsy on a cost-minimisation basis with modafinil. The PBAC considered the two medicines would have the same health benefit and the equi-effective doses to be armodafinil 250 mg and modafinil 348.55 mg, resulting in a dose relativity of 5:7 as proposed by the resubmission.</p> <p>The PBAC had previously considered the clinical trial data in November 2015, which was based on an indirect comparison between three randomised controlled trials.</p> <p>The PBAC maintained its previous view that there was no apparent unmet clinical need for armodafinil. The PBAC noted the resubmission's claims of differences in plasma concentrations and dose response, however the PBAC were not convinced that these differences would result in armodafinil having any appreciable clinical advantage over modafinil.</p> <p>The PBAC noted that over time, armodafinil may cease to be cost-effective due to decreases in the modafinil price as a result of patent expiry and the introduction of generic versions of modafinil. The PBAC noted that at some point in the future, the Minister may wish to seek advice from the PBAC regarding the ongoing cost-effectiveness of armodafinil.</p> <p>The PBAC noted that the resubmission proposed cost savings to Government upon the listing of armodafinil, however considered that these savings will not be realised if the price of modafinil decreases over time.</p> <p>The PBAC recommended under Section 101(3BA) of the National Health Act, that armodafinil should be treated as interchangeable on an individual patient basis with modafinil.</p>

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<p>BEVACIZUMAB 100 mg/4 mL injection, 1 x 4 mL vial 400 mg/16 mL injection, 1 x 16 mL vial</p> <p>Avastin®</p> <p>Roche Products Pty Limited</p> <p>Change to listing (Minor Submission)</p>	<p>Advanced cervical cancer</p>	<p>Re-submission to request Section 100 Authority Required (STREAMLINED) listing for the treatment of patients with persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation, in combination with platinum-based chemotherapy or topotecan plus paclitaxel.</p>	<p>The PBAC recommended the Section 100 Authority Required (STREAMLINED) listing for bevacizumab in combination with platinum-based chemotherapy plus paclitaxel for the treatment of persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation. The recommendation was made on the basis of cost-effectiveness of bevacizumab with chemotherapy compared with chemotherapy alone.</p> <p>The clinical evidence presented to the PBAC was a randomised phase III trial.</p> <p>On the basis of direct evidence presented by the November 2015 submission, the comparison of bevacizumab plus chemotherapy and chemotherapy alone resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately 3.5 months prolongation in median overall survival over a median follow-up of 61 weeks.</li> <li>• Approximately 2.3 months prolongation in median progression free survival for over a median follow-up of 52 weeks.</li> <li>• Approximately 15 additional patients would experience a serious adverse event, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of 20.7 weeks.</li> <li>• Approximately 21 additional patients would experience serious adverse events of special interest, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of 20.7 weeks.</li> </ul> <p>The PBAC considered that the incremental cost-effectiveness ratio was at the high end of what would be considered cost-effective, but that this was acceptable in the context of a relatively small population with a high clinical need for treatments for patients with persistent, recurrent or metastatic cervical cancer.</p>

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<p>BORTEZOMIB 3 mg injection, 3 mg vial</p> <p>Velcade®</p> <p>Janssen-Cilag Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Multiple myeloma</p>	<p>To request a Section 100 EFC Authority Required listing for a new strength (3mg vial) of bortezomib for multiple myeloma.</p>	<p>The PBAC recommended the Authority Required Section 100 (Efficient Funding of Chemotherapy) listing of the new 3 mg vial strength of bortezomib for all currently reimbursed indications of bortezomib for the treatment of multiple myeloma. This listing would not change the way patients seek treatment and have no financial impact for the Government.</p>
<p>BEE VENOM, PAPER WASP VENOM AND YELLOW JACKET VENOM</p> <p>Insect allergen extract injection set containing 550 micrograms with diluent</p> <p>Hymenoptera Honey Bee Venom® Hymenoptera Yellow Jacket Venom® Hymenoptera Paper Wasp Venom®</p> <p>Stallergenes Australia Pty Ltd</p> <p>Out of session recommendations (Late paper submission)</p>	<p>insect allergen extract</p>	<p>To request General Schedule PBS listing of insect allergen extract - honey bee venom, yellow jacket venom and paper wasp venom due to a shortage of supply of currently PBS listed products.</p>	<p>The PBAC recommended listing of new forms of bee venom, paper wasp venom, and yellow jacket venom on the PBS on the basis of equivalent cost to the currently listed respective venom products. The requested restriction was in line with that for the currently listed products.</p> <p>The PBAC noted the correspondence from the President of the Australasian Society of Clinical Immunology and Allergy (ASCIA) expressing support for the expedited listing of these replacement products and emphasising their life saving nature.</p> <p>The PBAC considered that there is a clinical need for the supply of these venoms to be maintained on the PBS.</p>

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<p>CERTOLIZUMAB PEGOL 200 mg/mL injection, 2 x 1 mL syringes</p> <p>Cimzia®</p> <p>UCB Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Moderate to severe active rheumatoid arthritis, ankylosing spondylitis and severe psoriatic arthritis</p>	<p>To request an additional PBS item number for the loading dose of Cimzia for the three currently listed indications.</p>	<p>The PBAC recommended that the loading doses at weeks 0, 2 and 4 should be allowed under one co-payment rather than under the three co-payments as currently required. The PBAC noted that the change will result in patients undertaking the 20-week initial treatment having to pay one co-payment for the three loading doses and another three co-payments, instead of the total of six co-payments as currently required.</p>
<p>COBIMETINIB and VEMURAFENIB cobimetinib 20 mg tablet, 63 vemurafenib 240 mg tablet, 56</p> <p>Cotellic® Zelboraf®</p> <p>Roche Products Pty Limited</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Unresectable Stage III or IV malignant melanoma</p>	<p>Authority Required (STREAMLINED) listing for the treatment BRAF V600 mutation positive unresectable Stage III or IV malignant melanoma.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of vemurafenib in combination with cobimetinib, for the treatment of BRAF V600 mutation positive unresectable or metastatic melanoma, on a cost-minimisation basis against dabrafenib + trametinib at an equi-effective dose of vemurafenib 960 mg twice daily + cobimetinib 60 mg once daily (Days 1–21 of each 28 cycle) versus dabrafenib 150 mg twice daily + trametinib 2 mg once daily.</p> <p>The evidence presented to the PBAC was a comparison of three randomised controlled trials.</p> <p>The PBAC considered that vemurafenib + cobimetinib would have the same health benefit as dabrafenib + trametinib. The PBAC noted that the sponsor of vemurafenib + cobimetinib would be required to share the current Risk Share Arrangement and Special Price Arrangement for dabrafenib + trametinib, and also any applicable price and rebate consequences following the conclusion of the managed access scheme for trametinib.</p>

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<p>DARUNAVIR + COBICISTAT darunavir 800 mg + cobicistat 150 mg tablet, 30</p> <p>Prezcobix®</p> <p>Janssen-Cilag Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>HIV infection</p>	<p>Re-submission to request Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of HIV infection in combination with other antiretroviral agents in patients who are antiretroviral treatment naïve or in patients who are treatment experienced with no darunavir resistance associated mutations</p>	<p>The PBAC recommended the Section 100 Highly Specialised Drugs Program (HSD) listing of darunavir with cobicistat fixed dose combination (FDC) for the treatment of HIV. The PBAC recommended the special arrangements under the HSD Community Access Program, Authority Required (STREAMLINED). The PBAC considered that it was appropriate, in line with treatment guidelines for the darunavir with cobicistat FDC to be available to patients who are being treated for the first time or have been treated previously.</p> <p>The PBAC recommended the listing of darunavir with cobicistat on a cost-minimisation basis with atazanavir plus ritonavir provided concomitantly in the treatment naïve setting and darunavir plus ritonavir provided concomitantly in the treatment experience setting. The PBAC considered that darunavir with cobicistat fixed dose combination would give patients the same clinical benefit as currently listed HIV treatments.</p> <p>The clinical evidence considered by the PBAC included a Phase 3, randomised, open label trial, pharmacokinetic studies and an indirect comparison of one non-randomised study to single arms of four randomised trials.</p>

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<p>DEXAMETHASONE 700 microgram implant, 1  Ozurdex®  Allergan Australia Pty Ltd  New listing  (Major Submission)</p>	<p>Diabetic macular oedema</p>	<p>Resubmission for Authority Required listing for the treatment of visual impairment due to diabetic macular oedema in patients with pseudophakia (i.e. artificial lens following cataract surgery) or who are scheduled for cataract surgery.</p>	<p>The PBAC recommended Authority Required listing of dexamethasone implant, on the basis of inferior effectiveness and inferior safety compared with ranibizumab and aflibercept and thus on appropriately adjusted estimates of cost-effectiveness.</p> <p>The resubmission presented indirect comparisons of dexamethasone implant versus aflibercept injection based on eight randomised controlled trials involving either dexamethasone implant or aflibercept injection for treatment of visual impairment due to diabetic macular oedema. Consistent with its previous finding for the comparison between dexamethasone implant and ranibizumab injection, the PBAC concluded from the evidence provided overall that dexamethasone implant is less effective and less safe than either ranibizumab or aflibercept injection. However, the PBAC recommended that the listing be restricted to patients with pseudophakic lens or who are also scheduled for cataract surgery, who also have a contraindication to, or have failed to respond to a VEGF inhibitor, or where a VEGF inhibitor is otherwise unsuitable. The PBAC recognised an unmet clinical need for this therapy among these patients.</p> <p>The PBAC considered that the resubmission’s cost-minimisation approach was not justified because the claim of non-inferiority of dexamethasone implant versus ranibizumab or aflibercept injection was not supported by the clinical evidence presented in the original submission or this resubmission.</p>

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<p>EVOLOCUMAB 140 mg/1 mL injection, 1 mL injection device, 1</p> <p>Repatha®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Familial hypercholesterolaemia</p>	<p>Resubmission for Authority Required listing for the treatment of familial hypercholesterolaemia.</p>	<p>The PBAC recommended the Authority Required listing of evolocumab under Section 85, for the treatment of homozygous familial hypercholesterolaemia (FH). In making this recommendation, the PBAC considered that the homozygous FH population (with an abnormality in both of the two copies of the specific gene) represent a small, definable, patient group, in whom there is a high level of clinical need.</p> <p>On the basis of direct evidence presented in the re-submission, the comparison of evolocumab (monthly) and placebo in patients with homozygous familial hypercholesterolaemia resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately a 30% relative reduction in low-density lipoprotein (LDL) levels over a 12-week treatment duration.</li> <li>• No apparent difference in adverse events over a 12-week treatment duration.</li> </ul> <p>The PBAC considered that reduction of LDL was a clinically meaningful outcome for the homozygous FH population.</p> <p>The PBAC did not recommend listing for the treatment of heterozygous familial hypercholesterolaemia. On the basis of direct evidence presented in the re-submission, the comparison of evolocumab (fortnightly/monthly) and placebo in patients with heterozygous familial hypercholesterolaemia resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately a 60% relative reduction in LDL levels over a 12-week treatment duration.</li> <li>• No apparent difference in adverse events over a 12-week treatment duration.</li> </ul> <p>The PBAC accepted the clinical trial evidence that demonstrated a statistically significant decrease in LDL outcomes when treated with evolocumab compared to ezetimibe or placebo, but considered that the translation of these changes to health outcomes was important for the assessment of the heterozygous population.</p> <p>The PBAC considered that the outcomes of the economic analysis were</p>

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			<p>uncertain and that the additional cost to the health system for the claimed health benefit was too high at the price proposed by the sponsor. The PBAC noted that the FOURIER study will report on cardiovascular outcomes including mortality data, and these clinical data may give additional certainty to the cost-effectiveness claim.</p> <p>The clinical evidence presented to the PBAC included nine randomised controlled trials.</p>
<p>EXENATIDE 2 mg powder for injection pre-filled pen</p> <p>Bydureon®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Type 2 diabetes mellitus (dual and triple therapy)</p>	<p>To request an Authority Required (STREAMLINED) listing of a new dual chamber pen presentation.</p>	<p>The PBAC recommended exenatide - Injection 2 mg per dose pre-filled pen as an Authority Required (Streamlined) benefit for the treatment of type 2 diabetes mellitus, under the same circumstances and on the same basis as the previously recommended exenatide 2 mg single dose tray presentation.</p>

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<p>FOLLITROPIN ALFA 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices</p> <p>Bemfola®</p> <p>Finnox Biotech Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Assisted reproduction</p>	<p>To request listing of Bemfola (follitropin alfa), a similar biological medicinal product, with the same indications and restrictions as the currently PBS listed brand of follitropin alfa (Gonal-f), including a Section 100 (IVF Program) Authority Required (STREAMLINED) listing for controlled ovarian hyperstimulation in women undergoing assisted reproductive technologies and General Schedule Restricted Benefit listings for anovulatory infertility and hypogonadotrophic hypogonadism.</p>	<p>The PBAC recommended the listing of follitropin alfa (Bemfola) as a biosimilar of follitropin alfa (Gonal-f), on a cost-minimisation basis to follitropin alfa (Gonal-f), where the equi-effective doses are 1.0 I.U follitropin alfa (Bemfola) and 1.0 I.U follitropin alfa (Gonal-f). The PBAC recommended that the same indications that apply to follitropin alfa (Gonal-f) should apply to follitropin alfa (Bemfola). Gonal-f is currently listed on the General Schedule for anovulatory infertility and hypogonadotrophic hypogonadism, and on the Section 100 IVF Program for Assisted Reproductive Technology.</p> <p>The PBAC advised the Minister that it considered the Gonal-f and Bemfola brands of follitropin alfa could not 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. The PBAC advised that this is primarily due to differences in the strengths, number of pens per pack and maximum quantities between the brands, which make substitution at the pharmacy level difficult from a practical perspective.</p> <p>The PBAC considered a range of other factors in forming its view on brand substitution (“a” flagging) including:</p> <ul style="list-style-type: none"> <li>• The results from randomised clinical trials FIN1001, with regard to pharmacokinetic bioequivalence, and FIN3001, with regard to oocyte retrieval, support a finding that Bemfola has equivalent effectiveness and equivalent safety compared to Gonal-f.</li> <li>• Subjects in FIN3001, i.e. women receiving ART, may be the most “sensitive” population to identify differences, if any, in the benefits and harms associated with Bemfola with Gonal-f.</li> <li>• FIN3001 excluded patients who had received more than one previous treatment cycle. Whilst the number of previous treatment cycles, if any, was not recorded, it is possible that some patients in this trial were treatment-naïve. Results were not separately reported for these patients.</li> <li>• The submission did not provide any evidence regarding the efficacy and safety of switching patients between Bemfola and Gonal-f or vice versa.</li> <li>• The TGA has declared Bemfola a biosimilar to Gonal-f.</li> </ul>

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<p>GLUCOSE INDICATOR BLOOD 100 strips</p> <p>VivaChek Ino</p> <p>Boian Surgical Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Diabetes</p>	<p>To request PBS listing of a new brand of blood glucose test strips.</p>	<p>The PBAC recommended listing of Attest VivaChek Ino Blood Glucose Test Strips under the same conditions as currently PBS listed blood glucose test strips.</p>
<p>LLENALIDOMIDE</p> <p>5 mg capsule</p> <p>10 mg capsule</p> <p>15 mg capsule</p> <p>25 mg capsule</p> <p>Revlimid®</p> <p>Celgene Pty Ltd</p> <p>Matters Outstanding</p> <p>(Other Submission)</p>	<p>Multiple myeloma</p>	<p>To inform the PBAC of a new price offered by the sponsor for lenalidomide as a first line therapy in the treatment of patients with newly diagnosed symptomatic multiple myeloma (NDMM) who are ineligible for stem cell transplant.</p>	<p>The PBAC recommended the listing of lenalidomide, in combination with dexamethasone as first line therapy for patients who are newly diagnosed with multiple myeloma (NDMM), as a Section 100 (Highly Specialised Drugs Program) listing, on the basis of acceptable cost-effectiveness at the new offered price.</p> <p>As previously, the PBAC acknowledged there is a high clinical need for oral therapies in the treatment of multiple myeloma (MM). The PBAC recalled that input received from the Consumer Hearing at the November 2015 meeting indicated a strong preference for oral therapies for the treatment of MM. The PBAC also noted input received from an individual healthcare professional in support of the listing.</p>

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<p>LEUPRORELIN                      22.5 mg injection: modified release [1 x 22.5 mg syringe] (&amp; inert substance diluent [1 x 2 mL syringe], 1 pack                      30 mg injection: modified release [1 x 30 mg syringe] (&amp; inert substance diluent [1 x 2 mL syringe], 1 pack                      7.5 mg injection: modified release [1 x 7.5 mg syringe] (&amp; inert substance diluent [1 x 2 mL syringe], 1 pack                      45 mg injection: modified release [1 syringe] (&amp; inert substance diluent [1 syringe], 1 pack</p> <p>Lucrin®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate; Central precocious puberty</p>	<p>To request a Restricted Benefit listing to replace current Authority Required and Authority Required (Streamlined) listings, in line with the current listing for goserelin</p>	<p>As requested by the sponsor, the PBAC recommended amending the current PBS listings for intramuscular injection leuporelin (Lucrin) for the treatment of locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate, and central precocious puberty (CPP), from Authority Required to Restricted Benefit.</p> <p>The PBAC noted this amendment would ensure consistency with goserelin, another gonadotrophin hormone releasing (GnRH) agonist, which was changed from Authority Required (STREAMLINED) to Restricted Benefit as part of the Post Market Review of Authority Required PBS listings. As a flow on from this recommendation for leuporelin (Lucrin), the PBAC also recommended that subcutaneous version of leuporelin (Eligard) and triptorelin for the treatment of locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate, and nafarelin for the treatment of endometriosis (all GnRH agonists) be amended from Authority Required to Restricted Benefit.</p>

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<p>LINAGLIPTIN LINAGLIPTIN and METFORMIN linagliptin 5 mg tablet, 30 linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60</p> <p>Trajenta® Trajentamet®</p> <p>Boehringer Ingelhiem Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>Authority Required (STREAMLINED) listing for use in combination with insulin in patients with type 2 diabetes mellitus.</p>	<p>The PBAC recommended an Authority Required (Streamlined) listing of linagliptin for treatment of type 2 diabetes mellitus in combination with insulin, on a cost-minimisation basis with dapagliflozin in combination with insulin.</p> <p>The PBAC recommended an Authority Required (Streamlined) listing of linagliptin with metformin (FDC) for the treatment of type 2 diabetes mellitus in combination with insulin, on a cost-minimisation basis to the individual components taken concomitantly in combination with insulin.</p> <p>The submission was based on two indirect comparisons of numerous randomised controlled trials:</p> <ul style="list-style-type: none"> <li>• An indirect analysis comparing linagliptin 5 mg plus insulin with dapagliflozin plus insulin, using placebo plus insulin as the common comparator.</li> <li>• An indirect analysis comparing linagliptin 5 mg plus insulin with sitagliptin plus insulin, using placebo plus insulin as the common comparator.</li> </ul>
<p>LINAGLIPTIN LINAGLIPTIN and METFORMIN linagliptin 5 mg tablet, 30 linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60</p> <p>Trajenta® Trajentamet®</p> <p>Boehringer Ingelhiem Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>Re-submission for Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.</p>	<p>The PBAC recommended the PBS listing of linagliptin in triple oral combination with metformin and a sulfonylurea on a cost-minimisation basis with sitagliptin.</p> <p>The PBAC recommended linagliptin with metformin FDC for use with a sulfonylurea on a cost-minimisation basis with its individual components taken concomitantly.</p> <p>The submission was based on a series of indirect comparisons of randomised controlled trials using placebo + metformin + sulfonylurea as common comparator.</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>
<p>LIPEGFILGRASTIM 6 mg/0.6mL, 1 x 0.6 mL injection</p> <p>Lonquex®</p> <p>TEVA Pharma Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Neutropenia</p>	<p>Section 100 (Highly Specialised Drugs Program) Authority Required listing for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in line with the current listings for pegfilgrastim.</p>	<p>The PBAC recommended an Authority Required listing of lipegfilgrastim under Section 100 (Highly Specialised Drugs Program) for prophylaxis of chemotherapy induced neutropenia. The recommendation was made on a cost-minimisation basis with filgrastim where the equi-effective doses are lipegfilgrastim 6 mg once per chemotherapy cycle, pegfilgrastim 6 mg once per chemotherapy cycle and filgrastim injection 5 microgram/kg/day for 11.25 days.</p> <p>The submission presented two head-to-head randomised trials.</p>
<p>LUTROPIN ALFA and FOLLITROPIN ALFA + LUTROPIN ALFA lutropin alfa 75 international units injection [1 x 75 international units vial] (&amp; inert substance diluent [1 x 1 mL vial], 1 follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&amp; inert substance diluent [1 vial], 1</p> <p>Luveris® Pergoveris®</p> <p>Merck Serono Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Assisted reproduction</p>	<p>To request increased maximum quantities for Luveris and Pergoveris</p>	<p>The PBAC recommended amending the maximum PBS quantities for the current Section 100 listings of follitropin alfa + lutropin alfa and lutropin alfa from seven to 14, consistent with the maximum PBS quantities available for other drugs used for ovarian stimulation.</p>

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<p>MORPHINE                      10 mg/1 mL solution for injection, 5 x 1 mL ampoules                      20 mg/1 mL solution for injection, 5 x 1 mL ampoules                      50 mg/5 mL solution for injection, 5 x 5 mL ampoules                      100 mg/5 mL solution for injection, 5 x 5 mL ampoules</p> <p>Morphine Juno®</p> <p>Juno Pharmaceuticals Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Pain</p>	<p>To request an Unrestricted benefit listing of a new brand and additional strengths of morphine injection.</p>	<p>The PBAC recommended listing the 10 mg/mL, 20 mg/mL, 50 mg/5 mL, and 100 mg/5 mL strengths of morphine (as morphine hydrochloride) under the same circumstances as per the current listings for morphine (as morphine sulfate and morphine tartrate). The PBAC recommended that the price of morphine be determined on a price per mg basis in line with the currently listed injections containing morphine sulfate and morphine tartrate, including taking into account the currently listed 120 mg/1.5 mL vial containing morphine tartrate.</p>

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<p>OCRIPLASMIN 0.5 mg/0.2 mL injection, 1 x 0.2 mL vial</p> <p>Jetrea®</p> <p>Alcon Laboratories (Australia) Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Vitreomacular traction</p>	<p>Re-submission for Authority required listing for the treatment of vitreomacular traction.</p>	<p>The PBAC recommended the Authority Required listing of ocriplasmin for the treatment of vitreomacular traction (VMT), a disease of the eye, excluding patients with VMT that had an epiretinal membrane (ERM) or vitreomacular adhesion with a diameter greater than 1500 micrometres, on the basis of appropriately adjusted estimates of cost-effectiveness compared to watchful waiting with or without vitrectomy (eye surgery).</p> <p>The clinical evidence considered by the PBAC included three head-to-head randomised clinical trials.</p> <p>The primary outcome of the ocriplasmin trials showed, for example, that ocriplasmin resolved vitreomacular adhesion (VMA) in the eye without surgery, 28 days after treatment. Any relationship between this result (measured a short time after treatment) with other patient-relevant outcomes (such as improved eye sight or a need for eye surgery in the future) had not been adequately explored in the submission. However, the PBAC considered that there were the negative impacts to patients following eye surgery. The PBAC considered that the clinical value of ocriplasmin with respect to the patient-relevant outcomes of improving eye sight and of preventing, rather than delaying, eye surgery in the long-term remained unclear, but acknowledged that ocriplasmin provides a net clinical benefit to some patients.</p>
<p>PEMETREXED 1000 mg powder for I.V. infusion</p> <p>Pemetrexed MYX™</p> <p>Mayne Pharma International Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Locally advanced or metastatic non-small-cell lung cancer and mesothelioma</p>	<p>To request listing of an additional strength of pemetrexed, 1000 mg, on the PBS. This accompanies a request for generic listing of Pemetrexed MYX at 100 mg and 500 mg.</p>	<p>The PBAC recommended listing pemetrexed 1 g under Section 100 (Efficient Funding of Chemotherapy) for the treatment of locally advanced or metastatic non-small cell lung cancer and mesothelioma. The PBAC recommended the same circumstances and (ex-manufacturer) price per mg as the currently listed strengths of pemetrexed.</p>

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<p>PEMETREXED 1000 mg powder for injection</p> <p>DBL Pemetrexed™</p> <p>Hospira Pty Limited</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Locally advanced or metastatic non-small-cell lung cancer and mesothelioma</p>	<p>To request listing of an additional strength of pemetrexed, 1000mg, on the PBS.</p>	<p>The PBAC recommended listing pemetrexed 1 g under Section 100 (Efficient Funding of Chemotherapy) for the treatment of locally advanced or metastatic non-small cell lung cancer and mesothelioma. The PBAC recommended the same circumstances and (ex-manufacturer) price per mg as the currently listed strengths of pemetrexed.</p>
<p>RIOCIGUAT 0.5 mg tablet, 42 and 84 packs 1 mg tablet, 42 and 84 packs 1.5 mg tablet, 42 and 84 packs 2 mg tablet, 42 and 84 packs 2.5 mg tablet, 42 and 84 packs</p> <p>Adempas®</p> <p>Bayer Australia Ltd</p> <p>Change to recommended listing</p> <p>(Major Submission)</p>	<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</p>	<p>Resubmission for Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of inoperable CTEPH or persistent CTEPH subsequent to pulmonary endocardectomy.</p>	<p>The PBAC recommended the listing of riociguat, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program) for the treatment of patients with inoperable CTEPH or persistent CTEPH subsequent to pulmonary endarterectomy. The PBAC was satisfied that riociguat provides, for some patients, a significant improvement in efficacy over placebo.</p> <p>On the basis of the direct evidence presented by the re-submission, treatment with riociguat in comparison to placebo over 16 weeks resulted in an average increase of 46 metres in the distance able to be walked in 6 minutes. By comparison, participants were able to walk approximately 350 metres in 6 minutes at the beginning of the trial.</p> <p>On the basis of the direct evidence presented by the re-submission, every 100 patients treated with riociguat in comparison to placebo resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately 18 additional patients with an improvement by ≥1 WHO functional class over 16 weeks.</li> <li>• Approximately 12 additional patients with dizziness over 16 weeks.</li> <li>• Approximately 8 additional patients with hypotension over 16 weeks.</li> </ul> <p>The PBAC considered that the claim of superior comparative effectiveness, with regards to improvement in 6MWD and WHO functional class, was reasonable. The PBAC considered that a claim of inferior comparative safety, with regards to a higher incidence of dizziness and hypotension was reasonable.</p>

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			<p>The resubmission addressed some of the PBAC’s previous concerns with the economic model structure. While the PBAC considered that the economic modelling overall remained unreliable, considering the limitations in the available data the PBAC considered that the most appropriate incremental cost-effectiveness ratio (ICER) for decision making may be around \$45,000 – \$75,000 per quality adjusted life year. In the context of the clinical need for an effective treatment for this condition, the small patient population, a tight restriction, and a revised price offer, the PBAC pragmatically considered that the cost-effectiveness was acceptable enough to allow recommendation in this instance.</p>
<p>SIMEPREVIR 150 mg capsule,  Olysio®,  Janssen-Cilag Australia Pty Ltd  Out of session recommendations  (Late paper submission)</p>	<p>Chronic hepatitis C (CHC) infection</p>	<p>To seek a PBAC recommendation to change the current Section 100 Highly Specialised Drug Program public hospital listings for simeprevir (treatment naïve and treatment experience patients) to Authority required (telephone).</p>	<p>The PBAC recommended to change the current Section 100 (Highly Specialised Drug Program) public hospital listings for simeprevir (treatment naïve and treatment experience patients) to Authority required (telephone). The PBAC noted that, at the current list price of simeprevir, simeprevir prescribed with sofosbuvir would not be considered a cost-effective treatment for Hepatitis C, following the recent recommendation to list interferon-free oral treatment.</p>
<p>SECUKINUMAB 150 mg/mL injection, 1 x 1 mL injection device 150 mg/mL injection, 2 x 1 mL injection devices  Cosentyx®  Novartis Pharmaceuticals Australia Pty Ltd  Change to listing  (Major Submission)</p>	<p>Ankylosing spondylitis</p>	<p>Authority Required listing for the treatment of adults with active ankylosing spondylitis.</p>	<p>The PBAC recommended General Schedule Authority Required listing of secukinumab for the treatment of ankylosing spondylitis on a cost-minimisation basis with infliximab.</p> <p>The equi-effective doses were considered to be secukinumab 150 mg administered at weeks 0, 1, 2, 3, and 4 and followed by 150 mg every four weeks over 2 years, and infliximab 5mg/kg at weeks 0, 2 and 6 followed by 5mg/kg every six weeks.</p> <p>The submission was based on five indirect comparisons constructed from 12 placebo-controlled trials including one placebo-controlled trial of secukinumab.</p>

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<p>SECUKINUMAB 150 mg/mL injection, 1 x 1 mL injection device 150 mg/mL injection, 2 x 1 mL injection devices</p> <p>Cosentyx®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Psoriatic arthritis</p>	<p>Authority required listing for the treatment of adults with severe active psoriatic arthritis.</p>	<p>The PBAC recommended General Schedule Authority Required listing of secukinumab for the treatment of severe active psoriatic arthritis on a cost-minimisation basis with certolizumab pegol and ustekinumab.</p> <p>The equi-effective doses are secukinumab 150 mg or 300 mg administered at weeks 0,1,2,3 and 4 then 150 mg or 300 mg every month, ustekinumab 45 mg administered at weeks 0, 4 and then every 12 weeks thereafter and certolizumab 400 mg at weeks 0, 2 and 4 followed by 200 mg every 2 weeks or 400 mg every 4 weeks.</p> <p>The submission was based on a series of five indirect comparisons sourced from nine placebo-controlled clinical trials of secukinumab versus adalimumab and its secondary comparators, using placebo as the common reference. A sixth indirect comparison was constructed between secukinumab and a meta-analysed pooled group of all bDMARDs.</p>
<p>SECUKINUMAB 150 mg/mL injection, 2 x 1 mL injection devices</p> <p>Cosentyx®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Severe chronic plaque psoriasis</p>	<p>To request an increase in the maximum quantity from 1 to 5 for initial treatment</p>	<p>The PBAC recommended that the loading doses at weeks 0, 1, 2 and 3 should be allowed under one co-payment rather than under the 4 co-payments as currently required. The PBAC noted that the change will result in patients undertaking the 16-week initial treatment having to pay one co-payment for the 4 loading doses and another three co-payments, instead of the total of 7 co-payments as currently required.</p>

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<p>SOMATROPIN 0.4 mg/0.25 mL powder for injection &amp; diluent in prefilled syringe</p> <p>Genotropin MiniQuick®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Growth hormone deficiency, Turner syndrome, Prader-Willi syndrome and chronic renal insufficiency</p>	<p>To request a Section 100 (Growth Hormone Program) Authority Required listing for the 0.4 mg strength Genotropin MiniQuick.</p>	<p>The PBAC recommended listing of the 0.4 mg strength of somatropin under the same circumstances to be consistent with the currently listed strengths of somatropin.</p>
<p>TACROLIMUS 750 microgram capsule 2 mg capsule</p> <p>Tacrolimus Sandoz®</p> <p>Sandoz Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Liver, kidney, lung or heart allograft transplantation in adults and children</p>	<p>To request the listing of additional strengths of tacrolimus 0.75 mg and 2 mg on the PBS under General schedule and Section 100 (Highly Specialised Drugs).</p>	<p>The PBAC recommended listing the additional strengths of tacrolimus, 750 micrograms and 2 mg, under the same circumstances and based on a same (ex-manufacturer) price per mg as the currently listed strengths of tacrolimus.</p>

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<p>TAMOXIFEN 20 mg tablet, 30</p> <p>Nolvadex-D®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Prevention of breast cancer</p>	<p>Restricted benefit listing for the primary prevention of breast cancer in patients with moderate or high risk of developing breast cancer.</p>	<p>The PBAC recommended a Restricted Benefit listing of tamoxifen for the reduction of breast cancer risk in patients at moderate to high risk of breast cancer, on the basis of acceptable cost-effectiveness compared to watchful waiting. The PBAC noted that this listing would be the first medicine for the prevention of cancer on the PBS. The PBAC noted that this submission arose from the September 2013 stakeholder meeting and thanked the Sponsor and other clinical organisations for facilitating this listing.</p> <p>The clinical evidence provided in the submission was based on a meta-analysis of four head-to-head trials comparing tamoxifen to placebo.</p> <p>On the basis of direct comparison evidence presented by the submission, for every 1,000 patients treated with tamoxifen in comparison to placebo, over a 10 year period:</p> <ul style="list-style-type: none"> <li>• approximately 14 fewer patients would develop breast cancer.</li> <li>• approximately 3 additional patients would develop endometrial cancer.</li> <li>• approximately 4 additional patients would develop deep vein thrombosis or pulmonary embolism.</li> <li>• approximately 7 additional patients would develop cataract.</li> <li>• approximately the same number of patients would die.</li> <li>• approximately the same number of patients would die of breast cancer.</li> </ul> <p>The PBAC viewed the sensitivity analyses in the economic analysis carried out during the consideration of the submission represented the most plausible and informative analyses for its decision-making. The PBAC considered these analyses to lie within the previously accepted cost-effectiveness range for a primary prevention strategy.</p>

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<p>TIOTROPIUM tiotropium 2.5 microgram/actuation inhalation: solution, 60 actuations</p> <p>Spiriva® Respimat®</p> <p>Boehringer Ingelhiem Pty Ltd</p> <p>Change to listing  (Major Submission)</p>	<p>Asthma</p>	<p>Re-submission for Restricted benefit listing for the treatment of severe asthma.</p>	<p>The PBAC recommended the Restricted Benefit listing of tiotropium as add-on therapy for the treatment of severe uncontrolled asthma. The PBAC was satisfied that tiotropium provides, for some patients, a significant improvement in efficacy over placebo.</p> <p>The PBAC considered that overall, the revised economic model structure was reasonable. The PBAC considered the base case incremental cost-effectiveness ratio (ICER) of \$15,000 - \$45,000/QALY to be a reasonably reliable estimate of the cost-effectiveness.</p> <p>The evidence presented to the PBAC was a meta-analysis of two randomised controlled trials.</p> <p>On the basis the combined analysis of the head to head trials, the comparison of tiotropium and placebo resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately a 100 mL reduction in trough FEV1 over a median duration of follow-up of exposure of 24 weeks.</li> <li>• Approximately 56 days difference in time until at least 25% of patients experienced a severe exacerbation with a 48 week follow up.</li> <li>• Approximately 134 days difference in time without an exacerbation (any severity) for 50% of the patients with a 48 week follow-up.</li> </ul> <p>On the basis of direct comparison evidence presented by the submission, for every 100 patients treated with tiotropium in comparison to placebo with a 48 week follow-up:</p> <ul style="list-style-type: none"> <li>• Approximately 13 fewer patients would have had an exacerbation (any severity)</li> <li>• Approximately 8 fewer patients would have had a respiratory, thoracic or mediastinal disorder.</li> </ul>

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<p>TOCILIZUMAB 162 mg/0.9 mL injection, 4 x 0.9 mL syringes</p> <p>Actemra®</p> <p>Roche Products Pty Limited</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Rheumatoid arthritis</p>	<p>To request an Authority Required listing for a subcutaneous injection presentation of tocilizumab.</p>	<p>The PBAC recommended the Authority Required listing of tocilizumab, delivered by a subcutaneous (SC) injection, for the treatment of severe active rheumatoid arthritis (RA) on a cost-minimisation basis to the biological disease modifying antirheumatic drugs (bDMARDS).</p> <p>The submission was based on a randomised controlled trial. Based on the trial evidence provided in the submission, the equi-effective doses were tocilizumab 162 mg in 0.9 mL administered subcutaneously weekly and tocilizumab 8 mg/kg administered intravenously on day 1 and day 29 and then every 28 day later.</p> <p>The PBAC considered that the outcomes of the randomised controlled trial supported a clinical claim that tocilizumab SC was non-inferior in terms of comparative effectiveness and comparative safety to tocilizumab IV. The PBAC noted that the submission stated that in demonstrating non-inferiority of tocilizumab SC to an existing bDMARD (ie IV tocilizumab) it is possible to infer that tocilizumab SC is non-inferior to all other PBS-listed bDMARDS.</p> <p>The PBAC considered that all bDMARDS were appropriate comparators, noting that infliximab was the lowest cost comparator. Based on the evidence presented in the submission, the PBAC was not satisfied that tocilizumab SC provides a significant improvement in efficacy or reduction of toxicity over infliximab. Therefore, there was no basis for tocilizumab SC to have a cost advantage over infliximab for an equivalent treatment period.</p>

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<p>TRIGLYCERIDES MEDIUM CHAIN oral liquid, 12 x 500 mL pouches</p> <p>Peptamen Junior Liquid® Peptamen Junior Advance®</p> <p>Nestlé Health Science (Nestlé Australia Ltd)</p> <p>Matters Outstanding  (Minor Submission)</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.</p>	<p>The PBAC recommended listing triglycerides medium chain formula, oral liquid 500 mL, 12 (Peptamen Junior Liquid®) and triglycerides medium chain formula, oral liquid 500 mL, 12 (Peptamen Junior Advance®) as a Restricted Benefit for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders on a cost-minimisation basis against triglycerides medium chain formula, oral powder 400 g (Peptamen Junior®) at an equivalent price per gram of energy.</p>
<p>TRIPTORELIN ACETATE 100 microgram/1 mL injection, 28 x 1 mL syringes</p> <p>Decapeptyl®</p> <p>Ferring Pharmaceuticals Pty Ltd</p> <p>New Listing  (Major Submission)</p>	<p>Assisted reproduction</p>	<p>Section 100 (IVF) Authority Required (STREAMLINED) listing for Assisted Reproductive Technology.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of triptorelin for assisted reproductive technology (ART) under Section 100 (IVF Program) on a cost-minimisation basis with nafarelin, where the equi-effective doses are triptorelin 100 micrograms (as acetate) daily and nafarelin 800 micrograms (base) daily over an ART treatment cycle.</p> <p>The submission presented an indirect comparison of triptorelin and nafarelin, based on two randomised trials, using ganirelix as the common reference.</p>

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<p>VILDAGLIPTIN VILDAGLIPTIN with METFORMIN vildagliptin 50 mg tablet, 60 vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60</p> <p>Galvus® Galvumet®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing  (Major Submission)</p>	<p>Type 2 diabetes mellitus</p>	<p>Resubmission for Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.</p>	<p>The PBAC recommended the PBS listing of vildagliptin in triple oral combination with metformin and a sulfonylurea on a cost-minimisation basis with dapagliflozin.</p> <p>The PBAC recommended vildagliptin with metformin FDC for use with a sulfonylurea on a cost-minimisation basis with its individual components taken concomitantly.</p> <p>The submission was based on an indirect comparison of six randomised controlled trials.</p>
<p>VISMODEGIB 150 mg capsule, 28</p> <p>Erivedge®</p> <p>Roche Products Pty Limited</p> <p>New listing  (Major Submission)</p>	<p>Metastatic or locally advanced basal cell carcinoma</p>	<p>Authority Required listing for the treatment of metastatic or locally advanced basal cell carcinoma.</p>	<p>The PBAC recommended the Authority Required listing of vismodegib for the treatment of metastatic or locally advanced basal cell carcinoma (BCC) inappropriate for surgery and curative radiotherapy.</p> <p>Data presented was from non-randomised trials and a retrospective surgical study that created significant uncertainty regarding the clinical benefit provided by vismodegib, however the PBAC considered that in this rare subgroup of BCC patients further data would not be available.</p> <p>The PBAC was satisfied that vismodegib provides, for a highly selected patient group, an improvement in efficacy over best supportive care. Vismodegib was not considered to be equivalent to surgery.</p>

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			<p>The PBAC considered the modelling approach to be inappropriate due to highly selective data inputs and assumptions. Vismodegib was not considered to be cost-effective based on the data submitted and the price proposed by the sponsor, however the PBAC recommended listing based on an unmet clinical need for the drug, with a price reduction and a proposed Risk Share Agreement that would limit the financial risk to government and ensure that the drug remains cost-effective.</p>